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Center for Drug and Health Plan Choice
Medicare Plan Payment Group

Date: June 8, 2009

To: All Part D Plan Sponsors

From: Tom Hutchinson, Director
Medicare Plan Payment Group

Subject: Final Medicare Part D DIR Reporting Requirements for 2008 Payment Reconciliation

On May 20, 2009, CMS released draft guidance on the reporting of direct and indirect remuneration (DIR) data for the contract year 2008 payment reconciliation. Comments on this draft guidance were accepted until May 27, 2009. CMS has made a few minor revisions to the guidance in response to the comments and questions received. In addition, CMS has extended the deadline for the submission of the DIR Report for Payment Reconciliation to **Monday, July 13, 2009** to allow Part D sponsors additional time to prepare, validate, and submit these data to CMS. Provided below is an overview of the revisions made to the guidance and a brief summary of the comments we received.

Revisions to the 2008 DIR Reporting Requirements Guidance

1. Commenters asked for clarification regarding whether Retiree Drug Subsidy (RDS) sponsors need to consider the requirements in this document for the purposes of RDS reporting. We have revised the guidance to clarify that RDS sponsors should refer to the RDS program guidance on rebates and other price concessions published on January 1, 2009 for information on reporting DIR for the RDS program.

2. As requested by commenters, we have revised the guidance to clarify that the requirement to report rebates received by long-term care pharmacies has been suspended for contract years 2008 and 2009.

3. In response to requests from commenters', we have revised Table 1– Examples of Remuneration That Are and Are Not Considered DIR to clarify that PBM penalty payments which do not impact the drug costs incurred by Part D sponsors are not considered DIR. One commenter requested clarification regarding whether PBM penalty payments associated with drug costs incurred in other coverage years must be reported on the 2008 DIR Report for Payment Reconciliation. As with all other types of DIR, only DIR associated with drug costs incurred in the 2008 coverage year should be reported on the 2008 DIR report.

Other Comments Received

1. Commenters requested clarification regarding when Part D sponsors are required to report changes in the DIR data submitted to CMS. As we indicated in the draft guidance, if there is a change in a sponsor's DIR data which is expected to have a material impact on the Part D sponsor's payments, the Part D sponsor should inform CMS of the change and request a reopening of its Part D payments. This is applicable to all potential changes in the DIR data including changes due to rebates received after the submission deadline which differ from estimated rebate amounts reported on the DIR report and legal judgment and settlement amounts received after the submission deadline. To the extent that the estimated rebate amounts provided on the DIR report differ by a negligible amount from the actual rebate amounts received after the submission deadline, Part D sponsors are not expected to request a reopening of their Part D payments.

2. A few commenters indicated that a PBM rebate guarantee that exceeds the total rebate amount received from the pharmaceutical manufacturer should not be considered DIR. The commenters explained that these guarantee amounts are refunds from PBMs for a portion of their administrative fees due to the failure to adequately perform the administrative service of negotiating rebates. We disagree with this recommendation. PBM rebate guarantees ensure that Part D sponsors receive a minimum rebate amount to reduce their drug costs. Thus, as rebate amounts which Part D sponsors receive from the PBM rather than pharmaceutical manufacturers, rebate guarantees must be reported as DIR.

3. A few commenters expressed concerns about the requirement to report DIR associated with rejected Prescription Drug Event (PDE) records that the Part D sponsor believes will ultimately be accepted by CMS. The commenters explained that this requirement requires speculation regarding whether CMS will ultimately accepted a PDE record. Commenters requested that CMS provide a specific list of reject codes for rejected PDEs which Part D sponsors can expect to be ultimately accepted by CMS.

   As we indicated in the draft guidance, Part D sponsors are required to report all applicable DIR received for Part D expenditures incurred during the contract year. Applicable DIR should only be excluded from the DIR Report for Payment Reconciliation if it is received for non-Part D expenditures. It is inappropriate for Part D sponsors to exclude DIR amounts from the DIR Report for Payment Reconciliation simply because the PDE records summarizing the associated drug costs are not accepted by CMS.

   We note that it is the responsibility of Part D sponsors to accurately identify their Part D expenditures and the associated DIR. Furthermore, Part D sponsors are responsible for submitting their PDE records in accordance with the PDE reporting requirements and working with CMS to address any technical issues. These actions will help to ensure that all appropriate PDE records are accepted by CMS and all appropriate Part D expenditures are included in Part D payment reconciliation.

4. A few commenters requested that CMS provide Part D sponsors with additional time to prepare the DIR Report for Payment Reconcilation by releasing the draft and final reporting requirements earlier for future contract years. We appreciate the commenters' concerns regarding providing sufficient time for Part D sponsors to make any necessary programming changes and conduct a thorough review of their DIR data prior to submission. We will consider providing the draft and final reporting requirements earlier in the year to provide additional time for Part D sponsors to prepare the DIR Report for Payment Reconciliation.

Please find attached the final revised guidance document, "Medicare Part D DIR Reporting Requirements for Payment Reconciliation- Contract Year 2008" on the reporting of DIR data for the purposes of the contract year 2008 Part D payment reconciliation. Please note that for contract year 2008, Part D sponsors will be required to submit the Attestation of Data Relating to CMS Payment to a Medicare Part D Sponsor prior to the completion of the 2008 Part D Payment Reconciliation. In this attestation, Part D sponsors will be required to certify that the PDE and DIR data submitted to CMS for the 2008 payment reconciliation is accurate, complete, and truthful. Additional guidance regarding this attestation will be provided at a later date.

Further Information:
For technical assistance and questions regarding the download or upload of the DIR Report for Payment Reconciliation, please contact the HPMS Help Desk at 1-800-220-2028 or hpms@cms.hhs.gov. For any other questions regarding this guidance, please contact Meghan Elrington at (410) 786-8675 or Meghan.elrington@cms.hhs.gov.

MEDICARE PART D DIR REPORTING REQUIREMENTS FOR PAYMENT RECONCILIATION- CONTRACT YEAR 2008

Table of Contents

MEDICARE PART D DIR REPORTING REQUIREMENTS FOR PAYMENT RECONCILIATION- CONTRACT YEAR 2008

I. Introduction

In December 2003, Congress passed the Medicare Prescription Drug Benefit, Improvement and Modernization Act (MMA), allowing coverage of outpatient prescription drugs under the new Medicare Part D benefit. Reinsurance payments and risk sharing are two of the payment mechanisms by which the Medicare Program reimburses Part D sponsors for providing prescription drug coverage under Medicare Part D. CMS is required by statute to calculate these payments using "allowable reinsurance costs" and "allowable risk corridor costs", which must be "actually paid". As defined at 42 C.F.R. 423.308, "actually paid" costs must be actually incurred by the Part D sponsor and net of any applicable direct or indirect remuneration (DIR). Section 1860D-15(f)(1)(A) of the Act requires Part D sponsors to fully disclose to CMS any information necessary for carrying out the payment provisions of Part D, including the calculation of reinsurance and risk sharing. Therefore, Part D sponsors are required to report drug costs and DIR associated with the Medicare prescription drug benefit to CMS for the purposes of determining reinsurance payments and risk sharing. Consistent with section 1860D-15(d)(2)(A), CMS payments to a Part D sponsor are conditioned upon the provision of this requisite data.

The purpose of this document is to provide an overview of CMS' DIR reporting requirements for Medicare Part D payment and the format of the DIR Report for Payment Reconciliation. This document explains the data elements to be reported by Part D sponsors at the distinct Plan level (i.e., data will be reported for each Plan Benefit Package or PBP offered under each Part D Contract) and the established reporting timeframes. CMS' goal is to ensure a common understanding of DIR reporting requirements and how these data will be used to determine Medicare Part D payments. These requirements will apply for Contract Year 2008. For guidance regarding the reporting of rebates and other price concessions for the RDS program, please see the Retiree Drug Subsidy Program Guidance available on the CMS website at http://www.cms.hhs.gov/EmployerRetireeDrugSubsid/Downloads/20090112RebateGuidancePaper.pdf.

II. Defining Direct and Indirect Remuneration (DIR)

Per 42 C.F.R. 423.308, direct and indirect remuneration (DIR) is any and all rebates, subsidies, or other price concessions from any source (including manufacturers, pharmacies, enrollees, or any other person) that serve to decrease the costs incurred by the Part D sponsor (whether directly or indirectly) for the Part D drug. Thus, DIR includes discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, and coupons. DIR also includes goods in kind, free or reduced-price services, grants, legal judgment amounts, settlements amounts from lawsuits or other legal

action, and other price concessions or similar benefits. However, rebates and other price concessions that are not considered to directly or indirectly impact drug costs incurred by the Part D sponsor are not included in DIR. Please see Table 1 below for examples of remuneration that are and are not considered DIR.

Table 1. Examples of Remuneration That Are and Are Not Considered DIR

Remuneration Considered DIR	Remuneration Not Considered DIR
Remuneration from pharmaceutical manufacturers (e.g. rebates, grants, reduced price administrative services or legal settlement amounts)	Bona Fide Service Fees from pharmaceutical manufacturers
PBM retained rebates	Remuneration for administrative services (e.g. PBM incentive payments)
PBM rebate guarantee amounts	Private Reinsurance Amounts
PBM penalty payments and repayments that impact Part D drug costs	PBM penalty payments and repayments that do not impact Part D drug costs
Dispensing incentive payments to pharmacies	Rebate amounts received by long term care (LTC) pharmacies
Prompt pay discounts from pharmacies	Claims data
Pharmacy payment adjustments	
Risk sharing amounts	

III. Examples of Remuneration Considered DIR

A. Remuneration from Pharmaceutical Manufacturers

CMS considers all remuneration received directly or indirectly from pharmaceutical manufacturers (with the exception of bona fide services fees) to be price concessions that serve to reduce the drug costs incurred by the Part D sponsor. As stated in the preamble to subpart G of the Medicare Part D final rule (p. 4308 - 4309), CMS has a responsibility to ensure that price concessions are not masked as administrative fees. Therefore, to guarantee that a Part D sponsor's administrative costs are not inappropriately shifted to its drug costs, Part D sponsors are required to report all rebates, grants, settlement amounts, or price concessions received from pharmaceutical manufacturers (whether directly or indirectly) as DIR with the exception of bona fide services fees. Please see page 7 for a discussion of bona fide service fees.

i. Administrative Services

When Part D sponsors receive administrative services from pharmaceutical manufacturers at a cost below market value, the difference between the fair market value of the administrative service and the price paid by the Part D sponsor is considered DIR. Similarly, when a Part D sponsor (directly or indirectly through their PBM) receives payments from pharmaceutical

manufacturers for administrative services which are above the fair market value of the services provided, the difference between the price paid by the pharmaceutical manufacturer and the fair market value of the administrative service is considered DIR. For example, in the case of rebate administration fees from pharmaceutical manufacturers which exceed fair market value but otherwise meet the definition of a bona fide service fee, Part D sponsors must report the differential between the rebate administration fee and the fair market value as DIR.

ii. Legal Judgments and Settlement Amounts

All legal judgments and settlement amounts received from pharmaceutical manufacturers for covered Part D drugs (with the exception of litigation concerning bona fide service fees) are considered price concessions which impact the drug costs incurred by the Part D sponsor and, therefore, must be reported as DIR. This includes legal judgments or settlement amounts from litigation due to inappropriate utilization, market competition, and the manipulation of the patient process.

B. PBM Retained Rebates

Rebates, discounts, and other price concessions from pharmaceutical manufacturers for purchases under the Medicare prescription drug benefit are considered DIR even if they are received by subcontractors of Part D sponsors, such as pharmacy benefit managers (PBMs), and retained by the subcontractor in lieu of higher service fees from the Part D sponsor. These amounts are considered price concessions received indirectly from pharmaceutical manufacturers which must be reported as DIR for payment purposes. In accordance with the guidance on "Reporting of Manufacturer Rebates in Part D" provided in the 2007 Call Letter, a Part D sponsor must report 100% of the manufacturer rebates, discounts, and other price concessions (with the exception of bona fide service fees) retained by its PBM as DIR, regardless of the relationship between the sponsor and the PBM and the provisions of the contract(s) between the sponsor and the PBM. Applicable rebate administration fees which the PBM receives from pharmaceutical manufacturers must also be reported to the extent that they do not represent bona fide service fees.

As stated in the 2007 Call Letter released on April 3, 2006, CMS must assume that if a PBM retains a portion of the manufacturer rebates it negotiates on behalf of a Part D sponsor, the direct payment the sponsor pays the PBM for its services will be less, such that the sponsor receives a price concession from the PBM. Thus, as additional administrative fees paid to the PBM, Part D sponsors **also** should account for these retained rebate amounts in the administrative expense component of their Part D bids.

C. PBM Rebate Guarantee Amounts [New Clarification]
Rebate guarantee amounts are rebate amounts received from PBMs to account for the difference between a rebate amount guaranteed by a PBM and the actual rebate amount received from a pharmaceutical manufacturer. These rebate amounts reduce the drug costs incurred by the Part D sponsor and therefore, are considered DIR.

D. PBM Penalty Payments and Repayments
Penalty payments or repayments from PBMs that directly or indirectly impact the drug costs incurred by the Part D sponsor are considered DIR. Some PBM penalty payments include a price concession for administrative services provided by the PBM as well as remuneration for drug cost. In these cases, only the portion of the PBM penalty which impacts the drug costs incurred by the Part D sponsor is considered DIR. Thus, the portion of the penalty payment which represents drug cost that has been reimbursed by the PBM must be reported as DIR. The remaining portion of the PBM penalty is not considered DIR because it does not directly or indirectly impact the drug costs incurred by the Part D sponsor.

For example, if a PBM is required to pay the Part D sponsor $1,000 plus claim costs due to an error associated with allowing coverage of a drug on step 2 of a step-therapy program, when a drug on step 1 of the same program should have been required, the amount paid by the PBM that is equivalent to the cost of the affected claims is considered DIR. The Part D sponsor must report this amount as DIR because the Prescription Drug Event (PDE) data submitted to CMS would not reflect this reduction in drug costs for the Part D sponsor. Alternatively, if the PBM is required to pay the Part D sponsor $1,000 plus the difference between the cost of the drug on step 2 and the cost of the drug on step 1, the portion representing drug cost reimbursed by the PBM (the difference between the cost of the two drugs) is considered DIR. In both examples, the remaining $1,000 payment received from the PBM does not directly or indirectly impact the drug costs incurred by the Part D sponsor and therefore, is not considered DIR.

Please note that in most cases, Part D sponsors should submit an adjusted PDE record with a revised gross drug cost if their PBM has administered the benefit incorrectly. In these cases, the PBM penalty associated with the errors in drug cost should not be reported as DIR since the PDE record has been adjusted to reflect the appropriate gross drug cost.

E. Dispensing Incentive Payments
Dispensing fees paid to pharmacies and other dispensing providers are considered part of the drug cost incurred by Part D sponsors. Therefore, dispensing incentive payments made to the pharmacy at the point of sale are part of the dispensing fee reported on the PDE record and are not reported as DIR. In contrast, dispensing incentive payments and adjustments to dispensing incentive payments made to pharmacies **after** the point of sale dispensing event

are not reflected in the drug costs reported on PDE records. As a result, these post- POS dispensing incentive payments and adjustments must be reported as DIR to ensure that the Part D sponsor's allowable reinsurance and risk corridor costs appropriately reflect the drug costs actually incurred by the Part D sponsor.

i. Generic Dispensing Incentive Payments

Generic dispensing incentive payments are payments made to pharmacies to encourage the dispensing of generic drugs. If a Part D sponsor makes a generic dispensing incentive payment to the pharmacy at the point of sale (POS), CMS considers it part of the dispensing fee and the sponsor or its third party submitter must report this cost as part of the dispensing fee on their PDE. As a result, generic dispensing incentive payments made at the point of sale are not reported as DIR. However, if the sponsor pays the pharmacy a generic dispensing incentive payment after the point of sale or make any post-POS adjustments to prospective generic dispensing incentive payments, the sponsor must report the post- POS payments or adjustments as DIR.

F. Prompt Pay Discounts from Pharmacies [New Clarification]

Part D sponsors may receive discounts from pharmacies for the timely payment of Part D claims. These prompt payment discounts are considered DIR and must be reported on the DIR Report for Payment Reconciliation if they are (i) received after the point of sale and (ii) not reflected on the PDE records submitted to CMS.

G. Pharmacy Payment Adjustments

Adjustments made to pharmacy payments after the point-of-sale that (i) directly or indirectly impact the drug costs incurred by the Part D sponsor and (ii) are not reflected in the PDE data are considered DIR. These adjustments include penalties or pharmacy repayments stipulated in the Part D sponsor's contract with its network pharmacies which represent incorrect drug costs that were paid or reported by the Part D sponsor due to an error made by the pharmacy. For these types of pharmacy penalties, the portion of the penalty that is equivalent to the amount by which the drug costs paid by the Part D sponsor or reported to CMS on the PDE data exceeds the correct drug costs is considered DIR. The remaining portion of the pharmacy penalty is considered a price concession for administrative services provided by the pharmacy that does not direct or indirectly impact the drug costs incurred by the Part D sponsor and therefore is not reported as DIR.

Please note that in most cases, the Part D sponsor should submit an adjusted PDE with a revised gross drug cost if the pharmacy made an error in determining the POS drug price. In these cases, the pharmacy payment adjustment should not be reported as DIR since it is already reflected in the gross drug cost reported on the PDE record. For example, if a Part D sponsor recoups an overpayment to the pharmacy due to an error in POS drug price and the recouped amount is reported to CMS via an adjusted PDE record with a revised

gross drug cost, the Part D sponsor would not report the pharmacy payment adjustment on the DIR Report for Payment Reconciliation.

Adjustments made to beneficiary cost-sharing due to changes in low-income subsidy eligibility status impact the low-income cost sharing subsidy amounts received from CMS. However, these adjustments do not impact the drug costs actually incurred by Part D sponsors. This type of adjustment does not affect the negotiated price or the plan's liability for the drug claim. As a result, these adjustments are not considered DIR.

Amounts credited to the Part D sponsor by the pharmacy due to beneficiary cost-sharing that exceeds the gross drug cost are considered DIR, provided that these payments are not already reflected in the covered plan paid (CPP) amounts reported on the PDE record. This credit occurs when the beneficiary's co-payment exceeds the negotiated drug price and the pharmacy credits the differential amount to the Part D sponsor. If this payment is not reflected in the CPP amount reported on the PDE record, the amount by which the beneficiary's co-payment exceeds the negotiated price must be reported as DIR to reduce the plan's allowable costs. Please note that in cases where the pharmacy retains this differential amount, this amount is considered payment to the pharmacy and, thus, is not reported as DIR.

H. Risk Sharing Amounts

It is permissible under the Part D rule for sponsors to enter into certain types of risk sharing arrangements with entities other than CMS. Risk sharing arrangements are arrangements in which the Part D sponsor shares risk with a provider (e.g., pharmacy) or other party involved in the administration or delivery of the Part D benefit. Any risk sharing arrangement between the sponsor and another party must be based on the cost of Part D covered drugs. Under no circumstances can a risk sharing arrangement be developed around administrative costs. Risk sharing amounts received from or credited to other parties constitute DIR and must be offset against prescription drug costs in the calculation of allowable reinsurance and risk corridor costs. As with other types of DIR, the value of risk sharing may be negative. Please note that private reinsurance amounts are not considered DIR. See page 8 for a discussion of amounts from private reinsurance arrangements.

IV. Examples of Remuneration Not Considered DIR

A. Bona Fide Service Fees

Bona fide service fees which Part D sponsors or subcontractors of Part D sponsors (such as PBMs) receive from pharmaceutical manufacturers are not considered price concessions that reduce the drug costs incurred by the Part D sponsor and, therefore, are not considered DIR. Bona fide service fees are fees paid by a manufacturer to an entity, that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the

manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug. Rebate administration fees paid to a Part D sponsor or a PBM, which meet the definition of a bona fide service fee, are not considered DIR and therefore, may be excluded from the DIR Report for Payment Reconciliation. In the case of rebate administration fees or other amounts from pharmaceutical manufacturers which exceed fair market value, but otherwise meet the definition of a bona fide service fee, the differential between the rebate administration fee or other amount and fair market value must be reported as DIR.

B. Remuneration for Administrative Services

Price concessions for administrative services which do not directly or indirectly impact the drug costs incurred by the Part D sponsor are not included in DIR. For example, price concessions from a pharmacy for administrative services only (excluding dispensing fees) which do not represent a change in the drug costs paid by the Part D sponsor, do not impact the drugs costs incurred by the Part D sponsor and, therefore, are not considered DIR.

i. PBM Incentive Payments [New Clarification]

Part D sponsors may pay incentive payments to PBMs for performing administrative services such as negotiating rebates and drug prices as well as increasing generic utilization. These incentive payments represent an increase in the administrative fees paid by the Part D sponsor to their PBM and therefore, are not considered DIR. This is in contrast to generic dispensing fees paid to pharmacies where the Part D sponsor pays a higher dispensing fee to the pharmacy as an incentive for dispensing generic drugs instead of brand drugs. The dispensing fee is a component of the negotiated price paid to the pharmacy. As a result, adjustments to the dispensing fee directly impact the drug costs incurred by the Part D sponsor and must be reported as DIR if applied after the point of sale.

C. Private Reinsurance Amounts

Private reinsurance arrangements are arrangements in which the Part D sponsor shares risk with a party otherwise uninvolved in the administration or delivery of the Medicare prescription drug benefit. Private reinsurance amounts do not constitute DIR and should not be reported on the DIR Report for Payment Reconciliation. Instead, similar to Part D sponsors' direct and indirect administration costs, reinsurance amounts from private reinsurance arrangements are included in the Part D sponsor's bid as a non-benefit expense.

D. Rebates Received by Long Term Care (LTC) Pharmacies

Pharmaceutical manufacturer rebates received by long term care (LTC) pharmacies are not considered DIR received by Part D sponsors which must be reported on the DIR Report for Payment Reconciliation. Part D sponsors purchase Part D drugs directly from these dispensing providers. The rebate

amounts and price concessions received by these dispensing providers do not serve to further reduce the drug cost paid by the Part D sponsor at the point of sale. However, Part D sponsors are required to report LTC pharmacy rebates to CMS quarterly for oversight purposes as described in the 2007 Call Letter. Please note that this reporting requirement has been suspended for the 2008 and 2009 contract years. Please see the November 24, 2008 HPMS memorandum entitled "Changes to Part D Reporting Requirement - LTC Pharmacy Rebate Data" for more information.

E. Claims Data

Claims data are not considered DIR and therefore must not be reported on the DIR Report for Payment Reconciliation. Instead, Part D sponsors should report all applicable claims data on PDE records. This policy is applicable to all claims data, including data received or processed after the PDE data submission deadline.

V. DIR Included on the DIR Report for Payment Reconciliation

Part D sponsors must report DIR associated with purchases under the Medicare prescription drug benefit on the DIR Report for Payment Reconciliation. DIR that is not generated from the sponsor's Medicare Part D book of business should not be included on this report. The DIR included on the DIR Report for Payment Reconciliation will be excluded from allowable reinsurance costs and allowable risk corridor costs when CMS calculates reinsurance and risk sharing payments during the Part D payment reconciliation process. As a result, Part D sponsors should consider their best expectation of DIR when developing their Part D bids.

Accurate and complete DIR data are necessary for the accurate completion of Part D payment reconciliation. Data reported on the DIR Report for Payment Reconciliation are subject to audit. Part D sponsors are required to maintain records of all related transactions, claims, contracts, and other materials. Please note that misrepresentations or omissions in the DIR data provided to CMS may result in Federal civil action and/or criminal prosecution. In addition, per 42 C.F.R. 423.343(d)(2) of the Part D Regulations, if a Part D sponsor does not provide adequate data to determine risk corridor costs, including DIR data, CMS assumes that the Part D plan's adjusted allowable risk corridor costs are 50 percent of the plan's target amount.

A. DIR Not Applied at the Point of Sale

Some DIR is reflected in the amount paid at the point of sale. To the extent that DIR is already taken into account in the gross drug cost (sum of ingredient cost, dispensing fee, applicable sales tax, and vaccine administration fee) reported to CMS on the PDE record, this DIR (with the exception of estimated rebates applied at the point of sale) should not be reported on the DIR Report for Payment Reconciliation. Please see page 10 for a discussion of estimated rebates applied at the point of sale.

B. Estimated Rebates Applied at the Point of Sale

Part D sponsors may elect to make rebates available to their beneficiaries at the point of sale by applying estimated rebates to the negotiated price at the point of sale. For rebates that were estimated and applied to the point of sale price, Part D sponsors are required to report the estimated rebate amounts in the "Estimated Rebate at POS" field of the PDE record.

Although Part D sponsors are required to report their gross drug costs on the PDE record net of any estimated rebates applied at the point of sale, they are **also** required to report the actual rebate amounts for these estimated rebates on the DIR Report for Payment Reconciliation. CMS will subtract the amounts reported in the Estimated Rebate at POS field of the PDE record for covered Part D drugs from the total DIR amount reported on the DIR Report for Payment Reconciliation when determining the appropriate DIR amount for the calculation of allowable reinsurance costs and adjusted allowable risk corridor costs. This will capture any difference between the estimated rebates and the actual rebates. In addition, this will ensure that only price concessions which were not already included in the gross covered drug costs reported to CMS are included in the DIR amount used to calculate allowable reinsurance costs and adjusted allowable risk corridor costs. For additional information, please see the June 1, 2007 memorandum, "Reporting Estimated Rebates Applied to the Point-of-Sale Price", available on the CMS website.

C. DIR for Covered Part D drugs

CMS provides reinsurance and risk sharing for costs associated with covered Part D drugs only. Covered Part D drugs, as defined in 42 C.F.R. 423.100, are Part D drugs that are included in a Part D plan's formulary or treated as included in the formulary as a result of the plan's exceptions process, a coverage determination appeal, or a transition period. When calculating allowable reinsurance and risk sharing costs, CMS will only apply DIR dollars for covered Part D drugs. Therefore, on the DIR Report for Payment Reconciliation, Part D sponsors are required to submit DIR for covered Part D drugs only. DIR for non-Part D covered drugs (drugs covered by the Part D sponsor which are not Part D drugs) should not be included on this report.

D. DIR Associated with Supplemental Benefits and Benefit Phases with 100% Coinsurance

Applicable DIR for covered Part D drugs must be reported in full on the DIR Report for Payment Reconciliation. This includes DIR for supplemental prescription drug benefits as well as DIR associated with drug purchases in the deductible phase and the coverage gap. Consistent with our instructions for the development of the Part D bids, all applicable DIR will be excluded from allowable costs when CMS determines final reinsurance and risk sharing payments.

E. DIR Associated with Rejected PDE Records [New Clarification]

All applicable DIR received for Part D plan expenditures incurred during the contract year must be reported on the DIR Report for Payment Reconciliation. DIR associated with non-Part D expenditures reported on rejected PDE records (for example, DIR from drug costs covered under Medicare Part B) may be excluded from the DIR Report for Payment Reconciliation. It is inappropriate, however, for a Part D sponsor to exclude from the DIR report all DIR associated with rejected PDE records when the Part D sponsor expects that a portion of the rejected PDE records will ultimately be accepted by CMS either prior to or after the Part D payment reconciliation. As a result, DIR received for Part D plan expenditures reported on PDE records that were initially rejected by CMS' systems but that the Part D sponsor believes will ultimately be accepted must be reported on the DIR Report for Payment Reconciliation.

F. Estimates of Expected DIR Not Yet Received

Part D sponsors must include on the DIR Report for Payment Reconciliation good faith estimates for DIR that is expected for the applicable contract year but has not yet been received. This includes estimates for rebates expected from pharmaceutical manufacturers that have not yet been received as well as estimates for DIR associated with claims for the contract year which are expected to be submitted and processed after the PDE data submission deadline. Estimated DIR amounts reported on the DIR Report for Payment Reconciliation will be included in the total DIR amount subtracted from Part D sponsors' drug costs when determining allowable reinsurance and risk corridor costs.

VI. Reporting Requirements

Part D sponsors must submit their DIR data at the plan benefit package (referred to as "plan") level on the DIR Report for Payment Reconciliation within 6 months of the end of the coverage year. **The submission deadline for the 2008 DIR Report for Payment Reconciliation is Monday, July 13, 2009.** This deadline applies to all Part D plans including non-calendar year Employer/Union-only Group Waiver Plans (EGWPs).

Some Part D sponsors may receive or record their DIR at the sponsor or contract level. In these cases, the Part D sponsor must allocate their DIR to the plan level by applying a *reasonable* allocation methodology.

Part D sponsors may also receive legal judgments or settlement amounts from lawsuits or other legal action, which are associated with drug costs incurred across multiple contract years. The portion of the judgment or settlement amounts associated with the drug costs for each contract year should be reported on the corresponding DIR Report for Payment Reconciliation. Thus, for legal judgments or settlement amounts from law suits or other legal action concerning drug costs for multiple contract years, Part D sponsors should use a

reasonable methodology to allocate the legal judgments or settlement amounts to each applicable contract year.

A brief description of any allocation methodology used must be submitted by the Part D sponsor on HPMS when uploading the DIR Report for Payment Reconciliation. Part D sponsors are expected to maintain documentation of any allocation methodology applied.

A. DIR Submission Information

Prior to uploading the 2008 DIR Report for Payment Reconciliation on HPMS, Part D sponsors are required to provide additional information at the contract level regarding their DIR and PDE data. A description of the information required is provided below.

1) **Description of Allocation Methodology**: Part D sponsors must provide a description of any methodology used to allocate DIR to the plan level. If this question is not applicable, Part D sponsors should enter "N/A".

2) **Name of PBM(s) for Claims Processing [New Requirement]**: Part D sponsors must provide the name of any PBM or other entity with which the sponsor contracted for the processing of claims or submission of PDE records for 2008. If the Part D sponsor conducted claims processing and PDE record submission internally and did not contract with a PBM for these services, the Part D sponsor should indicate "Self" for this question.

3) **Name of PBM(s) for Rebate Negotiation**: Part D sponsors must provide the name of any PBM or other entity with which the Part D sponsor contracted for the negotiation or processing of rebates for 2008. Part D sponsors that conducted rebate negotiation and processing using their internal resources and did not contract with a PBM for these services should indicate "Self" for this question. If the Part D sponsor did not negotiate or process rebates, the Part D sponsor should enter "N/A" for this question.

4) **Did PBM for Rebate Negotiation change from 2007 to 2008?**: Part D sponsors must indicate whether they contracted with a different PBM or entity in 2007 for the negotiation or processing of rebates. If the Part D sponsor did not negotiate or process rebates in 2007 and 2008, the sponsor should enter "N/A" for this question. If the Part D sponsor contracted with a PBM or other entity for the negotiation or processing of rebates in 2008 but not in 2007, the sponsor should enter "Yes" for this question. Similarly, if the sponsor contracted with a PBM or other entity for the negotiation or processing of rebates in 2007 but not in 2008, the sponsor should enter "Yes" for this question.

5) **Were any of the plans in the contract owned by a different sponsor in 2007? [New Requirement]**: Part D sponsors must indicate whether any of

the plans in the contract were owned by a different sponsor in 2007. For any applicable plans, the sponsor must provide the plan ID, the name of the sponsor which owned the plan in 2007, and the contract number that the plan was under in 2007. If all of the plans in the contract were owned by a different sponsor in 2007, the sponsor may indicate "all plans in contract" instead of listing all of the plan IDs.

6) **Did your parent organization acquire any of the plans in this contract during the 2008 contract year? [New Requirement]**: Part D sponsors must indicate whether any of the plans in the contract were acquired mid-contract year. For any applicable plans, the sponsor must provide the plan ID, the name of the sponsor which previously owned the plan, and the contract number that the plan was under prior to the sponsor's acquisition of the plan?

7) Reason for Resubmission: When resubmitting the DIR Report for Payment Reconciliation, Part D sponsors are required to provide an explanation for the resubmission of their DIR data.

B. DIR Report for Payment Reconciliation

The 2008 DIR Report for Payment Reconciliation was made available on June 1, 2009. Part D sponsors are currently able to download it from HPMS using the following navigation path: HPMS Homepage > Plan Bids > DIR Reporting > Contract Year 2008 > DIR Reporting (for Payment Reconciliation). This report is be downloadable to an MS Excel spreadsheet in the format provided in Section VIII: Report Format and Layout. Part D sponsors must prepare and upload to HPMS the 2008 DIR Report for Payment Reconciliation for each of their Part D plans (including non-calendar year Employer/Union-only Group Waiver Plans). In order to upload successfully, **Part D sponsors must use the actual downloaded MS Excel spreadsheet and name the file DIR.xls**.

Part D sponsors must prepare and submit the DIR Report for Payment Reconciliation to CMS for all of the Part D plans which they offered in 2008, even if they have no DIR to report for contract year 2008. For plans with no DIR to report for contract year 2008, the Part D sponsor must include a brief explanation in the column "Additional Comments".

Sponsors may upload the 2008 DIR Report for Payment Reconciliation as many times as they choose between June 1, 2009 and 11:59 p.m. EDT on Monday, July 13, 2009. CMS will use the DIR reported on the most recently uploaded report during payment reconciliation.

CMS will review the DIR data submitted. DIR reports which have been reviewed and accepted by CMS will receive an "accepted" status in HPMS. If CMS identifies a potential error, CMS will contact the Part D sponsor and the DIR report will receive a status of "not accepted" in HPMS. Part D sponsors may see the status of submitted DIR reports on the DIR Contract Status page in HPMS

using the following navigation path: HPMS Homepage > Plan Bids > DIR Reporting > Contract Year 2008 > DIR Reporting (for Payment Reconciliation) > DIR Contract Status Report. For technical assistance, Part D sponsors can contact the HPMS Help Desk at either 1-800-220-2028 or hpms@cms.hhs.gov. For other questions regarding the 2008 DIR Report for Payment Reconciliation, sponsors can contact Meghan Elrington at (410) 786-8675 or meghan.elrington@cms.hhs.gov.

C. Reporting Changes to the DIR Report for Payment Reconciliation [New Clarification]

CMS is aware that there are instances when Part D sponsors may receive unanticipated rebate amounts, settlement amounts, or other price concessions after the submission deadline which could result in changes to the DIR data reported to CMS. Per 42 C.F.R. §423.346, CMS has the authority to reopen and revise initial or reconsidered final Part D payment determinations within specified time periods. In cases of errors or material changes to the DIR data reported to CMS, Part D sponsors should inform CMS of such changes and may request that CMS, at its discretion, reopen and revise the sponsor's final Part D payment determinations to reflect the changes in DIR. CMS will review submitted reopening requests and make a determination on whether the sponsor's final Part D payment determinations will be reopened. Please see the May 8, 2008 HPMS memo, "The Part D Reopenings Process and the Part D Appeals Process" for additional guidance regarding how to submit a reopening request. Please note that the reopening process requires substantial CMS preparation and resources. Therefore, it may take some time to receive a determination regarding a request for reopening from CMS. In addition, Part D sponsors should not expect the reopening to be performed immediately after receiving a decision to reopen.

D. Attestation of Data Relating to CMS Payment to a Medicare Part D Sponsor

In accordance with 42 CFR 423.505(k)(5), prior to the completion of the 2008 Part D Payment Reconciliation, Part D sponsors will be required to submit an attestation, "Attestation of Data Relating to CMS Payment to a Medicare Part D Sponsor", in which they must certify that all information provided for the purposes of determining allowable reinsurance costs and risk corridor costs (for example, PDE data and DIR data) is accurate, complete, and truthful to the sponsor's best knowledge, information, and belief. Part D sponsors must certify in this attestation and maintain documentation that all entities which have generated or submitted this information on their behalf have certified that this information is accurate, complete, and truthful based on the entity's best knowledge, information, and belief.

In addition, Part D sponsors must submit a new attestation anytime the DIR Report for Payment Reconciliation is resubmitted as a result of a sponsor's request to reopen their Part D payments. Additional guidance regarding the

2008 Attestation of Data Relating to CMS Payment to a Medicare Part D Sponsor will be provided at a later date.

VII. Reporting Elements

Part D sponsors will be responsible for reporting multiple data elements related to DIR at the plan level. DIR data must be summarized for each plan and reported in aggregate to include multiple drugs and price concessions.

DIR # 1. PBM Retained Rebates

All rebates and applicable rebate administration fees associated with the Medicare prescription drug benefit which are received by PBMs from pharmaceutical manufacturers and retained by the PBMs must be reported in this column. Please note that rebates which PBMs have passed through to the Part D sponsor (and therefore, are not retained) are reported in column DIR #3, All Other Rebates.

DIR #2. Rebates Expected But Not Yet Received

Good faith estimates of rebate amounts that are expected for the applicable contract year, but have not yet been received are reported in this column. This column should not include rebate amounts which have been received by the sponsor prior to the latest submission of the DIR report unless the rebate amounts are received by the sponsor after the DIR data for the report is compiled. Part D sponsors are advised that the DIR data used to produce the DIR report should be reasonably current reflecting at a minimum the DIR amounts received up to three months prior to the submission deadline.

DIR # 3. All Other Rebates

All rebates associated with the Medicare prescription drug benefit are reported in this column with the exception of the rebate amounts reported in columns DIR #1 and DIR #2. Included in this column are rebate guarantee amounts from PBMs and rebates received from pharmaceutical manufacturers for Part D purchases, such as market share rebates. The actual rebate amounts received for rebates which were estimated and applied to the negotiated price at the point of sale are also reported in this column. Rebates and applicable rebate administration fees that PBMs have received from pharmaceutical manufacturers for Part D purchases and passed through to the Part D sponsor must also be included in this column.

Per 42 C.F.R. 423.464, Part D sponsors are required to coordinate benefits with State Pharmaceutical Assistance Programs (SPAPs) and entities providing other prescription drug coverage (described in 42 C.F.R. 423.464(f)(1)). CMS has taken many steps to help facilitate the coordination of benefits between Part D sponsors and third party providers of prescription drug coverage. However, there are instances in which Part D sponsors must reimburse third party payers for

Part D claims due to COB errors. All rebates associated with these incurred Part D drug costs must be reported in this column.

Also reported in this column are rebates associated with Plan-to-Plan (P2P) claims. Under the current process for reimbursing P2P claims, the Part D sponsor actually incurring the Part D drug costs (the plan of record) does not have claim level data and therefore is unable to receive rebates for these claims. The submitting plan, however, may receive rebates for these claims and is required to report them to CMS. Rebates received by the submitting plan for P2P claims must be reported in this column.

DIR # 4. Price Concessions for Administrative Services
Price concessions from pharmaceutical manufacturers for administrative services associated with the Part D benefit are reported in this column. This includes administrative services received by the Part D sponsor from pharmaceutical manufacturers at a cost below market value. The difference between the market value of the administrative service and the price paid by the Part D sponsor should be reported in this column. Also reported in this column are grants received by the Part D sponsor from pharmaceutical manufacturers for services and programs such as utilization management and medical education grants. Applicable price concessions for administrative services that are not associated with a specific drug must be reported in full in this column with no portion allocated for non-Part D Covered drugs. This DIR must fully accrue to the government and beneficiaries and cannot be kept by the Part D sponsor. Please note that PBM retained rebates must be reported in column DIR # 2, "PBM Retained Rebates", and are therefore not included in this column (DIR # 4).

DIR # 5. Generic Dispensing Incentive Payments and Adjustments
Reported in this column are generic dispensing incentive payments or adjustments made after the point of sale. Specifically, if a plan pays the pharmacy a prospective dispensing fee per event but recoups some of the fee if the pharmacy does not meet a target generic dispensing rate, the amount recouped by the plan must be reported to CMS as a positive adjustment that will reduce the drug costs of the Part D sponsor. Conversely, the sponsor should report payments made to the pharmacy after the point of sale as a negative adjustment.

DIR # 6. Risk Sharing Arrangement Payments and Adjustments
Gains or losses that the Part D sponsor may receive as a result of risk sharing arrangements with entities other than CMS that are permissible under the Part D rule are reported in this column. Risk sharing amounts received from other parties must be reported in this column as a positive adjustment. Risk sharing amounts credited to other parties must be reported in this column as a negative adjustment.

DIR # 7. Pharmacy Payment Adjustments
With the exception of adjustments to generic dispensing incentive payments, which are reported in column DIR # 5, applicable adjustments to pharmacy payments are reported in this column. These include penalties or pharmacy repayments stipulated in the Part D sponsor's contract with its network pharmacies which represent incorrect drug costs that were paid or reported by the Part D sponsor due to an error made by the pharmacy. For these types of pharmacy penalties, the portion of the penalty that is equivalent to the amount by which the drug costs paid by the Part D sponsor or reported to CMS on the PDE exceeds the correct drug costs must be reported as DIR in this column.

Applicable pharmacy adjustments that reduce the total payments made to the pharmacy should be reported as a positive adjustment that will serve to reduce the plan's drug costs. Applicable pharmacy adjustments that increase the total payments made to the pharmacy should be reported as a negative adjustment that increases the plan's drug costs.

Amounts credited to the Part D sponsor by the pharmacy due to beneficiary cost-sharing that exceeds the gross drug cost are also reported in this column, provided that these payments are not already reflected in the covered plan paid (CPP) amounts reported on the PDE data.

DIR # 8. All Other DIR
All applicable DIR (as well as adjustments to DIR) that is not reported in the previous columns must be included in this column. This includes legal judgments or settlement amounts from lawsuits or other legal action, which directly or indirectly impact the drug costs incurred by the Part D sponsor for contract year 2008. To report legal judgments or settlement amounts which impacted the drug costs incurred in prior contract years, Part D sponsors must request a reopening and submit a revised DIR Report for Payment Reconciliation for the applicable contract year. Legal judgments or settlement amounts paid by the Part D sponsor which serve to increase the drug costs incurred by the sponsor for contract year 2008 must be reported in this column as a negative adjustment. Legal judgments or settlement amounts received by the Part D sponsor which serve to decrease the drug costs incurred by the sponsor for contract year 2008 must be reported as a positive adjustment.

Legal fees associated with the lawsuit or legal action for each legal judgment or settlement amount received may be excluded from the amount reported on the DIR Report for Payment Reconciliation for the applicable contract year up to the total amount of the judgment or settlement associated with the applicable lawsuit or legal action. For example, Sponsor A received a settlement amount of $500,000 for law suit A which impacted drugs costs for contract year 2007 and $100,000 for law suit B which impacted drug costs for contract year 2008. Sponsor A incurred $100,000 in legal fees for law suit A and $125,000 in legal fees for law suit B. Sponsor A would report $400,000 on the 2007 DIR Report for

Payment Reconciliation and $0 on the 2008 DIR Report for Payment Reconciliation. Please note, however, that Part D sponsors cannot include legal fees associated with lawsuits or legal action in which the Part D sponsor is required to pay a judgment or settlement amount on the DIR Report for Payment Reconciliation as a negative adjustment.

PBM penalty payments or repayments are also included in this column. In cases where a PBM penalty represents incorrect drug costs that were paid or reported by the Part D sponsor due to an error made by the PBM, the portion of the penalty that is equivalent to the amount by which the drug costs paid by the plan or reported to CMS on the PDE exceed the correct drug costs should be reported as DIR.

DIR included in this column that is not associated with a specific drug, must be reported in full on the DIR Report for Payment Reconciliation with no portion allocated to non-Part D covered drugs. This DIR must fully accrue to the government and beneficiaries and cannot be kept by the Part D sponsor.

Other Text Description
A short description indicating the type of price concession, the type of entity from (or to) which the Part D sponsor is collecting (or paying) the amount (e.g. pharmacy, manufacturer, PBM), and the associated dollar amount is required in this column for each price concession or DIR adjustment included in column DIR # 8 – All Other DIR. This field must be left blank if there is no dollar amount reported in column DIR #8.

Total DIR
Reported in this column is the sum of all of the DIR reported for the Part D plan for contract year 2008. The values in this field are automatically generated on the DIR Report for Payment Reconciliation and represent a sum of the values reported in columns DIR #1 – DIR #8. If reporting zero total DIR dollars for a specific Part D plan, Part D sponsors must provide a short explanation in the "Additional Comments" column of the DIR Report for Payment Reconciliation.

Rebates at POS?
If the Part D sponsor applied (estimated) rebates to the negotiated price at the point of sale in contract year 2008, the Part D sponsor should enter "Y" in this column for each applicable Part D plan. Otherwise, this field should be left blank to indicate that rebates were not applied to the negotiated price at the point of sale.

Additional Comments
Additional notes or comments on the data provided in columns DIR #1- DIR # 8 are included in this column. For example, sponsors must provide a short explanation if reporting zero total DIR dollars for a specific Part D plan. In addition, Part D sponsors must provide a description in this column for any PBM

manual adjustments, PBM penalty amounts, and legal judgment or settlement amounts reported in column DIR #8- All Other DIR. Part D sponsors are also encouraged to provide a description for any risk sharing arrangement amounts reported in column DIR # 6.

VIII. Report Format and Layout

DIR Report for Payment Reconciliation
(With Sample Values)

Contract-Plan	DIR #1 – PBM Retained Rebates	DIR #2 – Rebates Expected But Not Yet Received	DIR # 3 – All Other Rebates	DIR # 4 – Price Concessions for Administrative Services	DIR # 5 – Generic Dispensing Incentive Payments and Adjustments	DIR # 6 – Risk Sharing Arrangement Payments and Adjustments	DIR # 7 – Pharmacy Payment Adjust ments	DIR # 8 – All Other DIR	Other Text Description	Total DIR	Rebates at POS?	Additional Comments
S0001-001	30500.25	10000.00	140500.65	2000.00	-3500.50	6000.00	-4500.00	0.00		181000.40	Y	DIR #6- Received $6000 from risk sharing arrangement with physicians for prescription drug costs.
S0001-002	0.00	750.00	13000.76	1500.25	-500.00	-2250.77	-1550.00	1500.00	1. DIR for PBM penalty: $1500.00	12450.24		DIR #6- Paid $2250.77 to physicians due to risk sharing arrangement for prescription drug costs. DIR #8- Received $1500 from PBM due to error in applying step therapy requirements.
S0001-003	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		0.00		No DIR due to very low membership, no claims with associated DIR.

File Record Layout:
DIR Report for Payment Reconciliation

Field Name	Field Type	Field Length	Field Description
Contract-Plan	Character	9	Contract number and plan ID, e.g. S0001-001. Automatically generated.
DIR #1 – PBM Retained Rebates	Number Required	12 digits before the decimal and 2 digits after	For each Part D plan, provide the sum of all applicable PBM retained rebates and applicable rebate administration fees. See guidance for details.
DIR #2 – Rebates Expected But Not Yet Received	Number Required	12 digits before the decimal and 2 digits after	For each Part D plan, provide a good faith estimate of the sum of applicable rebates expected but not yet received. See guidance for details.
DIR # 3 – All Other Rebates	Number Required	12 digits before the decimal and 2 digits after	For each Part D plan, provide the sum of all other applicable rebates including rebates for COB claims and P2P claims. See guidance for details.
DIR # 4 – Price Concessions for Administrative Services	Number Required	12 digits before the decimal and 2 digits after	For each Part D plan, provide the sum of applicable price concessions for administrative services. See guidance for details.
DIR # 5 – Generic Dispensing Incentive Payments and Adjustments	Number Required	12 digits before the decimal and 2 digits after	For each Part D plan, provide the sum of applicable generic dispensing incentive payments and adjustments. See guidance for details. For a negative value, enter a minus sign and the value for the field.
DIR # 6 – Risk Sharing Arrangement Payments and Adjustments	Number Required	12 digits before the decimal and 2 digits after	For each Part D plan, provide the sum of DIR from risk sharing arrangements. See guidance for details. For a negative value, enter a minus sign and the value for the field.
DIR # 7 – Pharmacy Payment Adjustments	Number Required	12 digits before the decimal and 2 digits after	For each Part D plan, provide the sum of applicable pharmacy payment adjustments. See guidance for details. For a negative value, enter a minus sign and the value for the field.
DIR # 8 – All Other DIR	Number Required	12 digits before the decimal and 2 digits after	For each Part D plan, provide the sum of all other applicable DIR not reported in columns DIR # 1-7. See guidance for details. For a negative value, enter a minus sign and the value for the field.
Other Text Description	Character	4000	Description required for **all** DIR reported for Part D plan in DIR # 8 for Part D plan. Please leave blank if no DIR reported in DIR #8 for Part D plan. See guidance for details.
Total DIR	Number Required	12 digits before the decimal and 2 digits after	Sum of all DIR reported for Part D plan. Automatically generated.
Rebates at POS?	Character	1	For each Part D plan, indicate "Y" if estimated rebates were applied to the negotiated price at the point of sale. Please leave blank if estimated rebates were not applied to the negotiated price at the point of sale.
Additional Comments	Character	4000	Additional comments on DIR data reported in columns DIR #1- DIR #8. See guidance for details.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-22-25
Baltimore, Maryland 21244-1850

Center for Medicare
Medicare Plan Payment Group

Date: June 10, 2010

To: All Part D Plan Sponsors

From: Cheri Rice, Deputy Director
Medicare Plan Payment Group

Subject: Final Medicare Part D DIR Reporting Requirements for 2009 Payment Reconciliation

On April 13, 2010, CMS released draft guidance on the reporting of direct and indirect remuneration (DIR) data for the contract year 2009 payment reconciliation. Comments on this draft guidance were accepted until April 30, 2010. CMS has made revisions to the guidance in response to the comments and questions received. Provided below is an overview of the revisions made to the guidance and a brief summary of the comments we received. Part D sponsors must submit the 2009 DIR Report for Payment Reconciliation to CMS by **Wednesday, June 30, 2010**.

Revisions to the 2009 DIR Reporting Requirements Guidance

1. We received several comments regarding the submission of updated DIR reports to reflect changes in the DIR data received by Part D sponsors. Some commenters recommended that CMS establish a threshold for materiality and only require Part D sponsors to report changes in their DIR data that exceed the established threshold. One commenter recommended requiring Part D sponsors to submit an updated DIR Report for the previous contract year only. While we appreciate the desire to minimize reporting burden, it is important that Part D sponsors fully inform CMS of changes to their cost data, including changes to their DIR data. Therefore, in the final guidance we have retained the requirement that Part D sponsors report changes in DIR for previously reported years. We have clarified in the final guidance that Part D sponsors will be required to report any changes in their DIR data that affect the total DIR reported to CMS for prior years. These changes must be reported even if the Part D sponsor has contracted with a different PBM since the initial submission of their DIR data. As CMS collects these data, we will use this information to consider establishing a materiality threshold for the reporting of changes in the DIR data. Please see pages 16 - 17 of the attached guidance.

2. Commenters requested clarification regarding the timeframe and format for reporting changes to the DIR data. We have revised the final guidance to clarify that Part D

sponsors must report changes in their DIR data by uploading updated DIR Reports in HPMS using the report template for the corresponding contract year (e.g. changes to the 2006 DIR data would be reported using the template for the 2006 DIR Report for Payment Reconciliation). Please see pages 16 - 17 of the attached guidance.

3. Commenters requested that CMS provide additional time for Part D sponsors to generate, review, and submit DIR Reports for previous years. Thus, for 2009, we are extending the deadline for the submission of updated 2006, 2007, and 2008 DIR Reports for Payment Reconciliation to Tuesday, August 31, 2010.

4. One commenter expressed concerns about the requirement to submit a separate Attestation of Data Relating to CMS Payment to a Medicare Part D Sponsor every time an updated DIR Report is submitted to CMS. We have revised the final guidance to require Part D sponsors to submit an attestation for updated prior year DIR Reports only when requested by CMS due to a determination regarding whether a sponsor's Part D payments will be reopened and revised. This requirement will ensure that Part D sponsors attest that the cost data submitted to CMS is accurate, complete, and truthful prior to a reopening and revision of their Part D payments. Also, this policy will limit how often Part D sponsors must submit an attestation for their DIR data. Please see page 17-18 of the attached guidance for additional information.

<u>Additional Comments Received</u>

1. One commenter requested that CMS clarify whether DIR amounts should be reported to CMS based on the year the associated drug costs were incurred or the year the DIR data was received. DIR amounts must be reported to CMS based on the contract year for which the associated drug costs were incurred. For example, DIR amounts received in 2007 for drug costs incurred in contract year 2006 must be reported on the 2006 DIR Report for Payment Reconciliation. This requirement ensures that when determining Part D payments, CMS applies the DIR amounts to the associated drug costs reported for the corresponding contract year.

2. Commenters asked for clarification regarding the reporting of legal judgment or settlement amounts received for multiple contract years. Consistent with the DIR reporting requirements for prior contract years, legal judgment or settlement amounts associated with drug costs incurred across multiple contract years must be allocated to the DIR Reports for each of the corresponding contract years. Part D sponsors must report legal judgment or settlement amounts on the DIR Report based on the contract year in which the associated drug costs were incurred. Thus, consistent with our guidance regarding reporting changes to the DIR Report, Part D sponsors must submit updated DIR Reports when legal judgment or settlement amounts are received for drug costs incurred in previous contract years.

3. In the draft guidance, we provided clarifying guidance regarding allocation methodologies for DIR data. In addition, we provided examples of methodologies for allocating rebates to the plan level in Table 2. One commenter requested clarification

regarding whether Part D sponsors may only use the allocation methodologies listed in Table 2 to allocate rebates to the plan level. Another commenter asked for guidance on whether allocation methodologies that are not considered reasonable for rebates may be applied to other types of DIR. Table 2 provides examples of allocation methodologies, and therefore is not a complete list of the allocation methodologies that a Part D sponsor may use to allocate their rebates to the plan level. Part D sponsors may use an allocation methodology that is not listed in Table 2. However, Part D sponsors must ensure that they apply an allocation methodology that is *reasonable.* A Part D sponsor may determine that an allocation methodology that is not reasonable for rebates, may be reasonable for other DIR amounts based on the manner in which the DIR is generated and received.

4. One commenter requested clarification regarding the reporting of pharmacy benefit manager (PBM) rebate guarantee amounts. Specifically, the commenter asked whether any adjustments are made to the DIR data reported to CMS to reflect the loss incurred by a PBM when providing a rebate guarantee to a Part D sponsor. As indicated on page 6 of the attached guidance, rebate guarantee amounts received from PBMs are considered rebate amounts that reduce the drug costs incurred by the Part D sponsor and therefore, must be reported as DIR. There is no adjustment made to the DIR Report to reflect the potential loss incurred by the Part D sponsor's PBM. DIR consists of rebates and other price concessions that serve to decrease the costs incurred by the Part D sponsor (directly or indirectly), not the costs incurred solely by the sponsor's PBM.

5. One commenter requested that CMS not require Part D sponsors to report rebate administration fees received by PBMs from pharmaceutical manufacturers on the DIR Report for Payment Reconciliation. The commenter stated that these data are sensitive, proprietary, and competitive. Instead, the commenter recommended that CMS allow PBMs to report these data directly to CMS. We disagree with this recommendation. Part D sponsors must be informed of the rebate administration fees received by their contracted PBMs to determine if these fees must be reported as DIR for the purposes of determining their Part D payments. For example, Part D sponsors must be able to determine if rebate administration fees exceed fair market value in order to ascertain whether they must be reported as DIR since fees above fair market value are not considered bona fide service fees.

Please find attached the final revised guidance document, "Medicare Part D DIR Reporting Requirements for Payment Reconciliation- Contract Year 2009" on the reporting of DIR data for the purposes of the contract year 2009 Part D payment reconciliation. Please note that for contract year 2009, Part D sponsors will be required to submit the Attestation of Data Relating to CMS Payment to a Medicare Part D Sponsor after the submission of the 2009 DIR Report for Payment Reconciliation. Part D sponsors will be required to certify that the PDE and DIR data submitted to CMS for the 2009 payment reconciliation are accurate, complete, and truthful. Additional guidance regarding this attestation will be provided at a later date.

Further Information:
For technical assistance and questions regarding the download or upload of the DIR Report for Payment Reconciliation, please contact the HPMS Help Desk at 1-800-220-2028 or hpms@cms.hhs.gov. For any other questions regarding this guidance, please contact Meghan Elrington at Meghan.elrington@cms.hhs.gov.

MEDICARE PART D DIR REPORTING REQUIREMENTS FOR PAYMENT RECONCILIATION- CONTRACT YEAR 2009

Table of Contents

MEDICARE PART D DIR REPORTING REQUIREMENTS FOR PAYMENT RECONCILIATION- CONTRACT YEAR 2009

I. Introduction

In December 2003, Congress passed the Medicare Prescription Drug Benefit, Improvement and Modernization Act (MMA), allowing coverage of outpatient prescription drugs under the new Medicare Part D benefit. Reinsurance payments and risk sharing are two of the payment mechanisms by which the Medicare Program reimburses Part D sponsors for providing prescription drug coverage under Medicare Part D. CMS is required by statute to calculate these payments using "allowable reinsurance costs" and "allowable risk corridor costs", which must be "actually paid". As defined at 42 C.F.R. 423.308, "actually paid" costs must be actually incurred by the Part D sponsor and net of any applicable direct or indirect remuneration (DIR). Section 1860D-15(f)(1)(A) of the Act requires Part D sponsors to fully disclose to CMS any information necessary for carrying out the payment provisions of Part D, including the calculation of reinsurance and risk sharing. Therefore, Part D sponsors are required to report drug costs and DIR associated with the Medicare prescription drug benefit to CMS for the purposes of determining reinsurance payments and risk sharing. Consistent with section 1860D-15(d)(2)(A), CMS payments to a Part D sponsor are conditioned upon the provision of this requisite data.

The purpose of this document is to provide an overview of CMS' DIR reporting requirements for Medicare Part D payment and the format of the DIR Report for Payment Reconciliation. This document explains the data elements to be reported by Part D sponsors at the distinct Plan level (i.e., data will be reported for each Plan Benefit Package or PBP offered under each Part D Contract) and the established reporting timeframes. CMS' goal is to ensure a common understanding of DIR reporting requirements and how these data will be used to determine Medicare Part D payments. These requirements will apply for Contract Year 2009. For guidance regarding the reporting of rebates and other price concessions for the RDS program, please see the Retiree Drug Subsidy Program Guidance available on the CMS website at http://www.cms.hhs.gov/EmployerRetireeDrugSubsid/Downloads/20090112RebateGuidancePaper.pdf.

II. Defining Direct and Indirect Remuneration (DIR)

Per 42 C.F.R. 423.308, direct and indirect remuneration (DIR) is any and all rebates, subsidies, or other price concessions from any source (including manufacturers, pharmacies, enrollees, or any other person) that serve to decrease the costs incurred by the Part D sponsor (whether directly or indirectly) for the Part D drug. Thus, DIR includes discounts, chargebacks, rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, and coupons. DIR also includes goods in kind, free or reduced-price services, grants, legal judgment amounts, settlement amounts from lawsuits or other legal

action, and other price concessions or similar benefits. However, price concessions that are not considered to directly or indirectly impact drug costs incurred by the Part D sponsor are not included in DIR. Please see Table 1 below for examples of remuneration that are and are not considered DIR.

Table 1. Examples of Remuneration That Are and Are Not Considered DIR

Remuneration Considered DIR	Remuneration Not Considered DIR
Remuneration from pharmaceutical manufacturers (e.g. rebates, grants, reduced price administrative services, or legal settlement amounts)	Bona Fide Service Fees from pharmaceutical manufacturers
PBM retained rebates	Remuneration for administrative services (e.g. PBM incentive payments)
PBM rebate guarantee amounts	Private Reinsurance Amounts
PBM penalty payments and repayments that impact Part D drug costs	PBM penalty payments and repayments that do not impact Part D drug costs
Dispensing incentive payments to pharmacies	Rebate amounts received by long term care (LTC) pharmacies
Prompt pay discounts from pharmacies	Claims data
Pharmacy payment adjustments	
Risk sharing amounts	

III. Examples of Remuneration Considered DIR

A. Remuneration from Pharmaceutical Manufacturers

CMS considers all remuneration received directly or indirectly from pharmaceutical manufacturers (with the exception of bona fide services fees) to be price concessions that serve to reduce the drug costs incurred by the Part D sponsor. As stated in the preamble to subpart G of the Medicare Part D final rule (p. 4308 - 4309), CMS has a responsibility to ensure that price concessions are not masked as administrative fees. Therefore, to guarantee that a Part D sponsor's administrative costs are not inappropriately shifted to its drug costs, Part D sponsors are required to report all rebates, grants, settlement amounts, or price concessions received from pharmaceutical manufacturers (whether directly or indirectly) as DIR with the exception of bona fide services fees. Please see page 9 for a discussion of bona fide service fees.

i. Administrative Services

When Part D sponsors receive administrative services from pharmaceutical manufacturers at a cost below market value, the difference between the fair market value of the administrative service and the price paid by the Part D sponsor is considered DIR. Similarly, when a Part D sponsor (directly or indirectly through their PBM) receives payments from pharmaceutical

manufacturers for administrative services which are above the fair market value of the services provided, the difference between the price paid by the pharmaceutical manufacturer and the fair market value of the administrative service is considered DIR. For example, in the case of rebate administration fees from pharmaceutical manufacturers which exceed fair market value but otherwise meet the definition of a bona fide service fee, Part D sponsors must report the differential between the rebate administration fee and the fair market value as DIR.

ii. Legal Judgments and Settlement Amounts

All legal judgments and settlement amounts received from pharmaceutical manufacturers for covered Part D drugs (with the exception of litigation concerning bona fide service fees) are considered price concessions which impact the drug costs incurred by the Part D sponsor and, therefore, must be reported as DIR. This includes legal judgments or settlement amounts from litigation due to inappropriate utilization, market competition, and the manipulation of the patient process.

B. PBM Retained Rebates

Rebates, discounts, and other price concessions from pharmaceutical manufacturers for purchases under the Medicare prescription drug benefit are considered DIR even if they are received by subcontractors of Part D sponsors, such as pharmacy benefit managers (PBMs), and retained by the subcontractor in lieu of higher service fees from the Part D sponsor. These amounts are considered price concessions received indirectly from pharmaceutical manufacturers which must be reported as DIR for payment purposes. In accordance with the guidance on "Reporting of Manufacturer Rebates in Part D" provided in the 2007 Call Letter, a Part D sponsor must report 100% of the manufacturer rebates, discounts, and other price concessions (with the exception of bona fide service fees) retained by its PBM as DIR, regardless of the relationship between the sponsor and the PBM and the provisions of the contract(s) between the sponsor and the PBM. Applicable rebate administration fees which the PBM receives from pharmaceutical manufacturers must also be reported to the extent that they do not represent bona fide service fees.

As stated in the 2007 Call Letter released on April 3, 2006, CMS must assume that if a PBM retains a portion of the manufacturer rebates it negotiates on behalf of a Part D sponsor, the direct payment the sponsor pays the PBM for its services will be less, such that the sponsor receives a price concession from the PBM. Thus, because retained rebates function as additional administrative fees paid to the PBM, Part D sponsors **also** should account for these retained rebate amounts in the administrative expense component of their Part D bids.

C. PBM Rebate Guarantee Amounts
Rebate guarantee amounts are rebate amounts received from PBMs to account for the difference between a rebate amount guaranteed by a PBM and the actual rebate amount received from a pharmaceutical manufacturer. These rebate amounts reduce the drug costs incurred by the Part D sponsor and therefore, are considered DIR.

D. PBM Penalty Payments and Repayments
Penalty payments or repayments from PBMs that directly or indirectly impact the drug costs incurred by the Part D sponsor are considered DIR. Some PBM penalty payments include a price concession for administrative services provided by the PBM as well as remuneration for drug cost. In these cases, only the portion of the PBM penalty which impacts the drug costs incurred by the Part D sponsor is considered DIR. Thus, the portion of the penalty payment which represents drug cost that has been reimbursed by the PBM must be reported as DIR. The remaining portion of the PBM penalty is not considered DIR because it does not directly or indirectly impact the drug costs incurred by the Part D sponsor.

For example, if a PBM is required to pay the Part D sponsor $1,000 plus claim costs due to an error associated with allowing coverage of a drug on step 2 of a step-therapy program, when a drug on step 1 of the same program should have been required, the amount paid by the PBM that is equivalent to the cost of the affected claims is considered DIR. The Part D sponsor must report this amount as DIR because the Prescription Drug Event (PDE) data submitted to CMS would not reflect this reduction in drug costs for the Part D sponsor. Any additional amount above the cost of the drug does not directly or indirectly impact the Part D sponsor's drug costs and is not considered DIR. Alternatively, if the PBM is required to pay the Part D sponsor $1,000 plus the difference between the cost of the drug on step 2 and the cost of the drug on step 1, the portion representing drug cost reimbursed by the PBM (the difference between the cost of the two drugs) is considered DIR. In both examples, the remaining $1,000 payment received from the PBM does not directly or indirectly impact the drug costs incurred by the Part D sponsor and therefore, is not considered DIR.

Please note that in most cases, Part D sponsors should submit an adjusted PDE record with a revised gross drug cost if their PBM has administered the benefit incorrectly. In these cases, the PBM penalty associated with the errors in drug cost should not be reported as DIR since the PDE record has been adjusted to reflect the appropriate gross drug cost.

E. Dispensing Incentive Payments
Dispensing fees paid to pharmacies and other dispensing providers are considered part of the drug cost incurred by Part D sponsors. Therefore, dispensing incentive payments made to the pharmacy at the point of sale are part of the dispensing fee reported on the PDE record and are not reported as

DIR. In contrast, dispensing incentive payments and adjustments to dispensing incentive payments made to pharmacies **after** the point of sale dispensing event are not reflected in the drug costs reported on PDE records. As a result, these post- POS dispensing incentive payments and adjustments must be reported as DIR to ensure that the Part D sponsor's allowable reinsurance and risk corridor costs appropriately reflect the drug costs actually incurred by the Part D sponsor.

i. Generic Dispensing Incentive Payments

Generic dispensing incentive payments are payments made to pharmacies to encourage the dispensing of generic drugs. If a Part D sponsor makes a generic dispensing incentive payment to the pharmacy at the point of sale (POS), CMS considers it part of the dispensing fee and the sponsor or its third party submitter must report this cost as part of the dispensing fee on their PDE. As a result, generic dispensing incentive payments made at the point of sale are not reported as DIR. However, if the sponsor pays the pharmacy a generic dispensing incentive payment after the point of sale or makes any post-POS adjustments to prospective generic dispensing incentive payments, the sponsor must report the post- POS payments or adjustments as DIR.

F. Prompt Pay Discounts from Pharmacies

Part D sponsors may receive discounts from pharmacies for the timely payment of Part D claims. These prompt payment discounts are considered DIR and must be reported on the DIR Report for Payment Reconciliation if they are (i) received after the point of sale and (ii) not reflected on the PDE records submitted to CMS. If a Part D sponsor expects to receive a prompt payment discount from a pharmacy, the Part D sponsor should reflect this discount on the PDE records submitted to CMS by reducing the reported drug costs.

G. Pharmacy Payment Adjustments

Adjustments made to pharmacy payments after the point-of-sale that (i) directly or indirectly impact the drug costs incurred by the Part D sponsor and (ii) are not reflected in the PDE data are considered DIR. These adjustments include penalties or pharmacy repayments stipulated in the Part D sponsor's contract with its network pharmacies which represent incorrect drug costs that were paid or reported by the Part D sponsor due to an error made by the pharmacy. For these types of pharmacy penalties, the portion of the penalty that is equivalent to the amount by which the drug costs paid by the Part D sponsor or reported to CMS on the PDE data exceeds the correct drug costs is considered DIR. The remaining portion of the pharmacy penalty is considered a price concession for administrative services provided by the pharmacy that does not directly or indirectly impact the drug costs incurred by the Part D sponsor and therefore is not reported as DIR.

Please note that in most cases, the Part D sponsor should submit an adjusted PDE with a revised gross drug cost if the pharmacy made an error in determining

the POS drug price. In these cases, the pharmacy payment adjustment should not be reported as DIR since it is already reflected in the gross drug cost reported on the PDE record. For example, if a Part D sponsor recoups an overpayment to the pharmacy due to an error in POS drug price and the recouped amount is reported to CMS via an adjusted PDE record with a revised gross drug cost, the Part D sponsor would not report the pharmacy payment adjustment on the DIR Report for Payment Reconciliation.

Adjustments made to beneficiary cost-sharing due to changes in low-income subsidy eligibility status impact the low-income cost sharing subsidy amounts received from CMS. However, these adjustments do not impact the drug costs actually incurred by Part D sponsors. This type of adjustment does not affect the negotiated price or the plan's liability for the drug claim. As a result, these adjustments are not considered DIR. Adjustments to beneficiary cost sharing should be reflected on the PDE records submitted to CMS.

Amounts credited to the Part D sponsor by the pharmacy due to beneficiary cost-sharing that exceeds the gross drug cost are considered DIR, provided that these payments are not already reflected in the covered plan paid (CPP) amounts reported on the PDE record. This credit occurs when the beneficiary's co-payment exceeds the negotiated drug price and the pharmacy credits the differential amount to the Part D sponsor. If this payment is not reflected in the CPP amount reported on the PDE record, the amount by which the beneficiary's co-payment exceeds the negotiated price must be reported as DIR to reduce the plan's allowable costs. Please note that in cases where the pharmacy retains this differential amount, this amount is considered payment to the pharmacy and, thus, is not reported as DIR.

H. Risk Sharing Amounts

It is permissible under the Part D rule for sponsors to enter into certain types of risk sharing arrangements with entities other than CMS. Risk sharing arrangements are arrangements in which the Part D sponsor shares risk with a provider (e.g., pharmacy) or other party involved in the administration or delivery of the Part D benefit. Any risk sharing arrangement between the sponsor and another party must be based on the cost of Part D covered drugs. Under no circumstances can a risk sharing arrangement be developed around administrative costs. Risk sharing amounts received from or credited to other parties constitute DIR and must be offset against prescription drug costs in the calculation of allowable reinsurance and risk corridor costs. As with other types of DIR, the value of risk sharing may be negative. Please note that private reinsurance amounts are not considered DIR. See page 10 for a discussion of amounts from private reinsurance arrangements.

IV. Examples of Remuneration Not Considered DIR

A. Bona Fide Service Fees

Bona fide service fees which Part D sponsors or subcontractors of Part D sponsors (such as PBMs) receive from pharmaceutical manufacturers are not considered price concessions that reduce the drug costs incurred by the Part D sponsor and, therefore, are not considered DIR. Bona fide service fees are fees paid by a manufacturer to an entity, that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.

Rebate administration fees paid to a Part D sponsor or a PBM, which meet the definition of a bona fide service fee, are not considered DIR and therefore, may be excluded from the DIR amounts reported on the DIR Report for Payment Reconciliation (i.e. excluded from columns DIR #1-DIR # 8 of the DIR Report). In the case of rebate administration fees or other amounts from pharmaceutical manufacturers which exceed fair market value, but otherwise meet the definition of a bona fide service fee, the differential between the rebate administration fee or other amount and fair market value must be reported as DIR. Although rebate administration fees that meet the definition of a bona fide service fee are not considered DIR, Part D sponsors are required to report these amounts to CMS in the column “Rebate Administration Fees”. This information will be used to ensure that rebate administration fees above fair market value are not excluded from the DIR data used for Part D payment reconciliation. The amounts reported under the Rebate Administration Fees column will not be included in the DIR amounts used to determine allowable reinsurance costs and allowable risk corridor costs.

B. Remuneration for Administrative Services

Price concessions for administrative services which do not directly or indirectly impact the drug costs incurred by the Part D sponsor are not included in DIR. For example, price concessions from a pharmacy for administrative services only (excluding dispensing fees) which do not represent a change in the drug costs paid by the Part D sponsor, do not impact the drugs costs incurred by the Part D sponsor and, therefore, are not considered DIR.

i. PBM Incentive Payments

Part D sponsors may pay incentive payments to PBMs for performing administrative services such as negotiating rebates and drug prices as well as increasing generic utilization. These incentive payments represent an increase in the administrative fees paid by the Part D sponsor to their PBM and therefore, are not considered DIR. This is in contrast to generic dispensing fees paid to pharmacies where the Part D sponsor pays a higher dispensing fee to the pharmacy as an incentive for dispensing generic drugs

instead of brand drugs. The dispensing fee is a component of the negotiated price paid to the pharmacy. As a result, adjustments to the dispensing fee directly impact the drug costs incurred by the Part D sponsor and must be reported as DIR if applied after the point of sale.

C. Private Reinsurance Amounts

Private reinsurance arrangements are arrangements in which the Part D sponsor shares risk with a party otherwise uninvolved in the administration or delivery of the Medicare prescription drug benefit. Private reinsurance amounts do not constitute DIR and should not be reported on the DIR Report for Payment Reconciliation. Instead, similar to Part D sponsors' direct and indirect administration costs, reinsurance amounts from private reinsurance arrangements are included in the Part D sponsor's bid as a non-benefit expense.

D. Rebates Received by Long Term Care (LTC) Pharmacies

Part D sponsors purchase Part D drugs directly from long term care (LTC) pharmacies. The rebate amounts and price concessions received by these dispensing providers do not serve to further reduce the drug cost paid by Part D sponsors at the point of sale. Therefore, pharmaceutical manufacturer rebates received by LTC pharmacies are not considered DIR.

E. Claims Data

Claims data are not considered DIR and therefore must not be reported on the DIR Report for Payment Reconciliation. Instead, Part D sponsors should report all applicable claims data on PDE records. This policy is applicable to all claims data, including data received or processed after the PDE data submission deadline.

V. DIR Included on the DIR Report for Payment Reconciliation

Part D sponsors must report DIR associated with purchases under the Medicare prescription drug benefit on the DIR Report for Payment Reconciliation. DIR that is not generated from the sponsor's Medicare Part D book of business should not be included on this report. The DIR included on the DIR Report for Payment Reconciliation will be excluded from allowable reinsurance costs and allowable risk corridor costs when CMS calculates reinsurance and risk sharing payments during the Part D payment reconciliation process. As a result, Part D sponsors should consider their best expectation of DIR when developing their Part D bids.

Accurate and complete DIR data are necessary for the accurate completion of Part D payment reconciliation. Data reported on the DIR Report for Payment Reconciliation are subject to audit. Part D sponsors are required to maintain records of all related transactions, claims, contracts, and other materials. Please note that misrepresentations or omissions in the DIR data provided to CMS may result in Federal civil action and/or criminal prosecution. In addition, per 42 C.F.R. 423.343(d)(2) of the Part D Regulations, if a Part D sponsor does not

provide adequate data to determine risk corridor costs, including DIR data, CMS assumes that the Part D plan's adjusted allowable risk corridor costs are 50 percent of the plan's target amount.

A. DIR Not Applied at the Point of Sale

Some DIR is reflected in the amount paid at the point of sale. To the extent that DIR is already taken into account in the gross drug cost (sum of ingredient cost, dispensing fee, applicable sales tax, and vaccine administration fee) reported to CMS on the PDE record, this DIR (with the exception of estimated rebates applied at the point of sale) should not be reported on the DIR Report for Payment Reconciliation.

B. Estimated Rebates Applied at the Point of Sale

Part D sponsors may elect to make rebates available to their beneficiaries at the point of sale by applying estimated rebates to the negotiated price. For rebates that were estimated and applied to the point of sale price, Part D sponsors are required to report the estimated rebate amounts in the "Estimated Rebate at POS" field of the PDE record.

Although Part D sponsors are required to report their gross drug costs on the PDE record net of any estimated rebates applied at the point of sale, they are **also** required to report the actual rebate amounts for these estimated rebates on the DIR Report for Payment Reconciliation. CMS will subtract the amounts reported in the Estimated Rebate at POS field of the PDE record for covered Part D drugs from the total DIR amount reported on the DIR Report for Payment Reconciliation when determining the appropriate DIR amount for the calculation of allowable reinsurance costs and adjusted allowable risk corridor costs. This will capture any difference between the estimated rebates and the actual rebates. In addition, this will ensure that only price concessions which were not already included in the gross covered drug costs reported to CMS are included in the DIR amount used to calculate allowable reinsurance costs and adjusted allowable risk corridor costs. For additional information, please see the June 1, 2007 HPMS memorandum, "Reporting Estimated Rebates Applied to the Point-of-Sale Price".

C. DIR for Covered Part D drugs

CMS provides reinsurance and risk sharing for costs associated with covered Part D drugs only. Covered Part D drugs, as defined in 42 C.F.R. 423.100, are Part D drugs that are included in a Part D plan's formulary or treated as included in the formulary as a result of the plan's exceptions process, a coverage determination appeal, or a transition period. When calculating allowable reinsurance and risk corridor costs, CMS will only apply DIR dollars for covered Part D drugs. Therefore, on the DIR Report for Payment Reconciliation, Part D sponsors are required to submit DIR for covered Part D drugs only. DIR for non-Part D covered drugs (drugs covered by the Part D sponsor which are not Part D drugs) should not be included on this report.

D. DIR Associated with Supplemental Benefits and Benefit Phases with 100% Coinsurance

Applicable DIR for covered Part D drugs must be reported in full on the DIR Report for Payment Reconciliation. This includes DIR for supplemental prescription drug benefits as well as DIR associated with drug purchases in the deductible phase and the coverage gap. Consistent with our instructions for the development of the Part D bids, all applicable DIR will be excluded from allowable costs when CMS determines final reinsurance and risk sharing payments.

E. DIR Associated with Rejected PDE Records

All applicable DIR received for Part D plan expenditures incurred during the contract year must be reported on the DIR Report for Payment Reconciliation. DIR associated with non-Part D expenditures reported on rejected PDE records (for example, DIR from drug costs covered under Medicare Part B) may be excluded from the DIR Report for Payment Reconciliation. It is inappropriate, however, for a Part D sponsor to exclude from the DIR report all DIR associated with rejected PDE records when the Part D sponsor expects that a portion of the rejected PDE records will ultimately be accepted by CMS either prior to or after the Part D payment reconciliation. As a result, DIR received for Part D plan expenditures reported on PDE records that were initially rejected by CMS' systems but that the Part D sponsor believes will ultimately be accepted must be reported on the DIR Report for Payment Reconciliation.

F. Estimates of Expected DIR Not Yet Received

Part D sponsors must include on the DIR Report for Payment Reconciliation good faith estimates for DIR that is expected for the applicable contract year but has not yet been received. This includes estimates for rebates expected from pharmaceutical manufacturers that have not yet been received as well as estimates for DIR associated with claims for the contract year which are expected to be submitted and processed after the PDE data submission deadline. Estimated DIR amounts reported on the DIR Report for Payment Reconciliation will be included in the total DIR amount subtracted from Part D sponsors' drug costs when determining allowable reinsurance costs and allowable risk corridor costs.

VI. Reporting Requirements

Part D sponsors must submit their DIR data at the plan benefit package (referred to as "plan") level on the DIR Report for Payment Reconciliation within 6 months of the end of the coverage year. **The submission deadline for the 2009 DIR Report for Payment Reconciliation is Wednesday, June 30, 2010.** This deadline applies to all Part D plans including non-calendar year Employer/Union-only Group Waiver Plans (EGWPs).

A. Allocation Methodology [New Clarification]

Some Part D sponsors may receive or record their DIR at the sponsor or contract level. In these cases, the Part D sponsor must allocate their DIR to the plan level by applying a *reasonable* allocation methodology. Generally, allocation methodologies which reflect differences in utilization and spending across plans for specific drugs are considered reasonable. Ideally, Part D sponsors should allocate rebates for a specific drug to the plan level based on the actual utilization of that specific drug. Table 2 provides examples of allocation methodologies and indicates whether the methodology is generally considered reasonable for allocating rebates to the plan level. When considering an allocation methodology for rebates, Part D sponsors should consider whether the rebate dollars are appropriately allocated to each plan given the drug costs associated with the rebatable drugs purchased under each plan.

Part D sponsors may also receive legal judgments or settlement amounts from lawsuits or other legal action, which are associated with drug costs incurred across multiple contract years. The portion of the judgment or settlement amounts associated with the drug costs for each contract year should be reported on the corresponding DIR Report for Payment Reconciliation. Thus, for legal judgments or settlement amounts from law suits or other legal action concerning drug costs for multiple contract years, Part D sponsors must use a *reasonable* methodology to allocate the legal judgments or settlement amounts to each applicable contract year.

A brief description of any allocation methodology used must be submitted by the Part D sponsor on HPMS when uploading the DIR Report for Payment Reconciliation. Part D sponsors are expected to maintain internal documentation of any allocation methodology applied.

Table 2. Examples of Methodologies for Allocating Rebates To the Plan Level

Allocation Methodology	Description	Considered Reasonable?	Explanation
Based on Actual Drug Utilization	Rebate amounts received for a specific drug are allocated to a plan based on the number of units of the specific drug that were purchased under the plan as a percent of the total number of units purchased by the sponsor.	Yes	Appropriately accounts for differences in a specific drug's utilization across Part D plans.
Based on Plan's Total Drug Spend	Rebate amounts received for multiple drugs are allocated to a plan based on the total drug spend under the plan as a percent of the total drug spend under all of the sponsor's Part D plans.	Yes	Approximates differences in utilization and spending on rebate eligible drugs across Part D plans.
Based on Plan's	Rebate amounts received for multiple drugs	Yes	Accounts for differences in

Brand Drug Spend	are allocated to a plan based on the total drug spend for brand drugs under the plan as a percent of the total drug spend for brand drugs under all of the sponsor's Part D plans.		utilization and spending on rebate eligible drugs across Part D plans.
Based on Total Drug Spend for Drugs in Preferred Brand Tier	Rebates received for multiple drugs are allocated to a plan based on the total drug spend for drugs in the plan's preferred brand tier as a percent of the total drug spend for drugs in the preferred brand tier of all of the sponsor's Part D plans.	Yes, if the sponsor only receives rebates for drugs in the preferred brand tier.	Accounts for differences in utilization and spending on rebate eligible drugs across Part D plans.
Based on Enrollment	Rebates received for multiple drugs are allocated to a plan based on the number of beneficiaries enrolled in the plan as a percent of the total number of beneficiaries enrolled in all of the sponsor's Part D plans.	No	Does not sufficiently approximate differences in utilization and spending on rebate eligible drugs across Part D plans.
Based on LIS Enrollment	Rebates received for multiple drugs are allocated to a plan based on the number of LIS beneficiaries enrolled in the plan as a percent of the total number of LIS beneficiaries enrolled in all of the sponsor's Part D plans.	No	Does not sufficiently approximate differences in utilization and spending on rebate eligible drugs across Part D plans.
Based on Billed Rebate Amounts	Rebates received for a specific drug are allocated to a plan based on the rebate amounts billed to the pharmaceutical manufacturer for the specific plan and drug as a percent of the total rebate amount billed to the pharmaceutical manufacturer for all of the sponsor's Part D plans.	Yes	Appropriately accounts for differences in a specific drug's utilization across Part D plans.
Based on Number of Claims	Rebates received for multiple drugs are allocated to a plan based on the number of claims under the plan as a percent of the total number of claims received under all of the sponsor's Part D plans. Thus, allocation is based on the total number of claims for all of the drugs rather than the number of claims received for each drug.	No	Does not sufficiently approximate differences in utilization and spending on rebate eligible drugs across Part D plans.

B. DIR Submission Information

Prior to uploading the 2009 DIR Report for Payment Reconciliation on HPMS, Part D sponsors are required to provide additional information at the contract level regarding their DIR and PDE data. A description of the information required is provided below.

1) **Description of Allocation Methodology**: Part D sponsors must provide a description of any methodology used to allocate DIR to the plan level. If this question is not applicable, Part D sponsors should enter "N/A".

2) **Name of PBM(s) for Claims Processing**: Part D sponsors must provide the name of any PBM or other entity with which the sponsor contracted for the processing of claims or submission of PDE records for 2009. If the Part D

sponsor conducted claims processing and PDE record submission internally and did not contract with a PBM for these services, the Part D sponsor should indicate "Self" for this question.

3) **Name of PBM(s) for Rebate Negotiation**: Part D sponsors must provide the name of any PBM or other entity with which the Part D sponsor contracted for the negotiation or processing of rebates for 2009. Part D sponsors that conducted rebate negotiation and processing using their internal resources and did not contract with a PBM for these services should indicate "Self" for this question. If the Part D sponsor did not negotiate or process rebates, the Part D sponsor should enter "N/A" for this question.

4) **Did PBM for Rebate Negotiation change from 2008 to 2009?**: Part D sponsors must indicate whether they contracted with a different PBM or entity in 2008 for the negotiation or processing of rebates. If the Part D sponsor did not negotiate or process rebates in 2008 and 2009, the sponsor should enter "N/A" for this question. If the Part D sponsor contracted with a PBM or other entity for the negotiation or processing of rebates in 2009 but not in 2008, the sponsor should enter "Yes" for this question. Similarly, if the sponsor contracted with a PBM or other entity for the negotiation or processing of rebates in 2008 but not in 2009, the sponsor should enter "Yes" for this question.

5) **Were any of the plans in the contract owned by a different sponsor in 2008?**: Part D sponsors must indicate whether any of the plans in the contract were owned by a different sponsor in 2008. For any applicable plans, the sponsor must provide the plan ID, the name of the sponsor which owned the plan in 2008, and the contract number that the plan was under in 2008. If all of the plans in the contract were owned by a different sponsor in 2008, the sponsor may indicate "all plans in contract" instead of listing all of the plan IDs.

6) **Did your parent organization acquire any of the plans in this contract during the 2009 contract year?**: Part D sponsors must indicate whether any of the plans in the contract were acquired mid-contract year. For any applicable plans, the sponsor must provide the plan ID, the name of the sponsor which previously owned the plan, and the contract number that the plan was under prior to the sponsor's acquisition of the plan?

7) Reason for Resubmission: When resubmitting the DIR Report for Payment Reconciliation, Part D sponsors are required to provide an explanation for the resubmission of their DIR data.

C. DIR Report for Payment Reconciliation

The 2009 DIR Report for Payment Reconciliation will be made available on June

10, 2010. Part D sponsors will be able to download it from HPMS using the following navigation path: HPMS Homepage > Plan Bids > DIR Reporting > Contract Year 2009 > DIR Reporting (for Payment Reconciliation). This report will be downloadable to an MS Excel spreadsheet in the format provided in Section VIII: Report Format and Layout. Part D sponsors must prepare and upload to HPMS the 2009 DIR Report for Payment Reconciliation for each of their Part D plans (including non-calendar year Employer/Union-only Group Waiver Plans). In order to upload successfully, **Part D sponsors must use the actual downloaded MS Excel spreadsheet and name the file DIR.xls**.

Part D sponsors must prepare and submit the DIR Report for Payment Reconciliation to CMS for all of the Part D plans which they offered in 2009, even if they have no DIR to report for contract year 2009. For plans with no DIR to report for contract year 2009, the Part D sponsor must include a brief explanation in the column "Additional Comments".

Sponsors may upload the 2009 DIR Report for Payment Reconciliation as many times as they choose between June 10, 2010 and 11:59 p.m. PDT on Wednesday, June 30, 2010. CMS will use the DIR reported on the most recently uploaded report during payment reconciliation.

CMS will review the DIR data submitted. DIR reports which have been reviewed and accepted by CMS will receive an "accepted" status in HPMS. If CMS identifies a potential error, CMS will contact the Part D sponsor. Part D sponsors may see the status of submitted DIR reports on the DIR Contract Status page in HPMS using the following navigation path: HPMS Homepage > Plan Bids > DIR Reporting > Contract Year 2009 > DIR Reporting (for Payment Reconciliation) > DIR Contract Status Report. For technical assistance, Part D sponsors can contact the HPMS Help Desk at either 1-800-220-2028 or hpms@cms.hhs.gov. For other questions regarding the 2009 DIR Report for Payment Reconciliation, sponsors can contact Meghan Elrington at (410) 786-8675 or meghan.elrington@cms.hhs.gov.

D. Reporting Changes to the DIR Report for Payment Reconciliation [New Clarification]

CMS is aware that there are instances when Part D sponsors may receive unanticipated rebate amounts, settlement amounts, or other price concessions after the submission deadline which could result in changes to the DIR data reported to CMS. Per 42 C.F.R. §423.346, CMS has the authority to reopen and revise initial or reconsidered final Part D payment determinations within specified time periods. Therefore, to ensure that CMS has the information needed to determine whether a reopening of a sponsor's final Part D payment determination is warranted, Part D sponsors must inform CMS of changes in their DIR data that affect the Total DIR reported to CMS.

To report a change or error in the DIR amounts reported for a prior contract year, Part D sponsors must submit an updated DIR Report in HPMS during the next DIR submission period using the report template for the corresponding year. For example, a Part D sponsor becomes aware of a change in the DIR amounts reported for contract year 2006 in September 2009. Since the next DIR submission period would be for the 2009 DIR Report for Payment Reconciliation, the Part D sponsor would be required to submit an updated 2006 DIR Report for Payment Reconciliation during the submission period for the 2009 DIR Report using the 2006 DIR Report template. If a Part D sponsor needs to resubmit their DIR data for a contract year more than 4 years prior to the submission timeframe (e.g. resubmit DIR data for 2006 during the 2011 submission period for 2010 DIR Reports), the sponsor should contact CMS using the contact information provided above.

As this is the first year of this policy, we have extended the 2010 submission period for updated prior year DIR Reports to August 31, 2010. Thus, Part D sponsors must submit separate updated DIR Reports for contract years 2006-2008 during the extended submission period, June 10, 2010 to August 31, 2010. Part D sponsors are not required to submit an updated DIR Report if there has been no change to the total DIR previously reported to CMS. Thus, if there have been changes in the DIR data that result in no change to the "Total DIR" column, Part D sponsors are not required to submit an updated DIR Report. CMS will review the updated DIR Reports as well as the PDE data to make a determination on whether the sponsor's final Part D payment determinations will be reopened.

In addition to submitting a revised DIR Report, Part D sponsors have the option to request that CMS, at its discretion, reopen and revise the sponsor's final Part D payment determinations to reflect their reported changes in DIR. In addition to the review mentioned in the paragraph above, CMS will review submitted reopening requests and make a determination on whether the sponsor's final Part D payment determinations will be reopened. Reopening requests must be submitted to StrategicHealthSolutions, LLC (Strategic) at PartDPaymentReview@Strategichs.com. Please see the May 8, 2008 HPMS memo, "The Part D Reopenings Process and the Part D Appeals Process" for additional guidance regarding how to submit a reopening request. Please note that the reopening process requires substantial CMS preparation and resources. Therefore, it may take some time to receive a determination regarding a request for reopening from CMS. In addition, Part D sponsors should not expect the reopening to be performed immediately after receiving a decision to reopen.

E. Attestation of Data Relating to CMS Payment to a Medicare Part D Sponsor

In accordance with 42 CFR 423.505(k)(5), Part D sponsors will be required to submit an attestation, "Attestation of Data Relating to CMS Payment to a

Medicare Part D Sponsor", after the submission of the DIR Report for Payment Reconciliation but prior to the completion of the 2009 Part D Payment Reconciliation. In this attestation, Part D sponsors must certify that all information provided for the purposes of determining allowable reinsurance costs and risk corridor costs (for example, PDE data and DIR data) is accurate, complete, and truthful to the sponsor's best knowledge, information, and belief. Part D sponsors must certify in this attestation and maintain documentation that all entities which have generated or submitted this information on their behalf have certified that this information is accurate, complete, and truthful based on the entity's best knowledge, information, and belief.

For DIR data submitted after the Part D payment reconciliation, Part D sponsors must submit a new attestation when requested by CMS due to a determination regarding whether sponsor's Part D payments will be reopened and revised. Additional guidance regarding the submission of the Attestation of Data Relating to CMS Payment to a Medicare Part D Sponsor will be provided at a later date.

VII. Reporting Elements

Part D sponsors will be responsible for reporting multiple data elements related to DIR at the plan level. DIR data must be summarized for each plan and reported in aggregate to include multiple drugs and price concessions.

DIR # 1. PBM Retained Rebates

All rebates and applicable rebate administration fees associated with the Medicare prescription drug benefit which are received by PBMs from pharmaceutical manufacturers and retained by the PBMs must be reported in this column. Please note that rebates which PBMs have passed through to the Part D sponsor (and therefore, are not retained) are reported in column DIR #3, All Other Rebates.

DIR #2. Rebates Expected But Not Yet Received

Good faith estimates of rebate amounts that are expected for the applicable contract year, but have not yet been received are reported in this column. This column should not include rebate amounts which have been received by the sponsor prior to the latest submission of the DIR report unless the rebate amounts are received by the sponsor after the DIR data for the report is compiled. Part D sponsors are advised that the DIR data used to produce the DIR report should be reasonably current reflecting at a minimum the DIR amounts received up to three months prior to the submission deadline.

DIR # 3. All Other Rebates

All rebates associated with the Medicare prescription drug benefit are reported in this column with the exception of the rebate amounts reported in columns DIR #1 and DIR #2. Included in this column are rebate guarantee amounts from PBMs and rebates received from pharmaceutical manufacturers for Part D purchases,

such as market share rebates. The actual rebate amounts received for rebates which were estimated and applied to the negotiated price at the point of sale are also reported in this column. Rebates and applicable rebate administration fees that PBMs have received from pharmaceutical manufacturers for Part D purchases and passed through to the Part D sponsor must also be included in this column.

Per 42 C.F.R. 423.464, Part D sponsors are required to coordinate benefits with State Pharmaceutical Assistance Programs (SPAPs) and entities providing other prescription drug coverage (described in 42 C.F.R. 423.464(f)(1)). CMS has taken many steps to help facilitate the coordination of benefits between Part D sponsors and third party providers of prescription drug coverage. However, there are instances in which Part D sponsors must reimburse third party payers for Part D claims due to COB errors. All rebates associated with these incurred Part D drug costs must be reported in this column.

Also reported in this column are rebates associated with Plan-to-Plan (P2P) claims. Under the current process for reimbursing P2P claims, the Part D sponsor actually incurring the Part D drug costs (the plan of record) does not have claim level data and therefore is unable to receive rebates for these claims. The submitting plan, however, may receive rebates for these claims and is required to report them to CMS. Rebates received by the submitting plan for P2P claims must be reported in this column.

DIR # 4. Price Concessions for Administrative Services

Price concessions from pharmaceutical manufacturers for administrative services associated with the Part D benefit are reported in this column. This includes administrative services received by the Part D sponsor from pharmaceutical manufacturers at a cost below market value. The difference between the market value of the administrative service and the price paid by the Part D sponsor should be reported in this column. Also reported in this column are grants received by the Part D sponsor from pharmaceutical manufacturers for services and programs such as utilization management and medical education grants. Applicable price concessions for administrative services that are not associated with a specific drug must be reported in full in this column with no portion allocated for non-Part D Covered drugs. This DIR must fully accrue to the government and beneficiaries and cannot be kept by the Part D sponsor. Please note that PBM retained rebates must be reported in column DIR # 2, “PBM Retained Rebates”, and are therefore not included in this column (DIR # 4).

DIR # 5. Generic Dispensing Incentive Payments and Adjustments

Reported in this column are generic dispensing incentive payments or adjustments made after the point of sale. Specifically, if a plan pays the pharmacy a prospective dispensing fee per event but recoups some of the fee if the pharmacy does not meet a target generic dispensing rate, the amount recouped by the plan must be reported to CMS as a positive adjustment that will

reduce the drug costs of the Part D sponsor. Conversely, the sponsor should report payments made to the pharmacy after the point of sale as a negative adjustment.

DIR # 6. Risk Sharing Arrangement Payments and Adjustments
Gains or losses that the Part D sponsor may receive as a result of risk sharing arrangements with entities other than CMS that are permissible under the Part D rule are reported in this column. Risk sharing amounts received from other parties must be reported in this column as a positive adjustment. Risk sharing amounts credited to other parties must be reported in this column as a negative adjustment.

DIR # 7. Pharmacy Payment Adjustments
With the exception of adjustments to generic dispensing incentive payments, which are reported in column DIR # 5, applicable adjustments to pharmacy payments are reported in this column. These include penalties or pharmacy repayments stipulated in the Part D sponsor's contract with its network pharmacies which represent incorrect drug costs that were paid or reported by the Part D sponsor due to an error made by the pharmacy. For these types of pharmacy penalties, the portion of the penalty that is equivalent to the amount by which the drug costs paid by the Part D sponsor or reported to CMS on the PDE exceeds the correct drug costs must be reported as DIR in this column.

Applicable pharmacy adjustments that reduce the total payments made to the pharmacy should be reported as a positive adjustment that will serve to reduce the plan's drug costs. Applicable pharmacy adjustments that increase the total payments made to the pharmacy should be reported as a negative adjustment that increases the plan's drug costs.

Amounts credited to the Part D sponsor by the pharmacy due to beneficiary cost-sharing that exceeds the gross drug cost are also reported in this column, provided that these payments are not already reflected in the covered plan paid (CPP) amounts reported on the PDE data.

DIR # 8. All Other DIR
All applicable DIR (as well as adjustments to DIR) that is not reported in the previous columns must be included in this column. This includes legal judgments or settlement amounts from lawsuits or other legal action, which directly or indirectly impact the drug costs incurred by the Part D sponsor for contract year 2009. To report legal judgments or settlement amounts which impacted the drug costs incurred in prior contract years, Part D sponsors must submit a revised DIR Report for Payment Reconciliation for the applicable contract year. Legal judgments or settlement amounts paid by the Part D sponsor which serve to increase the drug costs incurred by the sponsor for contract year 2009 must be reported in this column as a negative adjustment. Legal judgments or settlement

amounts received by the Part D sponsor which serve to decrease the drug costs incurred by the sponsor for contract year 2009 must be reported as a positive adjustment.

Legal fees associated with the lawsuit or legal action for each legal judgment or settlement amount received may be excluded from the amount reported on the DIR Report for Payment Reconciliation for the applicable contract year up to the total amount of the judgment or settlement associated with the applicable lawsuit or legal action. For example, Sponsor A received a settlement amount of $500,000 for law suit A which impacted drugs costs for contract year 2007 and $100,000 for law suit B which impacted drug costs for contract year 2008. Sponsor A incurred $100,000 in legal fees for law suit A and $125,000 in legal fees for law suit B. Sponsor A would report $400,000 on the 2007 DIR Report for Payment Reconciliation and $0 on the 2008 DIR Report for Payment Reconciliation. Please note, however, that Part D sponsors cannot include legal fees associated with lawsuits or legal action in which the Part D sponsor is required to pay a judgment or settlement amount on the DIR Report for Payment Reconciliation as a negative adjustment.

PBM penalty payments or repayments are also included in this column. In cases where a PBM penalty represents incorrect drug costs that were paid or reported by the Part D sponsor due to an error made by the PBM, the portion of the penalty that is equivalent to the amount by which the drug costs paid by the plan or reported to CMS on the PDE exceed the correct drug costs should be reported as DIR.

DIR included in this column that is not associated with a specific drug, must be reported in full on the DIR Report for Payment Reconciliation with no portion allocated to non-Part D covered drugs. This DIR must fully accrue to the government and beneficiaries and cannot be kept by the Part D sponsor.

Other DIR Text Description
A short description indicating the type of price concession, the type of entity from (or to) which the Part D sponsor is collecting (or paying) the amount (e.g. pharmacy, manufacturer, PBM), and the associated dollar amount is required in this column for each price concession or DIR adjustment included in column DIR # 8 – All Other DIR. This field must be left blank if there is no dollar amount reported in column DIR #8.

Total DIR
Reported in this column is the sum of all of the DIR reported for the Part D plan for the applicable contract year. The values in this field are automatically generated on the DIR Report for Payment Reconciliation and represent a sum of the values reported in columns DIR #1 – DIR #8. If reporting zero total DIR dollars for a specific Part D plan, Part D sponsors must provide a short

explanation in the “Additional Comments” column of the DIR Report for Payment Reconciliation.

Rebates at POS?
If the Part D sponsor applied (estimated) rebates to the negotiated price at the point of sale in the applicable contract year, the Part D sponsor should enter “Y” in this column for each applicable Part D plan. Otherwise, this field should be left blank to indicate that rebates were not applied to the negotiated price at the point of sale.

Rebate Administration Fees [New Requirement]
Rebate administration fees that meet the definition of a bona fide service fee and are received in connection with the Medicare Part D program must be reported in this column of the DIR Report for Payment Reconciliation. This includes rebate administration fees received by PBMs that are not passed through to the Part D sponsor. If the rebate administration fee exceeds fair market value, but otherwise meets the definition of a bona fide service fee, the differential between the rebate administration fee and fair market value must be reported in columns DIR #1, DIR #2, or DIR #3 as applicable. Bona fide service fees are not considered DIR, therefore **the amounts reported in this column of the DIR Report will not be included in the Total DIR column**. In addition, these amounts will not be excluded from allowable reinsurance costs and allowable risk corridor costs when CMS calculates reinsurance and risk sharing payments during the Part D payment reconciliation process.

Additional Comments
Additional notes or comments on the data provided in columns DIR #1- DIR # 8 are included in this column. For example, sponsors must provide a short explanation if reporting zero total DIR dollars for a specific Part D plan. In addition, Part D sponsors must provide a description in this column for any PBM manual adjustments, PBM penalty amounts, and legal judgment or settlement amounts reported in column DIR #8- All Other DIR. Part D sponsors are also encouraged to provide a description for any risk sharing arrangement amounts reported in column DIR # 6. If the Part D sponsor, or its PBM, receives bona fide service fees from pharmaceutical manufacturers other than rebate administration fees, a short description and the dollar amount associated with the Part D program should be reported in this column.

VIII. Report Format and Layout

DIR Report for Payment Reconciliation (With Sample Values)

Contract-Plan	DIR #1 – PBM Retained Rebates	DIR #2 – Rebates Expected But Not Yet Received	DIR # 3 – All Other Rebates	DIR # 4 – Price Concessions for Administrative Services	DIR # 5 – Generic Dispensing Incentive Payments and Adjustments	DIR # 6 – Risk Sharing Arrangement Payments and Adjustments	DIR # 7 – Pharmacy Payment Adjust ments	DIR # 8 – All Other DIR	Other DIR Text Description	Total DIR	Rebates at POS?	Rebate Administration Fees	Additional Comments
S####-001	30500.25	10000.00	140500.65	2000.00	-3500.50	6000.00	-4500.00	0.00		181000.40	Y	27,150.06	DIR #6- Received $6000 from risk sharing arrangement with physicians for prescription drug costs.
S####-002	0.00	750.00	13000.76	1500.25	-500.00	-2250.77	-1550.00	1500.00	1. DIR for PBM penalty: $1500.00	12450.24		1,867.54	DIR #6- Paid $2250.77 to physicians due to risk sharing arrangement for prescription drug costs. DIR #8- Received $1500 from PBM due to error in applying step therapy requirements.
S####-003	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		0.00		0.00	No DIR due to very low membership, no claims with associated DIR.

File Record Layout:
DIR Report for Payment Reconciliation

Field Name	Field Type	Field Length	Field Description
Contract-Plan	Character	9	Contract number and plan ID, e.g. S0001-001. Automatically generated.
DIR #1 – PBM Retained Rebates	Number Required	12 digits before the decimal and 2 digits after	For each Part D plan, provide the sum of all applicable PBM retained rebates and applicable rebate administration fees. See guidance for details.
DIR #2 – Rebates Expected But Not Yet Received	Number Required	12 digits before the decimal and 2 digits after	For each Part D plan, provide a good faith estimate of the sum of applicable rebates expected but not yet received. See guidance for details.
DIR # 3 – All Other Rebates	Number Required	12 digits before the decimal and 2 digits after	For each Part D plan, provide the sum of all other applicable rebates including rebates for COB claims and P2P claims. See guidance for details.
DIR # 4 – Price Concessions for Administrative Services	Number Required	12 digits before the decimal and 2 digits after	For each Part D plan, provide the sum of applicable price concessions for administrative services. See guidance for details.
DIR # 5 – Generic Dispensing Incentive Payments and Adjustments	Number Required	12 digits before the decimal and 2 digits after	For each Part D plan, provide the sum of applicable generic dispensing incentive payments and adjustments. See guidance for details. For a negative value, enter a minus sign and the value for the field.
DIR # 6 – Risk Sharing Arrangement Payments and Adjustments	Number Required	12 digits before the decimal and 2 digits after	For each Part D plan, provide the sum of DIR from risk sharing arrangements. See guidance for details. For a negative value, enter a minus sign and the value for the field.
DIR # 7 – Pharmacy Payment Adjustments	Number Required	12 digits before the decimal and 2 digits after	For each Part D plan, provide the sum of applicable pharmacy payment adjustments. See guidance for details. For a negative value, enter a minus sign and the value for the field.
DIR # 8 – All Other DIR	Number Required	12 digits before the decimal and 2 digits after	For each Part D plan, provide the sum of all other applicable DIR not reported in columns DIR # 1-7. See guidance for details. For a negative value, enter a minus sign and the value for the field.
Other Text Description	Character	4000	Description required for **all** DIR reported in DIR # 8 for Part D plan. Please leave blank if no DIR reported in DIR #8 for Part D plan. See guidance for details.
Total DIR	Number Required	12 digits before the decimal and 2 digits after	Sum of all DIR reported for Part D plan. Automatically generated. Does not include amounts reported in Rebate Administration Fees column.
Rebates at POS?	Character	1	For each Part D plan, indicate "Y" if estimated rebates were applied to the negotiated price at the point of sale. Please leave blank if estimated rebates were not applied to the negotiated price at the point of sale.
Rebate Administration Fees	Number Required	12 digits before the decimal and 2 digits after	For each Part D plan, provide the sum of all rebate administration fees considered bona fide service fees. See guidance for details.
Additional Comments	Character	4000	Additional comments on data reported on DIR Report for Payment Reconciliation. See guidance for details.

IX. Steps for Submitting DIR Report for Payment Reconciliation [New Clarification]

1. Enter DIR Submission Information
    a. Go to the DIR Submission Information page using the following pathway: HPMS Homepage > Plan Bids > DIR Reporting > Contract Year 2009 > DIR Reporting (for Payment Reconciliation) > DIR Submission Info.
    b. For each contract, provide a response for each question or enter "N/A" as applicable. If the 2009 DIR Report for Payment Reconciliation was previously submitted, provide a reason for resubmitting the DIR Report.

2. Download DIR Report Template
    a. Go to the DIR Download page using the following navigation path: HPMS Homepage > Plan Bids > DIR Reporting > Contract Year 2009 > DIR Reporting (for Payment Reconciliation) > (Submission) Download.
    b. Select the contracts for your DIR Report.
    c. Download the DIR Report Template

3. Enter data into DIR Report Template to create new DIR Report
    a. Enter the DIR values for each plan into the DIR Report Template.
        i. If your organization has no DIR to report for plan, enter $0 in DIR columns #1-#8 and provide an explanation in the "Additional Comments" column of the DIR Report.
        ii. If a value is entered in DIR column #8, "All Other DIR", enter a description of the amounts entered in the "Other Text Description" column.
        iii. The amounts in the "Total DIR" column are automatically generated. Review the totals in this column to ensure that they are correct.
        iv. If your organization applied estimate rebates at the point of sale, enter "Y" in the "Rebates at POS" column. Otherwise, leave this field blank.
    b. Enter the amounts for any rebate administration fees considered bona fide service fees in the "Rebate Administration Fees" column.
    c. Enter a description and dollar amount for any other bona fide service fees received in the "Additional Comments" column of the DIR Report.

4. Save DIR Report as **DIR.xls**. The DIR report cannot be uploaded if it is not named DIR.xls.

5. Upload DIR Report
    a. Go the DIR Upload page using the following navigation path: HPMS Homepage > Plan Bids > DIR Reporting > Contract Year 2009 > DIR Reporting (for Payment Reconciliation) > (Submission) Upload.
    b. Upload the completed DIR Report saved as DIR.xls.

c. If you receive any error messages, make corrections to the DIR Report, save as DIR.xls, and attempt to upload again.
d. If you are unable to resolve the error messages, contact the HPMS Help Desk at either 1-800-220-2028 or hpms@cms.hhs.gov.

6. Review DIR Report saved in HPMS
   a. Go to the DIR Download page using the following navigation path: HPMS Homepage > Plan Bids > DIR Reporting > Contract Year 2009 > DIR Reporting (for Payment Reconciliation) > DIR Reports > DIR Data Report.
   b. Review the submission information and DIR values in the DIR Data Report saved on HPMS.
   c. Check the Total DIR values for each plan to ensure they are accurate.
   d. If there any errors, make corrections to the DIR Report, save as DIR.xls, and upload the corrected DIR report. If you are unable to resolve the errors, contact the HPMS Help Desk.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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CENTER FOR DRUG AND HEALTH PLAN CHOICE

TO: Medicare Advantage Organizations
Medicare Advantage-Prescription Drug Organizations
Cost-Based Contractors
Prescription Drug Plan Sponsors
Employer/Union-Sponsored Group Health Plans
Programs of All-Inclusive Care for the Elderly Organizations

FROM: Jonathan Blum, Acting Director, Center for Drug and Health Plan Choice

RE: Issuance of the 2010 Call Letter

DATE: March 30, 2009

I am pleased to provide you with the 2010 Call Letter for Medicare Advantage (MA) organizations (MAOs); section 1876 cost-based contractors; prescription drug plan (PDP) sponsors; demonstrations; Programs of All-Inclusive Care for the Elderly (PACE) organizations; and employer and union-sponsored group plans, including employer/union-only group waiver plans (EGWPs). The Call Letter contains information these organizations will find useful as they prepare their bids for the upcoming contract year.

We received approximately 190 comments from plan sponsors and plan sponsor associations; advocacy organizations and consumer groups; pharmaceutical manufacturers and their associations; members of Congress; States and State associations; pharmacists and pharmacy associations; providers and provider associations; and other individuals on the draft Call Letter we issued for public comment on February 23, 2009. We carefully considered all comments we received and have made revisions and clarifications in response to these comments in this final 2010 Call Letter.

In some areas, we received a number of constructive comments which we will consider addressing for future contract years. For example, we requested comments regarding whether, and if so, how we should calculate and disseminate information about plans' medical loss ratios. Given this issue's complexity, we will continue evaluating methodologies for possible future implementation. We will also continue to study the issue of our reassignment processes for low-income subsidy (LIS) eligible individuals for potential future improvements that are consistent with our statutory authority. We will also continue to work with plans that are losing members to identify appropriate ways to reach out to these members to explain how they can remain in their current plan and what their premium liability will be if they choose to do so.

As we indicated in the draft document, the 2010 Call Letter focuses on new guidance necessary for preparing for contract year 2010. Sponsoring organizations continue to remain responsible for familiarizing themselves with statutory requirements, regulations, and guidance governing the MA and Part D programs, including the Medicare Managed Care and Prescription Drug Benefit Manuals. CMS will separately issue technical and procedural clarifications regarding bid and formulary submissions, benefits, HPMS data, CMS marketing models, and other operational issues of interest to sponsoring organizations.

We hope this information helps you implement and comply with CMS policies and procedures as you prepare either to offer a plan for the first time or continue offering plans under the MA and/or Part D programs.

2010 Call Letter

How to Use this Document

The 2010 Call Letter contains information on the Part C, cost-based, and Part D programs combined into one document. Also, we indicate when sections apply to PACE and employer and union-sponsored group health plans. Section A provides MA, MA-PD, and cost plan guidance; Section B provides information for Part D sponsors; Section C contains marketing-related information that applies to all plan types; and Section D contains attachments to the material contained in Sections A-C.

If you have questions concerning this Call Letter, please contact Vanessa Duran at Vanessa.Duran@cms.hhs.gov or Rosetta Hicks at Rosetta.Hicks@cms.hhs.gov.

Section A – 2010 MA, MA-PD, and COST PLAN SECTIONS

Note on 2010 MA, MA-PD, and Cost Plan portion of the Call Letter

With few exceptions, Medicare Advantage organizations (MAOs) offering a prescription drug benefit (MA-PDs) and cost plans offering a Part D benefit (Cost-PDs) must follow all Part D requirements in addition to following MA or cost plan guidance as applicable. All MA-PDs and Cost-PDs should follow the Part D guidance as specified in Section B of this Call Letter and especially the Prescription Drug Benefit Manual and Part 423 of Title 42 of the Code of Federal Regulations (CFR). Such requirements include the formulary and pharmacy access requirements specified in Chapters 5 and 6 of the Prescription Drug Benefit Manual and the Part D portion of this Call Letter. Our discussion in Section A focuses primarily on the MA and cost plan operational guidance that we want to bring to your attention as you prepare for the 2010 contract year. Section C contains marketing-related information that applies to MAOs, cost plans, and PDPs. We will, however, highlight information related to the Part D benefit that is specific to MA-PDs and Cost-PDs. Unless otherwise indicated, all regulatory references in this section are to Title 42, Part 422 of the CFR.

2010 MA, MA-PD, and Cost Plan Calendar

In order to assist you in meeting all deadlines for renewal, enrollment, bidding, and other provisions as you prepare to offer health care benefits in 2010, we are including a calendar of key dates and timelines. Please note that, except as otherwise specified in statute or regulation, the dates given here are subject to change. Organizations should also note that these dates are not exhaustive, and they must consult the appropriate sections of the Part C, cost plan, and Part D regulations and guidance for important information associated with these timelines. The Part D section of this Call Letter includes a table of key dates for Part D sponsors including MA and Cost organizations offering a prescription drug benefit under Part D. Organizations should continue to monitor the general applications timeline posted on the CMS website at http://www.cms.hhs.gov/MedicareAdvantageApps/.

NOTE: Employer/Union-Only Group Waiver Plans (EGWPs) are subject to the same timeline and requirements set forth below, except for dates or requirements that do not apply or are modified due to existing employer group waivers.

2010 MA, MA-PD and Cost-Based Plan Calendar **(All dates, unless identified as statutory, are subject to change)**	
2009	
March 27, 2009	2010 Call Letter released.
March 30, 2009	Release of Health Plan Management System (HPMS) formulary submissions module.
April 1, 2009	Conference call with industry to discuss the 2010 Call Letter.
April 2, 2009	Medicare Advantage and Part D National Conference
April 6, 2009	Announcement of CY 2010 MA Capitation Rates and MA and Part D Payment Policies.
April 10, 2009	2010 Plan Creation Module, Plan Benefit Package (PBP), and Bid Pricing Tool (BPT) available on HPMS.

2010 MA, MA-PD and Cost-Based Plan Calendar **(All dates, unless identified as statutory, are subject to change)**	
2009	
April 20, 2009	2010 Formulary Submissions due from all sponsors offering Part D (11:59 p.m. EDT).
May 1, 2009	***Voluntary Non-Renewal***: CMS strongly encourages MA and MA-PDs to notify CMS of an intention to non-renew a county or counties for individuals, but continue the county for "800 series" EGWP members, by May 1, 2009. Additionally, CMS strongly encourages MA and MA-PDs to submit partial county service area reduction requests affected by non-renewal of a contract by May 1, 2009. Requests must include documents for justification that meet the county integrity rule as outlined in Chapter 4 of the Medicare Managed Care Manual.
May 15, 2009	CMS begins accepting CY 2010 bids via HPMS.
Mid-May 2009	CMS sends contract eligibility determinations to applicants based on review of the 2010 applications for new contracts or service area expansions.
Tentative Date May 29, 2009	Industry training on Annual Notice of Change (ANOC)/Evidence of Coverage (EOC) and other marketing models.
Late Spring/Early Summer, June 2009	Update of the MA/PDP Enrollment, Eligibility, and Disenrollment Guidelines.
June 1, 2009	Deadline for submission of CY 2010 bids for all MA, MA-PD, cost, "800 series" EGWP and Direct Contract EGWP applicants and renewing organizations; deadline for cost plans wishing to appear in the 2010 Medicare Options Compare to submit PBPs (11:59 p.m. PDT). ***Voluntary Non-Renewal***: Deadline for MA and MA-PDs to submit a contract non-renewal, service area reduction notice to CMS for CY 2010. Deadline also applies to an MAO that intends to terminate a current MA and/or MA-PDs Plan Benefit Package (i.e., Plan 01, Plan 02) for CY 2010. Medicare cost-based contractors and cost-based sponsors encouraged to submit a non-renewal or service area reduction notice to CMS.
June 5, 2009	CMS begins accepting CY 2010 marketing material for review.
June 8, 2009	CMS begins accepting Supplemental Formulary files, Free First Fill file, Partial Gap file, Excluded Drug file, Over the Counter (OTC) drug file, and Home Infusion file through HPMS. CMS begins accepting CY 2010 Actuarial Certifications in HPMS.

2010 MA, MA-PD and Cost-Based Plan Calendar **(All dates, unless identified as statutory, are subject to change)**	
2009	
June 30, 2009	Final date for MA, MA-PD and cost-based organizations to submit CY 2009 marketing materials for CMS' review and approval. NOTE: This date does not apply to CY 2009 file and use materials since these may be filed with the regional office five calendar days prior to their use.
August, 2009	***Non-Renewal***: CMS to release a Special Election Period (SEP) letter to MA and MA-PDs plans remaining in the service areas of plans that have non-renewed. Additionally, CMS to post the model final non-renewal notification letter, and State-specific final notification letter. Release of the 2010 Part D National Average Monthly Bid Amount, the Medicare Part D Base Beneficiary Premium, the Part D Regional Low-Income Premium Subsidy Amounts, and the Medicare Advantage Regional PPO Benchmarks. Rebate reallocation begins. Five business day rebate reallocation period begins after release of RPPO benchmarks.
Early August, 2009	Cost-based plans are encouraged to submit their summary of benefits (SBs) by this date so that materials can be reviewed and approved prior to the publishing of "Medicare Options Compare" and the *Medicare & You* handbook.
August 1, 2009	Deadline for CMS to inform currently contracted organizations of CMS' decision not to authorize a renewal of a contract for 2010.
August 3, 2009	MA-PD plans are expected to submit non-model Low Income Subsidy (LIS) riders to the regional office for review.
August 14, 2009	MA-PD plans are expected to submit Low Income Subsidy (LIS) riders to the regional office for review. Cost plans offering Part D are expected to submit Low Income Subsidy (LIS) riders for review. Dual eligible SNPs that are fully integrated with the State are expected to submit the Annual Notice of Change and Summary of Benefits to the regional office for review.
Late August, 2009	***Non-Renewal***: Final date for CMS to approve MA and MA-PD's final beneficiary notification letter of non-renewal.
Late August/Early September 2009	CMS completes review and approval of 2010 bid data. Submission of attestations, contracts, and final actuarial certifications.
September, 2009	MA, MA-PD organizations and, if applicable, Medicare cost-based plans preview the 2010 *Medicare & You* plan data in HPMS prior to printing of the CMS publication (not applicable to EGWPs).

2010 MA, MA-PD and Cost-Based Plan Calendar **(All dates, unless identified as statutory, are subject to change)**	
2009	
September 18, 2009	Broker/agent compensation structures must be submitted to CMS.
October 1, 2009	MA, MA-PD organizations and Medicare cost-based plans may begin CY 2010 marketing activities. Once an organization begins marketing CY 2010 plans, the organization must cease marketing CY 2009 plans through mass media or direct mail marketing (except for age-in mailings). Organizations may still provide CY 2009 materials upon request, conduct one-on-one sales appointments and process enrollment applications. MA, MA-PD organizations, and Medicare cost-based plans are required to include information in CY 2009 marketing and enrollment materials to inform potential enrollees about the possibility of plan (benefit) changes beginning January 1, 2010. Deadline for Cost, MA, and MA-PD organizations to request a plan correction to the plan benefit package (PBP). Last date for contracting MAOs to provide CMS with evidence of contracting with the State in order to operate a Medicaid subset dual eligible SNP for CY 2010. Dual eligible SNPs that are fully integrated with the State that plan to use a non-standardized, non-combined EOC are expected to submit for regional office review.
October 2, 2009	***Non-Renewal***: Medicare cost-based contractors and cost-based sponsors to submit a non-renewal or service area reduction notice to CMS.
October 9, 2009	Tentative date for 2010 plan benefit data to be displayed on Medicare Options Compare and for 2010 plan drug benefit information to be displayed on the Medicare Prescription Drug Plan Finder on Medicare.gov (not applicable to EGWPs).
Mid-October, 2009	***Non-Renewal***: CMS to issue an acknowledgement letter to all Medicare cost-based plans that are non-renewing or reducing their service area.
October 15-20, 2009	CMS mails the 2010 *Medicare & You* handbook to Medicare beneficiaries.
October 31, 2009	CY 2010 standardized, combined Annual Notice of Change (ANOC)/Evidence of Coverage (EOC) is due to all MA, MA-PD members, and members of cost-based plans offering Part D. MA and MA-PD organizations must mail the combined ANOC/EOC before this

2010 MA, MA-PD and Cost-Based Plan Calendar **(All dates, unless identified as statutory, are subject to change)**	
2009	
	date to ensure receipt by members by October 31. Organizations are not required to mail the Summary of Benefits (SB) to existing members when using the combined, standardized ANOC/EOC. Exception: Dual eligible SNPs that are fully integrated with the State are not required to use the standardized, combined ANOC/EOC. Dual eligible SNPs that are fully integrated with the State must mail an Annual Notice of Change and Summary of Benefits before this date to ensure receipt by members by October 31. All MA-PDs and cost-based plans offering Part D must mail their LIS riders and abridged or comprehensive formularies before this date to ensure receipt by members by October 31.
November 2, 2009	***Non-Renewal***: The final beneficiary non-renewal notification letter must be a personalized letter and received by MA, MA-PD, and cost-based plan enrollees by November 2, 2009.
November 15, 2009	2010 Annual Coordinated Election Period begins. All organizations must hold open enrollment (for EGWPs, see Chapter 2 of the Medicare Managed Care Manual, Section 30.4.4). Marketing guidelines require that MA, MA-PD, and cost-based organizations mail a CY 2010 EOC to each new member no later than when they notify the new member of acceptance of enrollment. Organizations offering Part D must mail their Low Income Subsidy Rider (LIS) and abridged or comprehensive formularies with the EOC for new members. New members with an effective date of 1/1/2010 or later do not need to (but may) receive the ANOC portion of the standardized/combined ANOC/EOC.
Tentative Date – November 17, 2009	Notices of Intent for CY 2011 due for MA, MA-PD, cost, "800 series" EGWPs and Direct Contract EGWPs.
Tentative Date – November 25, 2009	CMS issues pending HPMS contract numbers for CY 2011 to MA, MA-PD, cost, and EGWP contracts.
November – December, 2009	***Non-Renewal***: CMS to issue "close out" information and instructions to MA, MA-PDs, and cost plans that are non-renewing or reducing service areas.
December 1, 2009	Medicare cost-based plans not offering Part D must send the combined ANOC/EOC for receipt by members by December 1, 2009.
December 1, 2009	***Non-Renewal***: Cost-based plans must publish a CMS-approved public notice of non-renewal in one or more newspapers of general circulation covering each community or county in their contract areas.

2010 MA, MA-PD and Cost-Based Plan Calendar **(All dates, unless identified as statutory, are subject to change)**	
2009	
December 31, 2009	2010 Annual Coordinated Election Period ends. Dual eligible SNPs that are fully integrated with the State must mail an Evidence of Coverage, LIS riders and abridged or comprehensive formularies before this date to ensure receipt by members by December 31.
2010	
January 1, 2010	Plan Benefit Period Begins.
January 1 – March 31, 2010	MA Open Enrollment Period (OEP).
Early January, 2010	Automated CY 2011 applications released.
Early January, 2010	Industry training on CY 2011 applications.
Late February, 2010	Applications due for CY 2011.

I. Contracting Process

Multiple and Low Enrollment Plan Offerings by MAOs

Many MA organizations offer a large number of plan benefit packages per contract. In some cases, these plan offerings have very low enrollment and virtually indistinguishable benefit differences. MA organizations should undertake to eliminate plan offerings for 2010 that have little or no enrollment, and duplicative plan offerings that are not easily distinguished by beneficiaries and could cause beneficiary confusion. In order to facilitate this change, CMS will authorize the transition of existing beneficiaries in eliminated plans to another plan offered by the MAO under appropriate circumstances. An example of such a circumstance includes when a sponsoring organization has another MA plan with similar benefits, formularies, premiums, and network rules. If the organization does not offer such a plan, beneficiaries enrolled in a plan that the MA organization terminates will be disenrolled to Original Medicare absent an active election of a different plan. We note that these individuals will have a special election period (SEP) to change plans, consistent with our existing non-renewal policy.

Organizations offering more than one plan in a given service area should ensure plan differences are transparent, readily discernable to beneficiaries and meant to provide the highest value at the lowest cost. Examples of meaningful differences in plan benefit design include, but are not limited to, plans with and without the Part D benefit, and plans with and without specific supplemental benefit options, and different plan types.

Based on previous experiences in the Medicare Advantage program, we believe that multiple plan offerings by MAOs may not result in beneficiaries choosing a plan which best suits their health care needs, but can, instead, confuse beneficiaries. Additionally, we are concerned that the current multitude of MA plan offerings may conceal aspects of a plan, such as high cost sharing for certain services, which are not advantageous to beneficiaries. In order for beneficiaries to have a choice of plans that represent genuine differences we would expect MAOs to offer no more than three MA plans by plan type in a market area, and ensure that each plan offered is readily distinguishable from the others based on plan type, benefits offered, access, or other features that permit beneficiaries to choose a health care plan most suitable to their needs.

Similarly, low enrollment can be an indication of financial instability, and is detrimental to the spreading of risk, both of which can adversely affect the ability of health plans to provide high quality health care at an affordable price while continually protecting beneficiaries. There are currently large numbers of plan offerings with fewer than 10 enrollees. As a result, we will review all MA plans with low enrollments for more than three years. CMS recognizes that there may be factors, such as beneficiary population served and geographic location, which may make lower enrollments reasonable, and will take such information into account when evaluating specific plans.

CMS encourages MAOs that have questions about the appropriateness of plan offerings to contact CMS early in the process in advance of the bid filing deadline so that MAO plan offerings will have a greater likelihood of success in the application and bidding processes. The ultimate goal is that plan offerings will represent genuine choice and high value health care options to beneficiaries.

In response to public comments, CMS is considering rule making to limit plans to no more than a specified number of benefit designs in a given service area and to require consolidation of plans with low enrollment.

Dual Eligibles and Cost Sharing

MIPPA outlined several new provisions for dual eligibles enrolled in Special Needs Plans (SNPs). One provision put a limitation on out-of-pocket costs for full-benefit dual eligibles and qualified Medicare beneficiaries (QMBs) enrolled in SNPs. A dual SNP may not impose or permit providers to collect cost sharing that exceeds the amount of cost sharing that would be permitted with respect to the individual under title XIX if the individual were not enrolled in such a plan.

The 4138 IFC2 regulation extends this cost sharing limitation to all MA plans that have dual eligible enrollees and to all dual eligible categories for which a State provides coverage and chooses to protect beneficiaries from the cost sharing for Medicare A and B services. Under the new regulatory requirements at 42 CFR §422.504(g)(l)(iii), all MA organizations are responsible for ensuring that they do not impose cost sharing amounts on their dual eligible members that exceed the amount of cost sharing that would be permitted with respect to the individual under title XIX if the individual were not enrolled in an MA plan. In addition, all MA plans with dual eligible enrollees must inform providers and include in their provider contracts that dual eligible

enrollees will not be responsible for any plan cost sharing for Medicare A and B services when the state is responsible for paying those amounts.

Additionally, the contracts with providers should state that the provider will do this either by accepting the MA plan payment as payment-in-full or by billing the appropriate state source.

II. Benefit Design

Cost Sharing Guidance

CMS' goal is to establish a more transparent process so that beneficiaries will be able to better predict their out-of-pocket (OOP) costs in order to select a plan that best meets their individual health care needs and be protected from excessively high or unexpected cost sharing. Toward that end, for MA plans that impose co-insurance (i.e., a percentage rather than a flat copayment amount) for any Part A or B services, CMS will likely not consider the imposition of this co-insurance to discriminate against high cost enrollees who might need the service in question if (1) the plan has an overall OOP maximum of $3,400[1], and (2) the co-insurance for renal dialysis, Part B drugs, psychiatric hospitalization, home health, and skilled nursing facility (SNF) services does not exceed the co-insurance that applies under Original Medicare, and (3) the plan does not exclude (carve out) any Part A/B services from the OOP maximum.

For MA plans that do not impose co-insurance in any service category:

- Plans with a plan-level OOP maximum amount not greater than $3,400 will have flexibility in establishing cost sharing amounts for individual services without the plan being found to be discriminatory as long as copayments for renal dialysis, Part B drugs, psychiatric hospitalization, and SNF services do not exceed the Original Medicare coinsurance amounts.

- Plans with a plan-level OOP maximum amount greater than $3,400 will receive greater scrutiny of cost sharing amounts for individual services in determining whether the plan is discriminatory.

- Plans without a plan level OOP maximum will receive the greatest scrutiny with respect to whether cost sharing amounts for individual services result in the plan being discriminatory.

CMS is considering amending the regulations that would impose a requirement for an OOP maximum amount.

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[1] The Medicare Advantage out-of-pocket (OOP) threshold is based on a beneficiary-level distribution of A/B cost sharing for individuals enrolled in original Medicare. The CY 2010 OOP threshold of $3,400 represents the 85th percentile of projected beneficiary spending in 2010. Stated differently, 15 percent of original Medicare beneficiaries are expected to incur $3,400 or more in Parts A and B deductibles and coinsurance in 2010.

While reviewing all benefit packages, CMS will continue to review cost sharing for services usually associated with chronic and acute conditions, high utilization and high costs such as inpatient acute and psychiatric hospital, outpatient hospital, home health, renal dialysis, Part B drugs, skilled nursing facility (SNF) and durable medical equipment (DME) services. Also note that benefit design and cost sharing amounts approved for CY 2009 will not automatically be acceptable for CY 2010 since a separate and distinct review is conducted each contract year.

For additional cost sharing guidance, please see Section 20.13, "Guidance on Acceptable Cost sharing and Deductibles," of Chapter 4, "Benefits and Beneficiary Protections," of the Managed Care Manual located at: http://www.cms.hhs.gov/manuals/downloads/mc86c04.pdf.

Plan Corrections for 2010

Expectations are that with the experience gained over the last four years of bid submissions, requests for plan corrections for CY 2010 will be minimal. As required by 42 CFR 422.254, submission of the final actuarial certification and the bid attestation serve as documentation that the final bid submission has been verified and is complete and accurate at the time of submission. A request for a plan correction indicates the presence of inaccuracies and/or the incompleteness of a bid and calls into question an organization's ability to submit correct bids and the validity of the final actuarial certification and bid attestation. Please be advised that an MAO requesting a plan correction will receive a corrective action warning letter.

However, even though we expect MAOs to ensure that the original plan benefit package (PBP) submission is a true representation of the benefits package being offered, the plan corrections module will be available in HPMS for CY 2010 benefits for a limited period, from early September until October 1, 2009. Consistent with marketing and open enrollment coordination, MAOs will not be able to request plan corrections for CY 2010 benefits packages after the October 1, 2009 deadline. This will ensure that correct bid information will be available for review on Medicare Options Compare in time for the open enrollment start date of November 15, 2009. It is important to note that only changes to the PBP that are supported by the Bid Pricing Tool (BPT) are allowed during the plan correction period.

Preventive Services Incentives

An incentive is an item or service that a plan offers conditional to an enrollee taking some action (e.g., receiving a flu shot), or participating in some program (e.g., a smoking cessation program). The terms "rewards" and "incentives" are used interchangeably.

CMS is committed to promoting the appropriate use of Medicare preventive benefits. Medicare covers a broad range of services to: (1) prevent disease; (2) detect disease early when it is most treatable and curable; and (3) manage disease so that complications can be avoided. Unfortunately, Medicare beneficiaries even with frequent visits to physician offices are not receiving all recommended preventive services for various reasons. The offering of a limited incentives program will provide Medicare Advantage Organizations an opportunity to improve preventive care participation by Medicare Advantage enrollees.

Guidelines for Incentives

CMS recognizes the potential value of a skillfully developed Incentive program to facilitate participation in prevention activities. However, CMS would like to emphasize that the primary focus of any plan benefit package design should be the delivery of Medicare Parts A and B benefits at the lowest cost. CMS will recognize an incentive program as appropriate and permissible if it meets the following criteria:

Required Criteria for Incentives

The incentive:

1. Must be offered to promote the delivery of Medicare covered preventive benefits;

2. Must be earned by doing activities that are either Medicare Advantage benefits – such as flu shots – or educational (in person or online) and directly health related – such as nutrition, blood pressure, weight loss, etc.

3. May not be tied to a specific health outcome, such as lowering weight or blood pressure;

4. May not be an item that is itself a health benefit (e.g., a free checkup);

5. May not consist of lowering or waiving of co-pays;

6. May not be items that are otherwise available, to the general public, for free.

   Additionally, incentives must be offered to current plan members only, for the entire contract year, and uniformly to all plan enrollees;

7. May not be used in pre-enrollment advertising, marketing, or promotion of the plan, such as in the PBP, SB, ANOC or EOC (rewards and incentives may only be discussed in post-enrollment notifications). The incentive program must be described in the PBP Notes;

8. May not be structured to steer enrollees to particular providers, practitioners, or suppliers;

9. May be discussed in direct mailings to enrollees (as long as there is no violation of the Health Insurance Portability and Accountability Act (HIPAA) privacy laws);

10. Each item must be of nominal value with a retail value monetary cap not to exceed $10 per item or $50 in the aggregate on an annual basis per member per year, figures based on guidance from the Office of Inspector General; and

11. When an incentive program incurs a cost, then this cost must be priced in the bid and combined with the cost of other non-covered benefits in line q of the MA BPT. Supporting documentation is required with the initial June bid submission. This is for accounting purposes only. Combining the costs with “Other Non-Covered” does not change the nature of incentives – which cannot be “benefits” – see item #4. For more information, see the CY 2010 BPT instructions.

12. May not be cash, monetary rebates, or gift cards, which CMS considers analogous to cash;

13. Must comply with all relevant fraud and abuse laws, including, when applicable, the anti-kickback statute (section 1128B(b) of the SSA) and civil monetary penalty prohibiting inducements to beneficiaries (section 1128A(a)(5) of the SSA);

14. Must be tracked and documented during the contract year;

15. Are subject to grievances by the enrollee: Consequently, the plan must explicitly advise enrollees of the right to grieve and the process for filing a grievance.

16. May not be tied directly or indirectly to the provision of any other covered item or service.

The Medicare Preventive services are as follows:

- "Welcome to Medicare" visit (includes a referral for an ultrasound screening for Abdominal Aortic Aneurysm for eligible beneficiaries)
- Adult Immunization--Influenza Immunization, Pneumococcal Vaccination, Hepatitis B Vaccination
- Colorectal Cancer Screening
- Screening Mammography
- Screening Pap Test and Pelvic Examination
- Prostate Cancer Screening
- Cardiovascular Disease Screening
- Diabetes Screening
- Glaucoma Screening
- Bone Mass Measurement
- Diabetes Self-Management, Supplies, and Services
- Medical Nutrition Therapy
- Smoking Cessation

More information on the Medicare Preventive Services can be found at:

http://www.cms.hhs.gov/PrevntionGenInfo/

http://www.medicare.gov/Health/Overview.asp

All incentive programs must also comply with section 1128A(a)(5) of the Social Security Act. This provision prohibits offering or transferring remuneration to a Medicare or Medicaid

beneficiary if the individual or organization making the offer knows or should know that the remuneration is likely to influence the beneficiary's choice of a particular provider, practitioner, or supplier. Incentives offered by a health plan to encourage a beneficiary to enroll in a plan generally do not implicate section 1128A(a)(5) (although such incentives may implicate the Federal anti-kickback statute or other fraud and abuse authorities); however, incentives that encourage a beneficiary to use a particular provider, practitioner, or supplier after enrollment potentially implicate the statute. There are exceptions for certain incentives to promote the delivery of preventive care services, provided that the incentives meet all of the conditions set out in the regulations. See 42 CFR 1003.101. The Office of Inspector General is responsible for enforcing section 1128A(a)(5). Further information about the application of section 1128A(a)(5) can be found on the Office of Inspector General's webpage at hppp://oig.hhs.gov.

Part C Supplemental Over-The-Counter (OTC) Benefit

The basic guidance on offering a supplemental, Part C over-the-counter (OTC) benefit was presented in the 2009 call letter. We update guidance in three areas:

- CMS will no longer use lists of OTC categories of items from outside sources. The CMS list of OTC categories of items is presented in Appendix I and will be incorporated in the next update of Chapter 4, "Benefits and Beneficiary Protections," of the Medicare Managed Care manual.

- OTC items belonging to categories on this list are classified as eligible, dual-purpose or non-eligible. A non-eligible item may not be offered by the plan either individually or as part of a packaged benefit. Any individual or combination of eligible items may be offered by the plan as a supplemental Part C benefit, either as an individual benefit or as part of a packaged benefit, and the enrollee may purchase these items without any further action. Any individual or combination of dual-purpose items may be offered by the plan as a supplemental Part C benefit, either as an individual benefit or as part of a packaged benefit; however, the plan must state in its marketing materials that an enrollee may only purchase these dual-purpose items if the enrollee a) first discusses the purchase of the items with their personal provider, and b) their personal provider orally recommends the item for a specific diagnosable condition. The plan is responsible for notifying its enrollees on the precise set of OTC categories of items that it furnishes.

- An OTC supplemental Part C benefit, whether of an individual or packaged set of items, whether paid for by direct reimbursement or through a debit card, must provide the enrollee with access to the benefit. CMS has interpreted access as meaning a) access at a wide variety of chains and stores and b) identical payment methods at a wide variety of chains and stores.

More specifically, an MAO may not provide a supplemental, Part C, packaged OTC benefit by offering a debit card that is usable in only one pharmacy chain and allow catalog or direct reimbursement payment at other chains. By restricting the more convenient debit card to one chain, the MAO may be inadvertently steering enrollees to that pharmacy chain, and all forms of such steerage are prohibited.

As a result of many inquiries, we have expanded our guidance on catalogs. The following rules apply:

- Catalog form: A catalog can take the form of a hard paper catalog, a simple collection of sheets, or a web catalog;

- Catalog information: At a minimum the catalog, in any form, must contain 1) a list of categories of OTC items, 2) the classification of these categories as eligible, dual purpose or non-eligible, 3) prices, 4) clearly written footnotes indicating which categories of items are potentially, in certain circumstances, purchasable under Part B or Part D with an explicit statement that enrollees, when in these circumstances, should purchase the given items, not as an OTC item, but the same way they purchase Part B or Part D items, and 5) an 800 number or a mailing address with instructions on how to obtain the items. Each plan must list the CMS non-eligible categories in its catalog. A plan may not offer any category of OTC item unless it is listed on its catalog;

- Postal costs: A plan must cover the postal costs of shipping. For example, if a plan offers up to $25 a month in OTC items including typical incurred shipping and handling costs of $5 a month, then the plan cannot cap OTC purchases at $20 a month; rather the plan must absorb the $5 shipping and handling cost;

- Minimum purchase amount: Because plans must absorb postal costs CMS allows plans to place a minimum purchase amount. For example a plan offering up to $25 a month in OTC items may require a minimum purchase of $15. Each enrollee can then make up to one purchase per month with aggregate cost between $15 and $25; and

- Web catalogs: Although plans may provide a catalog through a website, the plans must notify each enrollee of their right to obtain a hard copy of the catalog upon request.

Obtaining Benefits during a Federal Disaster or Other Public Health Emergency

CMS appreciates MA plans' responsiveness to the federal disasters that occurred in 2008 such as the Midwest floods and Hurricanes Gustav and Ike. We are taking this opportunity to provide additional guidance to MA plans on actions they may take in connection with future emergencies or disasters.

In any declared emergency or disaster (for example, if the governor of the state in which the MA plan is located declares an emergency, or if FEMA (http://www.fema.gov/) issues a major disaster declaration in the MA plan's service area, or if the President declares an national emergency or the Secretary of Health and Human Services declares a public health emergency) MA Plans that are concerned about disruption of provision of needed benefits, may, without waiting for explicit CMS guidance, voluntarily implement all, or portions, of the guidance presented below.

The voluntary actions that plans may choose in order to facilitate provision of benefits are as follows:

- Each MAO may, at its discretion, allow Part A/B and supplemental plan-benefits to be furnished at specified non-contracted facilities (note, that Part A/B benefits must, per 42 CFR 422.204(b)(3), be furnished at certified facilities);

- Each MAO may, at its discretion, waive in full, or in part, requirements for authorization or pre-notification; and

- Each MAO may, at its discretion, temporarily reduce plan approved cost sharing amounts. Furthermore, although MAOs are required to notify enrollees 30 days in advance of plan changes, this 30-day notification requirement can be waived by CMS during a declared emergency provided all the changes (such as reduction of cost sharing and waiving authorization) benefit the enrollee.

We expect MA plans to resume normal operations once the emergency or disaster is over. Typically the source that declared the disaster will clarify when the disaster ends. However, in the case of disasters declared by FEMA, if the disaster period has not closed 30 days from the initial declaration, and if CMS has not indicated an end date to the disaster, plans should resume normal operations 30 days from the initial declaration.

CMS still reserves the right to assess each disaster or emergency on a case-by-case basis and issue further guidance supplementing or modifying the above guidance.

In response to certain disasters or emergencies, the Secretary of Health and Human Services may exercise his waiver authority under Section 1135 of the Social Security Act. Under the Section 1135 waiver authority (when invoked), CMS may *require* MA plans to allow enrollees affected by the emergency or disaster to receive care from non-network providers at in-network cost sharing.

During emergencies or disasters in which the Secretary has invoked his authority under Section 1135, information about the waivers is posted on the Department of Health and Human Services (DHHS) website (http://www.dhhs.gov/). The CMS web site (http://www.cms.hhs.gov) also will provide detailed guidance for MA plans in the event of a disaster or emergency in which the Secretary's 1135 waiver authority is being exercised. During these disasters and emergencies, MA plans should check these web sites frequently.

Phase-Out of Discriminatory Copayment Rates for Medicare Outpatient Psychiatric Services

Section 102 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) phases-out the discriminatory higher Part B cost sharing for outpatient psychiatric services beginning in CY2010. Under the original Medicare program, the beneficiary coinsurance for outpatient psychiatric services is effectively 50% because only 62.5% of such expenses are considered "incurred expenses" when determining the amount of payment and deductible – see 42 CFR 410.155. Beginning in CY2010 68.5% of such outpatient psychiatric services will be considered "incurred expenses," effectively reducing the original Medicare beneficiary coinsurance for such services to 45.2%. By 2014, outpatient psychiatric services will have the same effective beneficiary coinsurance as almost all other Part B services, which is 20%.

Bids Under Puerto Rico's Medicare Platino Program

In the draft Call Letter, CMS requested that Medicare Advantage Organizations that wish to offer a Platino plan in Puerto Rico in 2010 include a description of the benefits they would be offering under their comprehensive Platino plan in the bids submitted to CMS by the bid deadline of June 1, 2009. CMS has received numerous comments suggesting that committing to final Platino benefits by this date might expose Medicare Advantage Organizations to undue financial risks. This is because Platino plan benefit requirements may not be finalized by June 1. On the basis of these comments, CMS is now clarifying that it is now up to the discretion of the Medicare Advantage Organizations seeking to offer Platino plans in the Commonwealth to determine which mandatory supplemental benefits to include in the bid. In determining which mandatory supplemental benefits to include in the bid, plans should keep in mind that benefits included for 2010 cannot be modified after the bid submission deadline of June 1, 2009, regardless of negotiations with the Commonwealth after that date. Any additional benefits required by the Commonwealth of Puerto Rico to be offered in order to participate in the Platino program would be a separate negotiation and must be paid for by the Commonwealth of Puerto Rico through a supplemental premium that would not be evaluated or approved by CMS.

Bundling of Part D Home Infusion Drugs Under a Part C Supplemental Benefit

We are making various clarifications to our policy allowing MA-PD and cost plans offering Part D to cover Part D home infusion drugs under a bundle of services as part of a Part C supplemental benefit. These clarifications address issues that came up in our benefits review for contract year 2008. In addition, we are establishing new requirements with respect to cost sharing for Part D home infusion drugs covered as a bundled service under a Part C supplemental benefit.

Since the bundling option was made available in 2007, the number of MA-PD and cost plans choosing the option has increased. In contract year 2009, 267 PBPs within 45 contracts chose to bundle their Part D home infusion drugs under a Part C mandatory supplemental benefit. To ensure appropriate formulary coverage, we have required sponsors to provide, through the formulary submission module in HPMS, a file that clearly identifies the Part D home infusion drugs that will be offered as part of a mandatory supplemental benefit under Part C. We have also directed sponsors to consistently apply the option for the contract year (i.e., to always cover the home infusion drugs under the Part C supplemental benefit or under the Part D benefit), and to appropriately apportion costs between the Parts C and D components of their bids.

For 2010 contract year, we further clarify that:

- An MA-PD or cost plan that elects to bundle its Part D home infusion drugs under a Part C mandatory supplemental benefit must always cover those Part D home infusion drugs under the Part C supplemental benefit. Given uniform benefits requirements, plans electing to bundle must ensure that the bundle of services, which includes drugs, is available to all plan enrollees (including those residing in long-term care facilities) as a mandatory supplemental benefit under Part C.

- CMS will review sponsors' home infusion drug files as part of our formulary review process to ensure that only home infusion drugs are included as part of the Part C supplemental benefit. (Note: For a list of common home infusion drugs, refer to Appendix A of Chapter 6 of the Prescription Drug Benefit Manual.)

- The bundle of home infusion services offered under a mandatory Part C supplemental benefit must include both the home infusion drugs that would otherwise be covered under their Part D benefit and the services and supplies associated with their infusion.

In order to address the possibility that the bundling of home infusion drugs results in Part D formularies without at least two drugs in each category or class, we had previously waived the requirement at 42 CFR 423.120(b)(2)(i) that Part D sponsors' formularies include at least two Part D drugs in each category and class of covered Part D drugs – except where a particular category or class includes only one Part D drug – for applicable formulary categories or classes when Part D home infusion drugs are provided under a bundle of service as part of a mandatory supplemental benefit under Part C. That waiver remains in effect for 2010.

However, in addition, effective contract year 2010, CMS waives the definition of a Part D drug at 42 CFR 423.100 with respect to Part D drugs covered as part of a bundled benefit under a Part C supplemental benefit. We believe this waiver of the definition of a Part D drug will improve benefit coordination of home infusion therapy between Parts C and D, particularly since the services and supplies necessary for home infusion are never covered under Part D but would be provided as part of a bundle of service under a Part C mandatory supplemental benefit. This waiver is conditioned on the application of zero cost sharing for the bundle of home infusion services provided under a Part C supplemental benefit. Sponsors will not qualify for the waiver and, in turn, will not qualify to cover Part D home infusion drugs as part of a bundle of services under a Part C supplemental benefit without indicating on their PBPs that the applicable cost sharing for this bundle of services is $0. We are requiring this condition because if any cost sharing were assessed, it would be difficult to determine whether an enrollee would be better off with coverage of home infusion drugs under a Part C supplemental benefit or under Part D. Since this uncertainty would threaten the coordination rationale on which this waiver would be granted, we believe this approach provides enrollees in need of home infusion with improved continuity of care and avoidance of more costly institutional care by facilitating continuous access to home infusion drugs.

III. Bidding

General Bidding Guidance

The pricing in the Bid Pricing Tool (BPT) reflects the benefits submitted in the plan benefit package (PBP). To protect the integrity of the bid, once the bid is approved, the pricing cannot be altered. Similarly, after bids are approved, benefits cannot be added if they were not explicitly priced in the BPT and specifically included in the supporting documentation, nor can benefits be taken away. This includes attempts to include or exclude referral and/or prior authorization requirements. After the initial bid is submitted, there is little flexibility in correcting errors in the pricing, and any BPT corrections are subject to pre-approval by CMS. As in CY 2009, once BPTs and PBPs are approved, there will be a short window for requesting

plan corrections in CY 2010, thus quality control must be an integral part of the PBP and BPT submission process. Please ensure that the documentation in both the PBP and BPT is clear and accurate.

All benefits must be directly health-related (i.e., health care items and services whose primary purpose is to prevent, cure or diminish, actual or future, illness or injury) for which the MA plan incurs a bid-priced cost that is not solely administrative. Items and services that do not meet this definition are not benefits. Value-added items and services (VAIS) should not be included within the bid (PBP or BPT).

Bidding Instruction Updates

All updates for bidding will appear in the Bid Pricing Tool instructions.

Late Bid Submissions

The deadline for CMS to receive bids is no later than 11:59 p.m. PDT on Monday, June 1, 2009. CMS will not accept any bids received after that time. If the MAO experiences a technical difficulty when submitting to HPMS, they should contact the HPMS Help Desk at1-800-220-2028 or hpms@cms.hhs.gov before the deadline.

Rebate Re-allocation

Following CMS' publication in August 2009 of the 2010 Part D national average monthly bid amount, the Part D base beneficiary premium, the Part D regional low-income premium subsidy amounts, and the MA regional benchmarks, MAOs are allowed to reallocate Part C rebate dollars in the MA BPT for certain MA plan bids. Detailed guidance will be provided in the CY 2010 instructions for the MA BPT, scheduled to be released in early April.

Please note that the rebate re-allocation process is not an opportunity to redesign the basic A/B benefits package (benefits or premium). Unauthorized benefit changes may not be made during the rebate reallocation period. Specifically, changes to previously negotiated cost sharing amounts are not permitted and the rebate re-allocation period is not an opportunity to revise OOP maximum amounts. Further, no changes are permitted to be made to the allowed costs, administrative costs, or gain/loss margin in the Part D basic and Part D supplemental benefits.

In situations when MA-PD plans are allowed to re-allocate Part C rebate dollars in order to return to the Target Part D basic premium (due to "insufficient allocation" resulting in a Part D basic premium larger than the target premium or due to a reduction in the total amount of rebate for a regional plan), MAOs should make re-allocations that reflect the following priorities. Specifically, there may not be any reduction of rebate allocated to priority (3) unless reductions have first been made to priority (1), then priority (2) noted below.

1. Reduce or remove non-Medicare covered benefits;

2. Increase cost sharing for widely-used services such as primary care visits; and

3. As a last resort**,** increase cost sharing for more limited-use services such as inpatient,

skilled nursing facility (SNF), and home health care.

MAOs that do not adhere to this guidance may be asked to resubmit.

IV. Quality and Performance Measures

Part C Quality Reporting

Sections 422.152 and 422.516 of volume 42 of the Code of Federal Regulations (CFR) specify that Medicare Advantage plans must submit performance measures as specified by the Secretary and CMS. These performance measures include Healthcare Effectiveness Data and Information Set (HEDIS®), Health Outcome Survey (HOS), and Consumer Assessment Health Providers Survey (CAHPS®). Each year through HPMS CMS will release information about which HEDIS® measures are required to be reported by Medicare coordinated care plan types (HMO, PPO, §1876 Cost, and SNPs) for the contract year. As discussed below, beginning in 2010, PFFS and MSA plans will also be required to report certain HEDIS® measures. CMS will release information about which plans are required to participate in HOS and CAHPS®.

Requirement for PFFS and MSA Plans to have a Quality Improvement Program

Effective January 1, 2010, MIPPA repealed the statutory exemption for Private Fee-for-service (PFFS) plans and Medical Savings Account (MSA) plans from the requirement that MA plans have ongoing quality improvement programs. Beginning plan year 2010, PFFS and MSA plans are required by CMS regulations at 42 CFR §422.152(a)(1), (2) and (3) to implement quality improvement projects on an annual basis, implement chronic care improvement programs, and encourage their providers to participate in CMS and HHS quality improvement initiatives. Note that PFFS and MSA plans are required to meet 42 CFR §422.152(a)(3) only for their direct-contracting providers. CMS is requiring all plans to participate in this assessment activity to meet its strategic goal of achieving confident, informed consumers through transparent public reporting on health plan performance. In order to implement the quality improvement requirements, organizations should follow Chapter 5 of the Medicare Managed Care Manual and seek assistance from State Quality Improvement Organizations as well as CMS.

Quality Data Collection and Reporting for PFFS and MSA Plans

MIPPA requires that beginning plan year 2010 PFFS and MSA plans must also provide for the collection, analysis, and reporting of data that permits the measurement of health outcomes and other indices of quality. This provision is implemented in the federal regulations at 42 CFR §422.152(h). Beginning in plan year 2011, the requirements for PFFS and MSA plans cannot exceed the data collection and reporting requirements established for MA local plans that are PPO plans under 42 CFR §422.152(e). Federal regulations at 42 CFR §422.152(e) limits data collection to providers who are under direct contract with the plan.

For plan year 2010, the requirements for PFFS and MSA plans are not restricted to the requirements established for MA local plans that are PPO plans and must comply with the data collection and reporting requirements using administrative claims data only. Therefore, we are

requiring that PFFS and MSA plans collect and report to CMS all of the administrative Healthcare Effectiveness Data and Information Set (HEDIS®) measures based on claims data that are related to health outcomes and quality. PFFS and MSA plans will be required to gather data on the appropriate HEDIS® measures during plan year 2010 (measurement year) and report the audited data to CMS in June 2011 (reporting year). Only those PFFS or MSA contracts with contract-level enrollment of 1,000 enrollees or more as of July 1 of the measurement year are required to report the HEDIS data to CMS. Also, MAOs that have terminated contracts effective January 1st of the reporting year will not be required to submit a HEDIS report. Therefore, MAOs that terminate their PFFS or MSA contracts effective January 1, 2011 will not be required to submit a HEDIS report for 2010 for those contracts.

PFFS and MSA plans are required to report the HEDIS® data based on administrative claims data only from direct-contract, deemed (applicable to PFFS plans only), and non-contract providers; however, we will not use the data from deemed and non-contract providers for evaluation or enforcement purposes since data from these providers is required to be collected only for one year. Once the specifications for CY 2010 HEDIS® are finalized, we will provide guidance to PFFS and MSA plans to inform them of the specific HEDIS® measures they will be required to collect in 2010 and report to CMS in 2011.

For plan year 2011 and subsequent plan years, similar to MA local plans that are PPO plans, PFFS and MSA plans will be required to collect, analyze, and report health outcomes and quality data to the extent that data are furnished by providers who have a contract with the PFFS or MSA plan. We will provide guidance on the implementation of the health outcomes and quality data collection and reporting requirements for PFFS and MSA plans for plan year 2011 in future guidance.

CAHPS® Survey Administration

Starting with the 2011 annual Consumer Assessment of Healthcare Providers and Systems (CAHPS®) survey administration, all MA and Part D contracts with at least 600 enrollees as of July 1, 2010 will need to begin to pay for the CAHPS® data collection costs. The following types of organizations are included:

- All Coordinated Care contracts, including local and regional preferred provider organizations (PPOs) and contracts with exclusively SNP plan benefit packages.
- Cost contracts under section 1876;
- Private-Fee-For-Service and MSA contracts; and
- Prescription Drug Plans.

The Programs of All Inclusive Care for the Elderly (PACE), HCPP – 1833 cost plans, and employer/union only (PDP and PFFS) contracts are excluded from the CAHPS administration.

The Medicare CAHPS survey administration will mirror the survey administration for the Medicare Health Outcome Survey (HOS) and Hospital CAHPS. In late 2010, all MA and Part D

contracts in effect on or before January 1, 2010 will need to select an approved vendor to administer the 2011 survey. This survey will be conducted in early 2011. The approximate cost per fielded survey is $8; however, all MA and Part D contracts will need to negotiate the price with one of the approved survey vendors. For most contracts, the sample size is approximately 600 enrollees. Contracts that cover large geographic areas may have larger sample sizes. If a contract does not have information about their sample sizes from previous years, they can email CMS at CAHPS_MA_PartD@cms.hhs.gov to obtain those sample sizes.

In addition to approving the survey vendors to conduct the survey on behalf of all MA and Part D contracts, CMS will continue to draw the sample of enrollees for each contract, oversee each of the approved vendors, analyze the CAHPS® data for the plan ratings and produce individual-level contract reports for contracts to use for quality improvement. Vendors will be trained by CMS to collect and submit the data within specified timeframes. Further information will be provided at a later date about how to access the approved vendor list.

HOS Survey Administration

The current year HEDIS reporting category that reports Medicare Health Outcomes Survey (HOS) results applies to the following organization types with a minimum of 500 members with six months of continuous enrollment that had a Medicare contract in effect on or before January 1, of the previous year: (1) all coordinated care contractors, including local preferred provider organizations (PPOs) and regional PPOs; (2) 1876 Cost Plans with open enrollment; and (3) MA contracts with exclusively special needs plan benefit packages, regardless of institutionalized, chronically ill, or dual-eligible enrollment. In 2010, the reporting of HOS results will also apply to PFFS and MSA contracts meeting eligibility requirements.

All Programs of All Inclusive Care for the Elderly (PACE) with contracts in effect on or before January of the previous year are required by CMS to administer the HOS-Modified (HOS-M) survey for current year HEDIS reporting. A minimum enrollment threshold does not apply to the HOS-M. Note that, starting in 2010, the Minnesota Senior Health Options, Minnesota Disability Health Options, Wisconsin Partnership Programs, and Massachusetts MassHealth Senior Care Options MA contracts are required to report HOS and will no longer participate in HOS-M.

V. Compliance and Monitoring

Response to Complaint Tracking Module (CTM) Complaints

To ensure that Medicare Part C enrollees receive the highest quality of service in a timely manner, CMS will apply case resolution time standards with respect to CMS recorded complaints within the Health Plan Management System (HPMS) Complaints Tracking Module (CTM) in 2010.

Effective January 1, 2010, MA organizations will be expected to resolve at least 95% of Part C CTM complaints designated as “immediate need” within two calendar days, “urgent need” within seven calendar days and 95% of CTM complaints without an issue level within 30 days. The table below defines and summarizes these resolution time requirements.

Designation	Part C Definition	Resolution Time
Immediate Need	Defined as a complaint when a beneficiary has no access to care and an immediate need for care exists.	At least 95% of cases resolved within 2 calendar days of receipt.
Urgent Need	Defined as a situation when a beneficiary has no access to care, but no immediate need for service exists.	At least 95% of cases resolved within 7 calendar days of receipt.
Unclassified	Any other CTM complaints.	At least 95% of cases resolved within 30 calendar days of receipt.

CMS continues to reserve the right to reclassify any complaint that does not fit the above definitions as "immediate need" or "urgent" at our discretion.

Should an MA organization not meet the aforementioned 95% thresholds with respect to Part C complaints, CMS will consider these organizations out of compliance with one or more Part C requirements, including, but not limited to, requirements related to enrollment; coverage determinations, appeals, and claims processing.

Audit Approach

CMS' audit strategy in 2010 will reflect a move away from routine audits to more targeted, data-driven and risk-based audits. We will produce a performance profile of MAOs and Part D sponsors based upon reported data and comparative data across all MAOs and Part D sponsors and will target organizations that demonstrate poor performance. We will also focus on high-risk areas that have the greatest potential for beneficiary harm (e.g., enrollment operations, appeals & grievances). In addition to this risk-based approach, there will be some degree of random selection. The goal of the audits will be earliest possible detection and correction of issues and improvement in quality and performance of Part D sponsors and MAOs.

As part of CMS' program oversight, we also intend to assess the effectiveness of MAO and Part D sponsors' compliance programs, including the requirement for effective internal monitoring and auditing.

Part C and Part D Data Validation

CMS has the authority to establish information collection requirements for MAOs and Part D sponsors under 42 CFR §422.516 (a) and §423.514 (a), respectively. Using this authority, CMS issued Part C and D reporting requirements[2] in order to respond to inquiries that we have received and, more importantly, to improve program operations.

CMS has received many inquiries from Congress, oversight agencies, and the public about costs, availability of services, beneficiary use of available services, patient safety, grievance rates, and other factors pertaining to MAOs and PDPs. However, to date, CMS has not been able to address many of these inquiries due to either an absence of data with respect to MAOs or, despite collecting over three years' worth of data, data of questionable validity submitted by Part D sponsors.

To be useful for monitoring and/or performance measurement, Part C and Part D data reported by MAOs, cost plans, and Part D sponsors must be reliable, valid, complete, and comparable among sponsoring organizations. To meet these goals, and to better enable CMS to respond to inquiries and manage our programs, sponsoring organizations should undertake a data validation audit on reported Part C and Part D data effective for CY2010. This data validation audit represents a separate activity from current audit functions, such as finance, bid pricing tool (BPT), or programmatic audits, since it will focus only on reporting data consistent with the technical specifications CMS has published with respect to the Part C and D reporting measures.

CMS will work with a contractor to develop data validation specifications to ensure that the goals of reliability, validity, completeness, and comparability are met at the conclusion of the audit. The data validation specifications will focus on how organizations and sponsors compile numerators and denominators, take into account appropriate data exclusions, and verify calculations, computer code and algorithms. In addition, they will be used to inform how the MAOs, cost plans, and Part D sponsors collect, store, and report data. An inability to capture all the data that should populate a numerator or the denominator may result in an invalid measure. This is especially a consideration when health care organizations are reporting new measures and their IT reporting systems are not sufficiently developed to capture all the numerator or denominator data. The data validation audit process may be especially helpful to such organizations.

MAOs, cost plans, and Part D sponsors are responsible for acquiring the data validation audit resources through a contractor or through other means. As explained in the Part C and D Reporting Requirements Technical Specifications, auditing will be required at either the contract or PBP level as appropriate for each Part C and Part D measure. While organizations and sponsors should not use their own staff to conduct the data validation audit, they may use their own staff to assist the auditors in obtaining necessary information and documents. CMS believes

[2] See OMB #0938-1054 and OMB #0938-0992, respectively.

that use of external entities that are appropriately trained on the published technical specifications will ensure the independence of the data validation audits.

CMS expects to develop the methodology for data validation audits (i.e., the data validation specifications) for contract year 2010 in late 2009. Given the limited timeframe to produce the specifications, we do not believe that it will be possible to require a complete data validation audit of each data element reported for 2010. Thus, we expect to issue the data validation specifications in phases.

During the first phase, which will be performed in 2010, CMS will provide data validation audit specifications for the following measures:

Part C Measures	**Part D Measures**
Benefit Utilization, Grievances, Organization Determinations/Reconsiderations, Agent Compensation Structure	Grievances, Exceptions & Appeals, Drug Benefit Analyses

A sample of Part C and D sponsors will be asked to participate in a pilot study implementing the data validation specifications for the above listed measures in 2009. After the pilot study is completed, we expect to make information on the data validation specifications available to sponsoring organizations for a two-week comment period. During this comment period, sponsors and stakeholders will have an opportunity to provide input to CMS on the approach and procedures.

At the completion of the audits, MAOs, cost plans, and Part D sponsors should attest to meeting all the CMS-established technical specifications of the audit process. Additionally, MAOs, cost plans, and Part D sponsors will report to CMS the results of their audit and any measures for which they received a "not pass." We intend to treat a "not pass" on an audit as a failure to submit required data, which in turn may be considered non-compliance. In addition, MAOs, cost plans, and Part D sponsors that are found to be deficient may be requested to develop corrective action plans. Finally, we may adjust performance measurements to reflect the organizations' non-compliance with CMS audit specifications.

Further information on the data validation audit requirements, timing, and data submission requirements will be provided at a later date.

VI. Enrollment

Mandatory Use of the Online Enrollment Center (OEC)

CMS developed the OEC to facilitate enrollment into MAOs, MAOs offering Part D (MA-PDs), and Prescription Drug Plans (PDPs). The OEC is accessible through Medicare Options Compare (MOC) and Medicare Prescription Drug Plan Finder (MPDPF) on www.medicare.gov. In previous years, MAOs (with some exceptions) and Part D sponsors were encouraged, but not required, to participate in the OEC As of 2010, all MAOs (with the exceptions noted below) and Part D sponsors, must accept enrollment elections made via the OEC. The exceptions are as follows:

1) SNPs and Religious Fraternal Benefit (RFB) plans now have the option, but are not required, to participate in the OEC. Note that because SNPs must obtain additional eligibility information that is not captured by the OEC, enrollment requests received via the OEC cannot be considered complete until they obtain the required information, in accordance with Chapter 2, Section 20.11 of the Medicare Managed Care Manual.

2) Medical Savings Account plans (MSAs) still may not participate in the OEC because the beneficiary must provide additional financial and banking information in order to complete the enrollment request.

3) 800-Series Employer plans are prohibited from participating in the OEC because they are only available to certain employer groups, and availability through the OEC could cause beneficiary confusion.

4) Medicare Cost plans are not permitted to participate in the OEC because of enrollment format requirements specified at 42 CFR §417.430.

All MAOs and Part D sponsors participating in the OEC will have an "enroll" button associated with their offered individual market plans in MOC or MPDPF, as applicable. With the exception of MA-SNPs as described above, enrollments received through this method will constitute completed enrollment requests. At least once every business day, MAOs and Part D sponsors must log into the Administrative Console of the OEC and download pending enrollments. MAOs and Part D sponsors failing to download enrollments every business day are subject to compliance actions including, but not limited to, a request for a corrective action plan.

VII. Payment

PQRI Bonuses, E-Prescribing Incentives, and the Hospital Quality Initiative

Payments to physicians who have contracted with MAOs generally are governed by the terms of the contract, and it is up to the MAO whether to take eligibility for a Physician Quality Reporting Initiative (PQRI) bonus or e-prescribing incentive payment into account in establishing the amount the physician is paid. Payment of PQRI and e-prescribing amounts is optional with respect to contracting providers. It is optional in the sense that the MAO and contracting

providers are free to negotiate whether or not such bonus or incentive payments will be made part of the contract.

In the case of a PFFS plan, however, if the MAO offering the plan is meeting access requirements by paying what Medicare would pay, the MAO is required to include bonus and incentive amounts if the physician would receive them in connection with treating a Medicare beneficiary not enrolled in an MA plan.

Physicians who have not contracted with an MAO, but who provide covered professional services to an enrollee in an MA plan offered by the organization, are also potentially eligible for both the PQRI bonus payment and the e-prescribing incentive payment from the organization. When a physician is determined by original Medicare to have satisfied the requirements and qualified for an incentive under the PQRI, he or she should expect to receive a bonus check from any MAOs which he or she has billed as a non-contracted provider, or for which he or she has provided covered professional services under a PFFS plan that meets access standards by paying the Medicare payment rate. The amount of the PQRI payment is calculated just as it is calculated for traditional Medicare, that is to say a percentage (up to 1.5% for 2007 and 2008, and 2% for 2009 and 2010) of Medicare allowed charges for covered professional services submitted to the plan during the reporting period. When a physician is determined by Medicare to be a successful e-prescriber and qualifies for the 2% incentive under the 2009 E-prescribing Incentive Program, MAOs are required to pay non-contracted physicians 2% of the Medicare allowed charges for any applicable, covered professional services rendered in 2009 to a member of their plan. Such payments are due whether or not the non-contracting or "deemed" physician has participation status under the original Medicare program. This policy also applies to non-physician practitioners who would qualify for payments from traditional Medicare.

See the June 27, 2008, HPMS Notice entitled "Physician Quality Reporting Initiative (PQRI) 2007 Data File for additional information. CMS will provide a file in the summer of 2009 of 2008 PQRI bonuses that will be due. A file of 2009 PQRI and e-prescribing bonuses and incentives due will be provided in the summer of 2010. Bonus and incentive payments for claims incurred in a given year are payable the following year in a lump sum. Additional technical guidance will be provided at the time data files are released.

The Hospital Quality Initiative uses a variety of tools to stimulate and support improvements in the quality of care delivered by hospitals to Medicare beneficiaries. One initiative was introduced in section 501(b) of the MMA. In FYs 2005 and 2006 a hospital that did not submit performance data to original Medicare for ten quality measures received a 0.4% payment reduction in its annual payment update. Section 5001 of the DRA increased the payment reduction to 2% beginning in FY 2007. When reimbursing non-contracting and deemed providers, MAOs that rely on PC Group/Pricer to compute payment amounts need do nothing, since the statutory payment reduction has already been added to the file. Of the approximately 6,000 hospitals that received Medicare reimbursements each year, fewer than 100 did not participate in voluntary reporting under the Hospital Quality Initiative.

Risk Adjustment

Please see Appendix II – Risk Adjustment Implementation – for a timeline and additional information on risk adjustment for contract year 2010.

All Other Payment-Related Changes

All payment-related changes will appear in the *Announcement of CY 2010 MA Capitation Rates and Payment Policies & CY 2010 Part D Payment Notification*, which will be released in HPMS and posted on the CMS website on April 6, 2009.

VIII. Grievances, Organization Determinations, and Appeals

Including the Evidence of Coverage and Formulary in Case Files

For the 2009 plan year, CMS issued guidance strongly recommending that all Medicare health plans and Part D sponsors include complete copies of the relevant Evidence of Coverage (EOC) and formulary (Part D sponsors) with any case files sent to an independent review entity (IRE) for review. This recommendation is being extended for the 2010 plan year. The previous practice was to include relevant excerpts of these plan documents in case files. However, the Office of Medicare Hearings & Appeals (OMHA) ALJs have indicated that these documents are needed in their entirety in order to properly adjudicate appeals. Additionally, the Medicare Hearings & Appeals Council (MAC) recently declined to review certain Part D cases referred for motion review because the ALJ did not have access to a complete copy of the relevant Part D plan formulary and/or EOC at the time of the ALJ hearing. Therefore, it is in the plan's best interest to ensure that each case file sent to an IRE includes a CD with complete versions of the EOC and formulary relevant to an enrollee's specific case. Failure to include this information could result in an unfavorable appeals decision or CMS declining to refer an ALJ decision to the MAC for review.

If a plan chooses to implement this recommendation, the complete EOC and formulary (if applicable) that is relevant to the enrollee's appeal must be put on a CD and included with the case file that is sent to the IRE. Plans may not mail or fax hard copies of the complete EOC and/or formulary to the IRE. We will provide specific instructions about the process for submitting the CDs to the IRE in an upcoming HPMS memorandum and manual instructions.

IX. Special Needs Plans

Model of Care Reporting for New Applicants and Existing SNPs

MIPPA provides that all SNPs must have in place an evidenced-based model of care with appropriate networks of providers and specialists. The MAO offering the SNP must conduct an initial assessment and an annual reassessment of the individual's physical, psychosocial, and functional needs for each enrolled individual. In consultation with the individual as feasible, the MAO must develop a plan that identifies goals and objectives for that individual under the SNP, including measurable outcomes as well as specific services and benefits to be provided. The MAO must use an interdisciplinary team in the management of care.

The MIPPA care management requirements apply to all MAOs offering any type of SNP for the 2010 contract year. MAOs and applicants seeking to offer a new SNP, and MAOs expanding an existing 2009 SNP service area or modifying their enrollment population for 2010 will submit care management information for the specific SNP being offered through the CMS HPMS in the SNP proposal application. The MAOs and MA applicants will complete the full SNP proposal application, including the section addressing care management. The deadline for submitting the SNP proposal application to CMS is the same due date as MA applications.

The care management section of the SNP proposal application is divided into 10 subsections. These subsections are: 1) targeted special needs individuals, 2) goals, 3) staff structure and roles, 4) interdisciplinary care team, 5) provider network, 6) model of care training, 7) health risk assessment, 8) individualized care plan, 9) communication, and 10) performance and health outcomes measurement. Each subsection has a number of questions which are answered by either a "yes" or "no" response. Responses should be specific for the SNP being offered by the MAO and MA applicant. Keep in mind that the questions in the care management section are designed to provide CMS with an understanding and knowledge of the care management composition and functionality for the specific SNP being offered by the MAOs and MA applicant.

MAOs making no change to their operational 2009 SNP, which will be offered in 2010, will submit their SNP care management information through HPMS, too. The same care management information required for new MA SNP applicants is required for existing SNPs. CMS is finalizing the process to accept model of care information for SNPs that are not submitting new applications, but it will be a HPMS-based application identical, or very similar to, the one used by new applicants.

Institutional Equivalent SNP - Level of Care Assessment Tool

Beginning January 1, 2010, MIPPA required that MAOs offering institutional equivalent SNPs (I-SNPs) use the Level of Care (LOC) assessment tool currently utilized by the State in which they operate to determine whether beneficiaries who reside in the community, but need a skilled nursing facility level of care, are eligible to join the I-SNP. CMS has surveyed the appropriate agencies in 50 States, the District of Columbia, and the Commonwealth of Puerto Rico to determine what is presently in use, and we will monitor I-SNPs to ensure that they are using the State-appropriate tool. For I-SNPs operating in multiple states, this will mean using a different LOC assessment tool in each State. Further, we note that many States are presently revising their LOC assessment tools, and MAOs offering SNPs must stay current on the LOC tool being used by their State. We strongly encourage MAOs offering SNPs to maintain an ongoing liaison with the relevant State agencies on this topic.

MIPPA further requires that a qualified independent party conduct the screening of community-based prospective enrollees. This independent party cannot be an employee of the MAO or its parent organization, but should be an independent contractor or grantee. The independent party should not receive any kind of bonus or differential payment for qualifying members for the SNP. Presently, there is a wide range of parties with professional credentials contracted to use the LOC tool and to complete the assessment inquiry for States. Agents most typically are either registered nurses (RNs) or social workers who focus on elderly disabled populations. MAOs

offering I-SNPs should search for individuals with these credentials to conduct the assessments. Alternatively, they can choose to contract with the entity that presently performs the LOC assessment for the State. Finally, if the organization offering the I-SNP can demonstrate that individuals with other credentials are presently employed by the State in which they are operating to conduct the LOC assessment, CMS will consider it an acceptable practice. However, the burden of proof is on the MAO to demonstrate they are adopting the State practice.

SNP Quality Improvement and Chronic Care Improvement Programs

In addition to the collection, analysis, and reporting of HEDIS and Structure and Process measures, MIPPA specifically requires that SNPs evaluate their care management system within their internal performance improvement program. As a Medicare Advantage product, SNPs are already required to conduct quality improvement projects (QIP) and a chronic condition improvement program (CCIP) as performance improvement initiatives. CMS recommends that SNPs incorporate the evaluation of their care management model into their CCIP and/or QIP to meet both requirements in a consolidated activity and conserve resources.

Care management has been defined through MIPPA and subsequent CMS regulation (4138 IFC and 4131 F) as an evidence-based model of care having the following components for each eligible beneficiary:

- Target an exclusive dual-eligible, SNP-specific chronic condition, or institutional special needs population.
- Conduct an initial and annual comprehensive health risk assessment.
- Establish an interdisciplinary care team to manage care.
- Develop and implement an individualized care plan having objectives, measurable outcomes, and specific services and benefits.
- Establish a provider network having medical specialists appropriate to the target special needs population.
- Assure that providers apply nationally recognized practice protocols and guidelines that are documented.
- Establish integrated systems of communication to promote coordination of care.
- Coordinate care across healthcare settings and providers; (i.e.,) transitions of care.
- Train employed and contracted staff on the organization’s model of care.
- Deliver services to vulnerable individuals within the target population; (i.e.,) the frail/disabled, those having multiple chronic conditions, and those near the end-of-life.

- Deliver add-on services and benefits that meet the specialized needs of the unique targeted special needs individuals.

- Establish lines of accountability within the SNP to assure full implementation of the care management system

- Evaluate the effectiveness of the model of care for each plan benefit package.

MAOs offering SNPs may select one or more of these components to examine through a QIP or CCIP. The following examples illustrate this recommendation. While organizations offering program SNPs continue to have considerable latitude in selecting QIP and CCIP focus areas, CMS offers, based on our wide view of SNPs and the Medicare Advantage program, examples below of potentially beneficial QIP or CCIP projects.

Examples of QIPs for dual eligible SNPs:

- Evaluate whether the provision of add-on transportation services for low-income beneficiaries resulted in higher utilization rates of primary care and preventive health services (addresses the delivery of add-on services that meet beneficiary's specialized needs).

- Evaluate whether the medication reconciliation conducted by SNP personnel (a nurse, a case manager, an interdisciplinary care team member, or other SNP personnel) after beneficiaries were discharged from inpatient facilities resulted in a reduction of medication errors or adverse outcomes (addresses the coordination of care across healthcare settings).

Examples of QIPs for institutional or institutional equivalent SNPs:

- Evaluate whether the timely performance of the annual health risk assessment for institutional equivalent beneficiaries; (i.e., those not residing in nursing facilities) resulted in the identification of measurable functional decline and early intervention before an adverse outcome was experienced (addresses the annual performance of a health risk assessment).

- Evaluate whether the skilled nursing facility sent timely reports on beneficiary health status to the interdisciplinary care team resulting in a continuous update of the individualized care plan (addresses the integrated system of communication to promote coordination of care).

- Evaluate whether increased member visits by SNP-employed skilled personnel in participating nursing facilities resulted in the earlier identification and treatment of pressure sores and viral infections (address whether itinerant skilled personnel model is resulting in decline of treatable health problems).

Examples of QIPs for chronic condition SNPs:

- Evaluate whether the palliative care, pastoral care, and use of advance directives for beneficiaries near the end-of-life resulted in members or their caregivers reporting an improvement in quality of life (addresses whether end-of-life care planning approach is providing measurable aid and comfort).

- Evaluate whether beneficiaries having frequent direct contact with their interdisciplinary care team experienced fewer disease exacerbations requiring emergency room visits or hospital admissions (addresses whether interdisciplinary care team model is resulting in measurable decline in hospitalizations).

Examples of CCIPs:

- Cardiovascular disease – Develop and implement a physical exercise program (e.g., the 10,000 steps/day, chair-based exercising for the frail, aerobic exercise program), and evaluate whether regular participation in the physical exercise program reduced a targeted risk factor for heart attack.

- Chronic lung disease – Develop and implement a smoking cessation program, and evaluate whether participants' reduction in baseline cigarette consumption 1) reduced the number of visits to an Emergency Department for exacerbation of COPD or 2) reduced the frequency of contracting acute respiratory infections (pneumonia, acute bronchitis, etc.).

- Major depressive disorder – Develop and implement a depression screening program across the SNP provider network, and evaluate the rate of depression screening among providers in the network or the percentage of participants newly diagnosed with depression who receive timely treatment.

- Diabetes – Develop and implement a diabetic foot care clinic, and evaluate whether participants who regularly attended the clinic had a reduced incidence of new foot ulcers.

CMS reminds all MAOs, particularly those offering SNPs, that the requirement to conduct a meaningful QIP or CCIP is of great importance. These programs are an avenue by which MAOs not only improve the health outcomes of their members, but also raise their HEDIS scores and other quality indicators, which are reported publicly and increasingly factor into CMS's overall assessment strategy. QIP and CCIP monitoring has the potential to become an area of increased focus in CMS's oversight and audit activities.

In calendar year 2009, CMS will contract with an entity having quality improvement expertise to assist SNPs with development and implementation of their CCIP and QIP requirements. Contract initiatives will include asking SNPs about their current CCIP and QIP activities, identifying and publishing best practices, providing SNPs technical assistance to conduct their performance improvement activities, and producing a report on SNP performance improvement activity to inform CMS, the industry, and the healthcare community about trends and best practices. CMS will issue future guidance and contact information for SNPs to access this contracted technical assistance.

Chronic Condition SNPs Targeting More than One Condition

MIPPA directed CMS to convene a panel of clinical advisors to determine the specific chronic conditions that met the MIPAA statutory definition of a severe or disabling chronic condition in regard to SNPs. The convened panel identified 15 severe or disabling chronic conditions based on clinical criteria required by statute to ensure that only people who have these conditions are eligible to enroll in a chronic care condition SNP (C-SNP). These changes do not immediately impact Medicare beneficiaries, but become effective Jan. 1, 2010. The panel results are posted at http://www.cms.hhs.gov/specialneedsplans.

CMS believes that a C-SNP needs to have specific attributes beyond that of a standard Medicare Advantage (MA) coordinated care plan (CCP), in order to receive the special designation and marketing and enrollment accommodations. C-SNPs are expected to have specially designed PBPs that go beyond the provision of basic Medicare Part A/B services and care coordination that is required of all CCPs. These specially designed PBPs should include, but not be limited to:

1. Supplemental health benefits specific to the designated chronic condition;

2. Supplemental health services specific to the designated chronic condition;

3. Specialized provider networks (physicians, home health, hospitals, etc.) specific to the designated chronic conditions; and

4. Appropriate enrollee cost sharing structured around the designated chronic conditions and co-morbidities for all Medicare-covered and supplemental benefits.

Further, CMS believes that a C-SNP cannot be structured around multiple common co-morbid conditions that are not clinically linked in their treatment because this arrangement, by its very nature, leads to a general market product rather than a product tailored for a particular population.

CMS does recognize, however, that certain chronic conditions are commonly co-morbid and clinically linked. We also know that some MAOs presently operating a C-SNP serving multiple chronic conditions, in the interest of maintaining continuity for beneficiaries and their own operations, wish to maintain these multi-condition C-SNPs. Therefore, CMS is allowing multiple-condition C-SNPs under two scenarios – either a CMS-designated grouping of commonly co-morbid and clinically linked conditions, or a plan-customized multiple-conditions option.

Commonly Co-morbid and Clinically-Linked: Multiple condition C-SNPs will be permitted in cases where the conditions are commonly co-morbid and clinically linked.

- The conditions in question are, based upon CMS's data analysis, determined to be commonly co-morbid

- The conditions in question are, based upon recognized national guidelines such as those listed in the Guidelines Clearinghouse maintained by the Agency for Health Quality Research, clinically linked in their treatment.

Based on an analysis of commonly co-existing chronic conditions in the current Medicare population, CMS will allow the following multi-condition groupings of chronic conditions for Contract Year 2010:

Group 1	Diabetes mellitus and chronic heart failure
Group 2	Chronic heart failure and cardiovascular disorders
Group 3	Diabetes mellitus and cardiovascular disorders
Group 4	Diabetes mellitus, chronic heart failure, and cardiovascular disorders
Group 5	Stroke and cardiovascular disorders

For these groupings, CMS will accept applications (and bids) for multi-condition C-SNPs. For MAOs that are approved to offer a C-SNP targeting one of the above-listed groups, beneficiaries need only have one of the qualifying conditions (subject to verification of the condition) for enrollment. All beneficiaries in the service area with any one of the qualifying conditions (subject to verification) are entitled to enroll.

Of course, the application for the multi-condition SNP will still be assessed to determine adequacy in terms of creating a specialized product for the chronic conditions it serves. This includes the review of the model of care and provider network (examined via the application) and benefits package (examined via the bid).

Beneficiaries with All Qualifying Conditions: CMS will permit MAOs to develop their own multi-condition SNP combinations for enrollees with all of the qualifying chronic conditions in the combination. MAOs that pursue this customized option must verify that enrollees have all of the qualifying conditions in the combination. MAOs interested in pursuing this option for multi-condition C- SNPs are limited to groupings of the same fifteen conditions selected by the panel of clinical advisors that other C-SNPs must select. As with SNPs pursuing the Commonly Co-Morbid and Clinically-Linked Option, CMS will carefully assess the prospective multi-condition SNP proposal to determine the adequacy of its care management system for each condition in the combination.

In summary, MAOs may submit a proposal with their MA application by February 26, 2009 to offer one or more C-SNPs for Contract Year 2010 that meets one of the three required options:

1. A care management system (model of care), provider network, and plan benefit package that targets a single chronic condition from the list of 15 CMS-approved chronic conditions

2. A care management system (model of care), provider network, and plan benefit package that targets a group of commonly co-morbid and clinically linked chronic conditions

from the list of 5 CMS-approved multi-condition groupings outlined above in which the eligible beneficiary has **at least one** condition

3. A care management system (model of care), provider network, and plan benefit package that targets a plan-designed grouping of multiple chronic conditions from the list of 15 CMS-approved chronic conditions in which the eligible beneficiary has **all** conditions

Verifying Chronic Conditions for Enrollees in Chronic Condition Special Needs Plans

CMS understands that there is continued concern that some MA organizations offering C-SNPs may be enrolling beneficiaries who do not have the chronic condition(s) for which the C-SNP is structured. CMS reminds MA organizations offering C-SNPs of the requirement to verify that members have the chronic condition(s) appropriate for their product and that organizations should make sure their policies and operations are fully compliant with CMS's guidance on this subject. Further, CMS is informing MA organizations offering C-SNPs that CMS expects to conduct focused audits in the upcoming year to determine that they are verifying that enrollees have the condition(s) for which their product is designed.

SNP Enrollment Requirements for 2010

In view of the many changes in the statute and regulations that apply to SNPs for the 2010 contract year, CMS is providing general, preliminary guidance to MA organizations offering SNPs regarding the transition of existing membership during the 2009 to 2010 plan renewal process. Our goals are threefold: 1) consistent with the clear statutory intent of the recent MIPPA legislation, ensure that individuals in special needs plans are members of the groups that those plans are designed to serve; 2) carry out a seamless transition for all SNP members as we implement the new SNP requirements, and 3) ensure that all affected individuals are informed of their options in a clear and timely manner. CMS will issue detailed guidance later this spring that will outline the specific rules for plan transitions for SNP enrollees from 2009 to 2010.

General Guidance for Transitioning C-SNP Enrollees

As a general rule, MA organizations that currently offer a C-SNP that meets the criteria for renewal in 2010, or that will be modified to meet such criteria, must transition current enrollees of that C-SNP into the 2010 C-SNP under the following circumstances:

1. **A 2009 C-SNP is renewed as one of the allowable 2010 SNP plans.**

   Example: A C-SNP that serves beneficiaries with diabetes (at any stage) in 2009 will renew in 2010 as a C-SNP that targets the new category for beneficiaries with diabetes.

   In this situation, all enrollees in that C-SNP would remain enrolled for 2010, unless they elect another plan.

2. **A 2009 C-SNP targets multiple chronic conditions but for 2010 disaggregates into separate plans (PBPs), each targeting a single condition or multi-condition grouping.**

   Example: In 2009, a C-SNP serves individuals with diabetes, coronary artery disease, and COPD. In 2010, the organization non-renews this plan and offers three separate new plans.

   - One for cardiovascular disorders (covering four conditions: coronary artery disease, cardiac arrhythmias, peripheral vascular disease, or chronic venous thromboembolic disorder);
   - One for diabetes; and
   - One for chronic lung disorders (covering five conditions: asthma, emphysema, chronic bronchitis, pulmonary fibrosis, and pulmonary hypertension).

   In this example, individuals in the 2009 plan that fit one of the categories served by the 2010 plans will be transitioned via passive enrollment to the new plan that matches their condition, unless they elect to enroll in a different plan. Individuals in the non-renewed plan who do not fit into any of the new categories would not be eligible to enroll in one of the three new C-SNP plans.

3. **A 2009 C-SNP covers a condition that is subsumed into a larger category or into one of the five commonly co-morbid and clinically linked groups in 2010.**

   Example: In 2009, the SNP targets coronary artery disease which, in 2010, is part of the larger category of cardiovascular disorders.

   Assuming that the organization offers a plan that targets all cardiovascular disorders within that category, it would retain in the 2010 plan all beneficiaries with any of those conditions who were enrolled in the 2009 C-SNP, unless they elected to enroll in another plan.

We realize that these examples do not address all possible scenarios, such as situations where a 2009 SNP will not be renewed in 2010 and the organization does not offer a new C-SNP, or where an individual enrolled in a 2009 SNP that is continued in 2010 does not have the condition served by the plan in which he or she is enrolled. As noted above, the intent of the SNP program is that a plan serves exclusively those individuals who meet the established criteria for the SNP. We do not believe it is in the best interests of beneficiaries to be enrolled in a SNP that is not designed to serve their needs. Thus, in these situations, we will consider proposals for passively enrolling such individuals into a different plan in 2010. We would approve such proposals only if the organization can establish to CMS' satisfaction that the targeted plan is appropriate for that enrollee, that is, that the targeted plan has similar benefits, formularies, premiums, and network rules. Note that in all the cases described here, whether it involves the transition of an individual from one SNP to another, from a SNP to another MA plan, or from a SNP to original Medicare, affected beneficiaries would have a special election period (SEP) to choose a different plan.

Existing Dual Eligible SNP Members

In general, individuals who lose their Medicaid eligibility would retain the Medicaid benefits they received under the plan for the period of deemed continued eligibility described in section 50.2.5 of Chapter 2 of the Medicare Managed Care Manual. After this period, if they are no longer eligible for a SEP as dual eligibles, they would have an SEP to elect another MA plan or PDP. (See Section 30.4.4, #10).

General Reminder about Special Enrollments Periods for C-SNPs

In addition to the SEP opportunities discussed above, we would like to remind all MA organizations of the special enrollment opportunities for individuals with severe or disabling chronic conditions, as outlined in Section 30.4.4 of Chapter 2 of the Medicare Managed Care Manual:

- Individuals with severe or disabling chronic conditions have an SEP to enroll in a SNP designed to serve individuals with those conditions. This SEP ends once an individual enrolls in the C-SNP. Once the SEP ends, the individual may make enrollment changes only during applicable MA enrollment periods. This SEP also permits an individual who has a severe/disabling chronic condition that is not a focus of their current C-SNP to enroll in a C-SNP that focuses on this other condition. Eligibility for this SEP ends at the time the individual enrolls in the new SNP (See Section 30.4.4., #13).

- Individuals who are no longer eligible for the C-SNP because they no longer meet the specific special needs status also have an SEP to make a change (See Section 30.4.4, #10).

Definition of Subset

As a result of the MIPPA statute, effective January 1, 2010, any new dual eligible SNP, or existing SNP seeking to expand, must have a contract with the State Medicaid agency. According to CMS' current definition, dual eligible SNPs with contracts are termed as a "Medicaid subset." Therefore, in 2010, there will be only one definition for a Medicaid subset: a) serves dual eligible beneficiaries, b) has an executed State Medicaid Agency contract, and c) enrolls the Medicaid population identified in the executed State Medicaid Agency contract as the target population. We recognize the confusion caused by the wording of the attestation statements in the section entitled "State Medicaid Agency(ies) contract enrolled population", and have already identified that section as one that will be revised for 2011. For the 2010 SNP proposal, dual eligible SNP applicants should attest to the one (or more) enrolled population(s) that best describes the targeted population in their State Medicaid Agency contract. If that population is unknown at the time of proposal submission, dual eligible SNPs should indicate so in the State Medicaid Agency Contract Upload Document which permits a narrative description of the status of contract negotiations with the State.

New Dual Eligible SNPs Required to Contract with State Medicaid Agencies

Section 164 of MIPPA added a number of requirements specifically focusing on dual eligible SNPs with the goal of increasing coordination between the MAOs offering dual eligible SNPs and States. One such provision requires all organizations offering new dual eligible SNPs (i.e., those that provide for individuals eligible for both Medicare and Medicaid) or seeking to expand the service area of an existing dual eligible SNP have a contract with its respective State Medicaid agency in the 2010 contract year. CMS believes that dual eligible SNPs are best able to serve Medicare-Medicaid beneficiaries when they are well coordinated with State Medicaid programs. There is an exception to the State Medicaid agency contract requirement for dual eligible SNPs that were approved by CMS prior to 2009 and that do not currently have a State Medicaid agency contract. MA organizations may continue to operate these SNPs without a State contract in 2009 and 2010 (including accepting new enrollments) provided all other statutory requirements are met. This exception is specific to the aforementioned State contract requirement and does not relieve the organization of other MIPPA-created requirements, such as the care management, model of care and quality improvement program requirements that go into effect on January 1, 2010. Again, organizations cannot expand the service area of these SNPs if they do not have a State Medicaid agency contract.

The finalized State Medicaid contract is due to CMS by October 1, 2009 for the 2010 contract year. The plan must have a contract with the State Medicaid agency to provide benefits or arrange for benefits to be provided, for which such individual is entitled to receive as medical assistance under Title XIX. The contract between the MA dual eligible SNP and the State Medicaid agency must document each entity's roles and responsibilities with regard to dual eligible individuals. The required elements of the contract are discussed in 42 CFR 422.107.

Resources for State Medicaid Agencies

MIPPA also requires the Secretary of Health and Human Services to provide appropriate resources to assist the States in this contracting requirement. To accomplish this, CMS is seeking a contract creating a resource contact to work with States on Dual SNP contracts and related issues in 2009. Some of the responsibilities of the resource contact will include:

- Research issues raised by States;
- Address State inquiries regarding State and Federal policy coordination;
- Solicit and catalog relevant State materials; and
- Create communication forums for States to exchange ideas.

Concurrently, the resource contact will develop model and/or best practice documents to facilitate State-SNP relationships which foster Medicare-Medicaid benefit integration and meaningful coordination. This resource will provide technical assistance to the States as well as exist as a resource that is complementary to the interests of MAOs offering dual eligible SNPs.

X. Private Fee-For-Service Plans

Variation in Payment Rates to Providers

The MIPPA added a clarification to the statutory definition of a PFFS plan. Although payment rates cannot vary based on utilization of services by a provider (with the exception of certain preventive services), MIPPA clarified that a PFFS plan is permitted to vary the payment rates for a provider based on the specialty of the provider, the location of the provider, or other factors related to the provider that are not related to utilization. These changes were effective as of September 18, 2008. For a discussion of these changes, please see page 8 of our guidance document at

http://www.cms.hhs.gov/ManagedCareMarketing/Downloads/MIPPA_Imp_memo091208Final.pdf.

PFFS Provider Payment Independent Review Entity

CMS has received complaints from individual providers and provider associations stating that PFFS MAOs are not correctly paying deemed providers in accordance with the MAO's terms and conditions of payment. We remind PFFS MAOs of their responsibility to pay deemed providers at the payment rates consistent with their terms and conditions of payment. PFFS MAOs that are meeting access requirements by paying deemed providers at least at the Original Medicare rates are required to pay these providers at the appropriate amounts applicable under Original Medicare. To pay less than an amount specified in the PFFS MAO's terms and conditions of payment, particularly on a pattern basis, is a significant compliance issue.

As we indicated in a previous program memorandum, we have contracted with an experienced organization to serve as the independent review entity (IRE) for provider payment disputes between deemed and non-contracting providers and PFFS MAOs. We expect MAOs to fully cooperate with the PFFS reimbursement adjudication IRE.

Changes in Access Requirements for PFFS Plans

Effective January 1, 2010, MIPPA requires PFFS plans that are meeting Medicare access requirements under 42 CFR 422.114(a)(2) based on signed contracts with respect to a particular category of provider establish contracts or agreements with a sufficient number and range of providers to meet the access and availability standards described in section 1852(d)(1) of the Act. Section 1852(d)(1) of the Act describes the requirements that MAOs offering a MA plan must meet when selecting providers to furnish benefits covered under the plan when the MAO offers a "network" plan. Providers who have direct contracts with PFFS plans must meet the provider credentialing requirements described in 42 CFR §422.216(i). A discussion of this MIPPA requirement can be found on page 11 of our guidance document at: http://www.cms.hhs.gov/ManagedCareMarketing/Downloads/MIPPA_Imp_memo091208Final.pdf.

Requirement for Certain Non-Employer PFFS Plans to Use Contract Providers in 2011 and Subsequent Years

Effective January 1, 2011, MIPPA created a new requirement for certain non-employer MA PFFS plans to establish contracts with providers. Specifically, for plan year 2011 and subsequent plan years, MIPPA requires that non-employer/union sponsored PFFS plans that are operating in a "network area" must meet the access requirements described in section 1852(d)(4)(B) of the Act through contracts with providers. PFFS plans located in a "network area" may no longer meet access requirements by paying not less than the Original Medicare payment rate and having providers deemed to be contracted as provided under 42 CFR §422.216(f).

"Network area" is defined by MIPPA, for a given plan year, as the area that the Secretary identifies (in the announcement of the risk and other factors to be used in adjusting MA capitation rates for each MA payment area for the previous plan year) as having at least two network-based plans (such as an HMO plan, a PSO plan, a local PPO plan, a network regional PPO plan, a network-based MSA plan, or a section 1876 cost plan) with enrollment as of the first day of the year in which the announcement is made. Special needs plans and employer/union sponsored group health plans are not considered network-based plans. For plan year 2011, the list of "network areas" will appear in the *Announcement of Calendar Year (CY) 2010 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies.* which will be posted on the CMS website on April 6, 2009. We will use enrollment data for January 1, 2009 to identify the location of "network areas".

For purposes of determining the network area of a PFFS plan, we will determine whether any network-based plans with enrollment exist in each of the counties located within the PFFS plan's service area. Beginning in plan year 2011, in counties CMS has identified as network areas as per the statute , a PFFS plan operating in these counties must establish a network of contracted providers to furnish services in these counties in accordance with the section 1852(d)(4)(B) of the Act in order to meet access requirements. In such counties, a PFFS plan would no longer be able to meet access requirements through providers deemed to have a contract with the plan at the point of service in these counties. In counties where there are no network-based plan options, or only one network-based plan, the statute allows PFFS plans to meet access requirements in accordance with section 1852(d)(4) of the Act and 42 CFR §422.114(a)(2).

A discussion of this MIPPA requirement can be found on page 9 of our guidance document at: http://www.cms.hhs.gov/ManagedCareMarketing/Downloads/MIPPA_Imp_memo091208Final.pdf

CMS will issue guidance for MAOs making plans for contract year 2011 with respect to PFFS network requirements and beneficiary transitions in advance of the submission of Notices of Intent to apply for CY 2011.

A discussion of the requirement for all employer/union sponsored PFFS plans to use contracts with providers in 2011 and subsequent years can be found in Section A, subsection XIII, of this call letter.

PFFS Prior Notification

NOTE: Guidance explaining the prohibition on PFFS plans requiring prior authorization or referral requirements was included in the 2009 Call Letter, and in an HPMS memorandum dated May 29, 2008. This guidance explains the difference between the terms prior authorization and prior notification. In addition, this guidance explains the conditions under which PFFS plans may use prior notification, as well as actions CMS may take when plans improperly use prior notification as a form of prior authorization.

MA coordinated care plans may require prior authorization or referral as a condition for their plan members receiving certain covered services from providers. Prior authorization means that a coordinated care plan requires that an enrollee or provider obtain advance permission from the plan before a health care service will be paid for by the plan. It is important to note that PFFS plans are prohibited from imposing prior authorization requirements as a condition of their members obtaining health care services (MCM Chapter 4, Section 150.1). PFFS plans must pay providers according to their terms and conditions of payment for all medically necessary plan covered services enrollees receive from providers who are eligible to furnish Medicare services. PFFS plans must also furnish upon request of the member or a provider an advance determination of coverage if the provider or member wishes to confirm in advance of receiving or furnishing a service that it is a medically necessary plan covered service (see §422.216(e)).

Prior notification refers to a situation in which a PFFS plan offers a reduction in the standard plan cost sharing when:

- The provider from whom a plan enrollee is receiving plan-covered services voluntarily notifies the PFFS plan prior to furnishing those services; or

- The enrollee voluntarily notifies the PFFS plan prior to receiving plan-covered services from a provider.

Prior notification does not involve a medical necessity determination by the PFFS plan. It is simply notification by the member or a provider that a particular plan-covered service is being furnished.

Those PFFS plans requesting voluntary prior notification in their terms and conditions of payment for selected plan-covered services in return for reduced cost-sharing must:

- Clearly advise the enrollee that they may also obtain this service at the cost sharing level that applies in the absence of voluntary prior notification. (MCM Chapter 4, Section 50.1) and

- Have a CMS-approved bid that includes the differential cost sharing; and

- If an enrollee does not voluntarily prior notify a PFFS plan when obtaining a service, then the PFFS plan must still cover this service as long as it represents a medically-necessary service covered by the plan. However, in this case, the enrollee pays the cost sharing amount that applies in the absence of prior

notification. Plans may not otherwise impose fines or monetary penalties for non-participation in voluntary prior notification protocols.

We are issuing this guidance because CMS is concerned that the use of prior notification by PFFS plans is confusing to beneficiaries, misleading in terms of disclosing to plan members what cost sharing they must pay, and in some instances used inappropriately as a form of prior authorization. Specifically, CMS expects PFFS plans to market their plans in a way that prominently shows enrollees or prospective enrollees the standard plan cost sharing absent any prior notification cost sharing reductions that may be available. CMS will pay special attention to both the standard and the prior notification cost sharing amounts to ensure that they do not have the effect of discouraging the enrollment of beneficiaries requiring certain health care services. Any plan that does not clearly list its prior notification policies or uses such policies to require prior authorization will be considered not in compliance with the MA program regulations and subject to sanctions or civil money penalties.

In order to protect beneficiaries, CMS is considering rule making prohibiting prior notification.

XI. Medical Savings Account (MSA) Plans

A Medicare Medical Savings Account (MSA) plan is a type of Medicare Advantage plan that combines a high-deductible health plan with a medical savings account. Enrollees of Medicare MSA plans can use their savings account to help pay for health care that is not covered by the high-deductible health plan because the deductible has not been met. While generally, only Medicare-covered expenses will count towards the plan deductible, all MSA account dollars spent on "qualified medical expenses" are not taxed. Medicare MSA plans cannot offer Part D coverage. Under demonstration projects, some MSA rules have been waived to test MSA plans that are more similar to other consumer-directed health plans, like health savings accounts (HSAs) available in the private sector. Under these waivers, demonstration MSA plans may allow coverage of preventative services under the deductible, and cost sharing after the deductible has been met, up to a separate out-of-pocket limit.

Enrollees of MSA plans cannot receive Medicare Part D prescription drug coverage from their plan; however, MSA plan enrollees can join a stand-alone Medicare prescription drug plan (PDP). MSA savings account withdrawals can be used for Part D drug plan co-pays that will count towards TrOOP. If an enrollee does not have a PDP, MSA account dollars can be used for prescription or certain over-the-counter drugs that are qualified medical expenses and not be taxed.

We expect organizations offering this type of plan to fully explain its features to ensure that people with Medicare clearly understand the costs before and after the deductible is met, and how costs that count towards the deductible are tracked.

Further information:

- For more information on Medicare MSA plans, see CMS publication "Your Guide to Medicare Medical Savings Account Plans"

http://www.medicare.gov/Publications/Pubs/pdf/11206.pdf and the Medicare MSA website http://www.cms.hhs.gov/MSA.

- For information on Medicare MSA plans open for enrollment in 2009, see the Medicare Options Compare tool at http://www.medicare.gov/MPPF/Include/DataSection/Questions/Welcome.asp.

- CMS is in the process of developing a Medicare MSA manual, an audit guide for MSAs, marketing guidelines for MSAs, and a checklist to facilitate the development and review of draft MSA marketing materials.

MSA Transparency

Effective 2009, § 422.103(e) requires MSA plans to provide enrollees with available cost and quality information in their service area comparable to that provided to their commercial enrollees, and submit to CMS for approval a proposed approach to providing such information. Below are examples of what a plan could be expected to address:

- How the organization will provide cost and quality information to enrollees, including screenshots for any web-based tools used to meet this requirement.

- If they will use a web-based product to meet this requirement, how they will provide this information to enrollees that do not have access to the Internet.

- How their organization will obtain information regarding cost and quality in the requested service area and whether this information will be personalized to the member.

MIPPA Quality Improvement Program

We discuss the new MIPPA quality improvement program requirement for MSA and PFFS plans in Section A, Subsection IV, of this call letter.

XII. Section 1876 Cost Plans

Cost Plan Competition Provisions

Prior to MIPPA, for cases in which two or more local or regional coordinated care plans meeting minimum enrollment requirements were present in the service area or portion of a service area of a cost plan, CMS could not renew a contract during 2009 for the affected service area or portions of the cost plan's service area. MIPPA made several clarifications concerning these so-called cost plan competition provisions.

MIPPA revised current requirements by applying the competition provisions beginning in 2010. This means that plans will receive non-renewal notices in 2010 and will first be unable to offer a plan in the affected area(s) beginning 2011. As the statute requires that we use data over the

course of the entire year in making the determination, we will use 2009 enrollment data in determining whether a non-renewal for 2010 is required in 2011.

The MIPPA also clarified how the minimum enrollment requirements will be applied. For a discussion of these changes, please see page three of our guidance document at http://www.cms.hhs.gov/HealthPlansGenInfo/Downloads/MIPPA_Imp_memo091208Final.pdf or the September 18, final regulation codifying the MIPPA cost plan changes (73 FR 54226-54254).

Cost Plan Service Area Expansions

As has been the case since 1997, CMS cannot approve new cost plans for 2010. Also, we will continue our policy to deny applications for service area expansions (SAE) into areas where two or more local or regional plans meeting minimum enrollment requirements exist. Continuing cost plans not affected by the competition provisions and which meet all other requirements, can, however, apply to expand their service areas.

Consistent with our policy regarding cost plans offering a Part D benefit, we will no longer permit applications for mid-year service SAEs for cost plans that offer health care benefits only. Beginning January 1, 2010, no cost plan can apply for an SAE other than at the beginning of a program year.

Cost Contract Drug Benefits

A cost contract has the option of offering a Part D prescription drug benefit as an optional supplemental benefit. Each enrollee then has the option of purchasing this Part D drug benefit. If the enrollee declines to purchase the benefit, or if the plan does not offer the benefit, the enrollee has the right to enroll in a PDP. Cost contracts also have the right to offer a non-qualified drug benefit as an optional supplemental benefit if they do not offer a Part D prescription drug benefit.

The statute does not allow Medicare cost contracts to offer separate plans. Rather each cost contract may offer (none, one or many) optional supplemental benefit packages. As a matter of technological convenience, the PBP software calls each of these optional supplemental benefit packages a cost plan.

The following rules apply when a Medicare cost contract wishes to offer more than one optional supplemental benefit package: A Medicare cost contract:

- Cannot simultaneously offer both a qualified and non-qualified drug benefit in the same or distinct optional supplemental benefit packages; and
- Cannot offer an enhanced Part D drug benefit in one of its optional supplemental benefit packages unless the Medicare cost contract also offers a basic Part D drug benefit in the same or another optional supplemental benefit package.

XIII. Employer and Union-Sponsored Group Health Plans

Requirement for All Employer/Union Sponsored PFFS Plans to Use Contracts with Providers

Effective January 1, 2011, MIPPA revised the access requirements for employer/union sponsored PFFS plans. For plan year 2011 and subsequent plan years, MIPPA requires that all employer/union sponsored PFFS plans that have waivers under section 1857(i) of the Act must meet access requirements under 42 CFR §422.114(a) by establishing written contracts or agreements with a sufficient number and range of health care providers in their service area for all categories of services in accordance with the access and availability standards described in section 1852(d)(1) of the Act. A discussion of this MIPPA requirement can be found on page 12 of our guidance document at: http://www.cms.hhs.gov/ManagedCareMarketing/Downloads/MIPPA_Imp_memo091208Final.pdf.

We will issue operational instructions for implementing this requirement in future guidance.

Section B – 2010 Prescription Drug Plan Sections

Introductory Note

Most of the information in Section B of the 2010 Call Letter applies to all types of Medicare Part D sponsors; (i.e., prescription drug plan (PDP) sponsors, Medicare Advantage organizations (MAOs), and Cost Plan sponsors). MAOs and Cost Plan sponsors offering Part D benefit plans must review both the Part C and Part D sections of the Call Letter to obtain complete information concerning their Medicare contract obligations for 2010.

CALENDAR – PREPARATION FOR 2010

NOTE: Employer/Union-Only Group Waiver Plans (EGWPs) are subject to the same timeline and requirements set forth below, except for dates or requirements that do not apply or are modified due to existing employer group waivers.

2010 Part D Calendar ***(All dates, unless identified as statutory, are subject to change)***	
2009	
March 27, 2009	2010 Final Call Letter released.
March 30, 2009	Release of 2010 Health Plan Management System (HPMS) formulary submissions module.
April 1, 2009	Conference call to discuss 2010 Call Letter.
April 2, 2009	CMS Bid Conference
April 6, 2009	Announcement of CY 2010 MA Capitation Rates and MA and Part D Payment Policies.
April 10, 2009	2010 Plan Creation Module, Plan Benefit Package (PBP), and Bid Pricing Tool (BPT) available on HPMS.
April 20, 2009	Final day to submit 2010 formularies via HPMS (11:59 PM EDT).

2010 Part D Calendar ***(All dates, unless identified as statutory, are subject to change)***	
May 1, 2009	Sponsors are strongly encouraged to notify CMS by May 1, 2009 of any type of service area reduction, or conversion to offering employer-only contracts, so that CMS can make the required changes in HPMS to facilitate a sponsor's ability to correctly upload its bid in June.
Tentative Date May 22, 2009	Final marketing model documents will be available for all organizations. (Models containing significant revisions will be released for public comment prior to this date).
Mid-May 2009	CMS sends PDP sponsor contract eligibility determinations to Applicants based on review of the 2010 applications for new contracts or service area expansions.
May 15, 2009	CMS begins accepting CY 2010 bids via HPMS.
Tentative Date May 29, 2009	Industry training on ANOC/EOC and other marketing materials.
Late Spring/Early Summer, June 2009	Update of the MA/PDP Enrollment, Eligibility, and Disenrollment Guidelines.
June 1, 2009	Final day for PDP sponsors to submit CY2010 bids via HPMS (11:59 PM PDT). Non-Renewal: Deadline for MAOs, PDP sponsors to submit a non-renewal or service area reduction notice to CMS for CY2010.
Tentative Date – Late June 2009	Federal Register posting of draft 2011 Part D Applications for 60-day comment period

2010 Part D Calendar ***(All dates, unless identified as statutory, are subject to change)***	
June 5, 2009	CMS begins accepting CY2010 marketing material for review via HPMS Marketing Module.
June 8, 2009	CMS begins accepting 2010 supplemental formulary files, Free First Fill file, Partial Gap file, Excluded Drug file, Over the Counter (OTC) drug file, and Home Infusion file through HPMS. CMS begins accepting CY2010 Actuarial Certifications in HPMS.
June 30, 2009	Final date for PDP sponsors to submit CY2009 marketing materials for CMS' review and approval. NOTE: This date does not apply to CY2009 file & use materials since PDP sponsors may file these materials with the CMS regional office five calendar days prior to their use.
August 2009	CMS to release a Special Election Period (SEP) letter to PDP sponsors remaining in the service area of plans that have non-renewed. CMS to post annual non-renewal and service area reduction guidance that includes model final beneficiary letter. Release of the 2010 Part D National Average Monthly Bid Amount, the Medicare Part D Base Beneficiary Premium, the Part D Regional Low-Income Premium Subsidy Amounts, and the Medicare Advantage Regional PPO Benchmarks. Rebate re-allocation begins. Five business day rebate reallocation period begins after release of RPPO benchmarks.

2010 Part D Calendar ***(All dates, unless identified as statutory, are subject to change)***	
August 1, 2009	CMS issues contract non-renewal notices to those PDP sponsors CMS finds not qualified to offer Part D benefit plans in 2010.
August 3, 2009	PDP sponsors are expected to submit non-model Low Income Subsidy (LIS) riders to the CMS regional office for review.
August 14, 2009	PDP sponsors are expected to submit Low Income Subsidy (LIS) riders to the regional office for review.
Late August 2009	Final date for CMS to approve PDP's final beneficiary notification letter of non-renewal.
Late August/early September 2009	Submission of attestations, contracts, and final actuarial certifications. CMS completes review and approval of 2010 bid data.
September 2009	PDP sponsors preview the 2010 Medicare & You handbook plan data in HPMS prior to printing the CMS publication (not applicable to EGWPs).
September 18, 2009	Broker/agent compensation structures must be submitted to CMS.
Tentative Date – Late September 2009	Federal Register posting of draft 2011 Part D Applications for 30-day comment period
October 1, 2009	PDP sponsors may begin CY2010 marketing activities. Once an organization begins marketing CY 2010 plans, the organization must cease marketing CY 2009 plans through mass media or direct mail marketing (except for age-in mailings). Organizations may still provide CY

2010 Part D Calendar *(All dates, unless identified as statutory, are subject to change)*	
	2009 materials on request, conduct one on one sales appointments and process enrollment applications.
October 1, 2009	Last day for Part D sponsors to request plan benefit package (PBP) plan corrections via HPMS.
October 1, 2009	PDP sponsors are required to include information in CY2009 marketing and enrollment materials to inform potential enrollees about the possibility of plan (benefit) changes beginning January 1, 2010.
October 9, 2009	Tentative date for 2010 prescription drug benefit information to be displayed on the Medicare Prescription Drug Plan Finder on Medicare.gov (not applicable to EGWPs).
October 15-20, 2009	CMS mails *Medicare & You* handbooks to Medicare beneficiaries.
October 31, 2009	CY2010 standardized combined ANOC/EOC is due to all PDP members. PDP sponsors must mail the combined ANOC/EOCs before this date to ensure receipt by members by October 31. All PDP sponsors must mail their Low Income Subsidy (LIS) riders and abridged or comprehensive formularies before this date to ensure receipt by members by October 31.
November 2, 2009	Non-renewal: Final personalized beneficiary notification letter must be received by PDP enrollees.
November 15, 2009	Marketing guidelines require that PDP sponsors mail a CY 2010 EOC to each new member no later than when they notify the new member of acceptance of enrollment. PDP sponsors must mail their low income subsidy (LIS) riders and abridged or comprehensive

2010 Part D Calendar *(All dates, unless identified as statutory, are subject to change)*	
	formularies with the EOC for new members. New members with an effective date of 1/1/10 do not need to receive the ANOC portion of the standardized/combined ANOC/EOC.
November 15 – December 31	Annual Election Period: All PDP sponsors must hold open enrollment (EGWPs see Section 20.3.8 of the PDP Guidance: Eligibility, Enrollment and Disenrollment).
Tentative Date – November 17, 2009	Potential New PDP sponsors and existing sponsors seeking to expand currently contracted service areas must submit Notices of Intent to Apply for the 2011 contract year.
Tentative Date – November 25, 2009	CMS issues pending HPMS contract numbers to new Part D applicants for the 2011 contract year.
November – December, 2009	CMS to issue "close-out" information and instructions to PDP sponsors that are non-renewing or reducing service areas.
2010	
January 1, 2010	Plan benefit period begins.
Early January 2010	Final CY 2011 Part D applications are posted to the CMS website and HPMS. Applications released in HPMS for organizations seeking new Part D contracts or service area expansions.
Early January 2010	Industry training on CY 2011 applications.

2010 Part D Calendar *(All dates, unless identified as statutory, are subject to change)*	
Late February 2010	Applications due for CY 2011.

I. BIDDING/PAYMENT

Bidding Process

All updates and changes to the bidding process and bid pricing tool (BPT) will appear in the "Instructions for Completing the Medicare Prescription Drug Plan Bid Pricing Tool for Contract Year 2010."

Submission of a Valid Application, Bid, or Formulary Submission

Part D sponsors and organizations applying to qualify as sponsors are obligated by statute, regulation, and contract to meet several information submission deadlines in the course of applying to qualify to, or continuing to, operate a Medicare Part D contract. The most significant of these are deadlines related to applications for qualification as a sponsor, formulary submissions, and bid submissions. During the first four years of the Part D program (counting implementation activities during 2005), some organizations made submissions to CMS that have been either so lacking in required information or correct detail as to fail to constitute a valid, timely submission. In some instances, it even appeared to CMS that the organization might not have completed the preparation of its information and knowingly submitted incomplete or inaccurate information to avoid the significant consequences of failing to meet a Part D program deadline (i.e., failure to submit timely bid or formulary may result in non-renewal of a Medicare contract).

These submission deadlines are necessary to ensure that all applicants and Part D organizations are afforded the same period of time in which to prepare their files and that CMS substantially can meet its operational deadlines in preparation for the upcoming contract year. Organizations that make "placeholder" or substantially inaccurate submissions by stated deadlines may be attempting to defeat the purpose of deadlines. Therefore, during the application, formulary, and bid review processes for CY 2010 and beyond, CMS will consider the completeness and accuracy of the submission as factors in determining whether an organization has in fact met a submission deadline.

All three submission processes (application, formulary, and bid) afford sponsors opportunities to submit additional information after the initial deadline. However, CMS grants those additional submission opportunities only to allow organizations to provide clarifying information that builds on largely compliant initial submissions. Organizations must not rely on the period following the initial submission deadline as an opportunity to cure an incomplete or defective submission. When an organization's submissions appear to represent something other than a good faith effort to provide complete and accurate information, CMS may determine that the

organization has not met the submission deadline and may not accept any further submissions from the organization.

For each type of Part D-related information submission, CMS provides examples below of the application and formulary submission characteristics that would cause CMS to conclude that an organization had not, in fact, provided information that could be characterized as a valid, timely submission. CMS provides this list as an illustrative guide, and organizations should not read it as an exhaustive statement of the characteristics of an invalid application, formulary, or bid submission. CMS will evaluate the information provided in each submission in accordance with the principles described in this section.

Applications for Qualification as a Part D Sponsor

CMS wants to stress that organizations must submit complete applications. In order to submit a Part D application a series of attestations must be completed and a series of documents must be uploaded. CMS validates the documents that applying organizations provide and will reject any applications that are deemed invalid. Examples of invalid submission include applications that contain blank documents or blank spreadsheets. Such applications will not be considered to be completed applications under 42 CFR 423.502(b). In these instances, CMS would deny the application pursuant to 42 CFR 423.503(c).

Formulary Submissions

CMS wants to stress that organizations must upload complete formulary submissions. Submissions that do not indicate a good faith effort to provide an adequate formulary, as outlined in section 30.2 of Chapter 6 of the Medicare Part D Manual, will be considered a non-submission. In such an instance, CMS will non-renew or elect not to enter into a contract with the organization based on its failure to submit a timely bid, of which a formulary is a required element (42 CFR § 423.272(b)(2)(i)). This determination would not be subject to administrative appeal under 42 C.F.R. Part 423, Subpart N. (42 CFR § 423.506(d)). Submissions will not be considered if they are based solely on a previous year's Formulary Reference File (FRF), they include only one Part D drug in the majority of the formulary category and classes, or if they include a significantly lower number of Part D drugs as compared to all Part D sponsors' submissions.

Accuracy of Linkage Between HPMS Formulary and the Appropriate Contracts at Time of Formulary Upload

CMS reminds Part D sponsors that they must link all their associated contracts to an initial formulary submission on or before the formulary submission deadline. During the first four years of the Part D program, CMS spent significant time after the formulary submission deadline following up with sponsors to direct them to make the proper linkage. CMS is not obligated to double check on contracts that show no formulary link. Part D sponsors whose contracts are not linked to any timely formulary submission will be considered to have missed the formulary submission deadline and, therefore, may have their Medicare contract non-renewed.

Non-Renewals

CMS wants to emphasize that, pursuant to 42 CFR § 423.507(a)(3), existing Part D sponsors that voluntarily non-renew a Part D contract with CMS will be prohibited from offering a PDP in the specified service area for two years. CMS may, upon its determination that special circumstances exist, waive this prohibition.

Bids Under Puerto Rico's Medicare Platino Program

In the draft Call Letter, CMS requested that Part D sponsors that wish to offer a Platino plan in Puerto Rico in 2010 include the Platino benefits in the bids submitted to CMS by the bid deadline of June 1, 2009. CMS has received comments that persuaded us that this requirement might expose Part D plan sponsors to undue financial risks. This is because Platino plan benefit requirements may not be finalized by June 1. On the basis of these comments, CMS has now revised this requirement. Instead Part D sponsors seeking to offer a Platino plan in the Commonwealth should submit Part D bids that reflect only basic benefits, and should not include any Part D supplemental benefits, such as coverage of excluded drugs and cost sharing buy-downs that are (or will be) required by the Commonwealth for the Platino program in 2010.

The purpose of requiring all Platino plans to bid on a comparable benefit package is to be able to evaluate Platino plans bids on a "level playing field". Any supplemental benefits required by the Commonwealth of Puerto Rico will be a separate negotiation between the Commonwealth and the Part D sponsor and must be paid for by the Commonwealth of Puerto Rico through a supplemental premium that would not be evaluated or approved by CMS. We believe this policy places the Part D sponsors in a more comparable position to the stateside State Pharmacy Assistance Programs relative to the Commonwealth of Puerto Rico and CMS reconciliation. By having all Part D sponsors offering Platino plans in the Commonwealth submit only basic bids, their costs under the Part D benefit will be treated consistently with respect to Federal reinsurance subsidies and risk sharing.

II. FORMULARY

Access to Covered Part D Drugs

There will be no change in our six classes of clinical concern policy outlined in section 30.2.5 of Chapter 6 of the Prescription Drug Benefit Manual.

New PDE edits for NDCs not listed on the FDA's NDC Directory

CMS has been working on a project with the Food and Drug Administration (FDA) to increase transparency and clarity with respect to the regulatory status of prescription drug products in the marketplace. We are proposing to begin rejecting prescription drug event (PDE) submissions on January 1, 2010 with national drug codes (NDCs) for which the FDA is unable to provide regulatory status determinations through their regular processes. Specifically, CMS is exploring the feasibility of establishing PDE edits based on a comparison of NDCs that CMS uses to evaluate PDEs against NDCs listed on the FDA's NDC Directory. This comparison would help highlight NDCs for which it has not been affirmatively established that the product meets the

statutory definition of covered Part D drug [specified in Section 1860D-2(e)(1)(A) of the Social Security Act (the Act)].

Part D sponsors continue to be responsible for making coverage determinations regarding which drug products are Part D drugs based upon statutory and regulatory requirements. These determinations involve excluding non-prescription drug products (i.e. OTCs), excluding drug products in categories that are statutorily excluded from Part D (e.g., drugs used for the symptomatic relief of cough and colds), and excluding any remaining prescription drug products that do not otherwise satisfy the statutory definition of a Part D drug. Generally, these remaining prescription drug products can only satisfy the definition of a Part D drug if they are approved by the FDA for safety and effectiveness; however, some older unapproved prescription drug products on the market (and prescription drug products identical, related or similar to such older unapproved prescription drug products) potentially satisfy the definition.

Part D sponsors must rely on publicly available information, including information available from the FDA or CMS, to make these determinations. However, it has become increasingly clear that currently available information on the approval/marketing status of prescription drug products on the market is incomplete and that more guidance is needed to help ensure that Part D sponsors make consistent determinations across the Part D program. Specifically, it is unclear to the public that not all NDCs on the market (and listed on commercially available databases) have been appropriately reviewed and approved by the FDA or are eligible to be covered as older unapproved drugs, or that not all NDCs on the market (and included on commercially available databases) are properly listed with FDA as required by law.

As a result of collaborating with the FDA, CMS believes that it is best practice for Part D sponsors to consider the proper listing of a drug product with the FDA as a prerequisite for making a Part D drug coverage determination. Owners or operators of establishments engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs must register their establishments and list all drug products for commercial distribution through the FDA drug registration and listing system. Requirements for drug establishment registration and listing are set forth in section 510 of the Federal Food, Drug, and Cosmetic Act (the Act) and section 351 of the Public Health Service Act (the PHS Act), and 21 CFR Part 207.[3] Prescription drug products that are properly listed will appear in the FDA's NDC Directory. Neither the assignment of an NDC number nor inclusion on the NDC Directory denotes FDA approval of the product.

Similarly, CMS has not determined that all prescription drug product NDCs listed on the FDA's NDC Directory satisfy the definition of a Part D drug, nor has CMS determined that all non-listed prescription drug product NDCs fail to satisfy the definition of a Part D drug. However, CMS relies on the FDA to make regulatory status determinations regarding drug products and the FDA can only make these determinations if a drug is properly listed. Therefore, a Part D sponsor's Part D drug coverage determination process should *begin* with confirming that the prescription drug product NDC is properly listed with FDA.

[3] This guidance document does not apply to establishment registration and product listing information required solely under 21 CFR part 607, 21 CFR 807, and 21 CFR part 1271.

In support of our position that it is best practice for Part D sponsors to consider the listing of a prescription drug product NDC on the FDA's NDC Directory as a prerequisite for presuming a drug to meet the statutory definition of a covered Part D drug , CMS is proposing the following:

- CMS would request FDA assistance in performing the comparison and creating the resulting "Non-Matched NDC List." The Non-Matched NDC List would not be an all-inclusive list of NDCs that are unlisted with FDA; there may be other marketed drug products with NDCs that are not properly listed. Also, the fact that an NDC would be included on the Non-Matched NDC List would not be a finding that the drug product is improperly listed because, for example, the marketing and listing status of a prescription drug product may change over time

  Beginning January 1, 2010, CMS would establish PDE edits to reject NDCs on a prospective basis only for prescription drug product NDCs that are not listed on the FDA's NDC Directory because the FDA is unable to provide regulatory status determinations through their regular processes for these drug products. Specifically, CMS would establish edits based upon a comparison of NDCs that CMS uses to evaluate PDEs against NDCs listed on the FDA's NDC Directory.

- CMS would update its PDE edits to reflect the most current version of the Non-Matched NDC List. We anticipate that an initial comparison would be performed as early as possible in 2009 and an initial Non-Matched NDC List would be made available on the CMS website in the spring; however, we would utilize an updated version as the basis for establishing the January 1, 2010 PDE edits that would be made available as early as possible this fall so that Part D sponsors have sufficient time to make necessary systems changes and notify affected beneficiaries that would be negatively impacted. At this time, CMS does not expect the Non-Matched NDC list to be updated more than twice a year.

CMS cautions Part D sponsors about implementing changes to their CY2009 adjudication files based on the initial or updated Non-Matched NDC list. CMS is proposing a January 2010 implementation date for PDE edits to provide manufacturers, labelers, repackers, and distributors of unlisted products the opportunity to register and list with the FDA. Similarly, Part D sponsors should take steps to provide notice and inform their pharmacy benefit managers (PBMs) and network pharmacies about the NDCs that they determine not to be payable. This should discourage pharmacies from purchasing and stocking prescription drug products for Medicare Part D enrollees that potentially do not meet the statutory definition of a covered Part D drug. In addition, CMS will notify pharmacies on its pharmacy listserv when the Non-Matched NDC list is posted on the CMS website.

Part D sponsors, PBMs, pharmacies or other interested parties should contact the FDA's Drug Registration and Listing Team (nonlisted@fda.hhs.gov or 301-210-2897) if they believe that a prescription drug product NDC is improperly excluded from the FDA NDC Directory and therefore identified on the Non-Matched NDC list. Although CMS will accept NDC-level documentation in support of a determination that a prescription drug product is a Part D drug despite its inclusion on the Non-Matched NDC List, CMS will need to verify such documentation with the FDA before removing any related PDE edit. Therefore, submission of this information to CMS rather than to the FDA will only prolong the process. The most efficient method for getting CMS to remove such PDE edits is for the manufacturer, labeler, repacker, or

distributor to register and list the prescription drug product(s) NDC(s) with the FDA for listing on the FDA NDC Directory. Firms are encouraged to register and list electronically and may refer to the FDA draft guidance for industry on Providing Regulatory Submissions in Electronic Format – Drug Establishment Registration and Listing, July 2008 at http://www.fda.gov/cder/guidance/OC2008145(2).pdf.

CMS will continue to work closely with the FDA to determine whether additional guidance is necessary to provide further clarification on the Part D status of prescription drug products on the market. In addition, the Medicaid Program and Medicare Part B are working with Part D and FDA on this initiative to determine whether the information provided can be used to assist in the administration of their respective programs. Future guidance may be issued by each program to their respective stakeholders.

CY 2010 Formulary Reference File

As CMS noted in last year's call letter, the Formulary Reference File (FRF) for CY 2010 HPMS formulary submissions will be based on the National Library of Medicine's (NLM) standardized nomenclature for drugs, RxNorm. We believe that incorporating RxNorm data as part of formulary submissions will eliminate issues associated with the use of National Drug Codes (NDCs) as unique drug identifiers, as well as differences in the representation of drugs in various commercial databases. In addition, this change supports RxNorm as a health information technology standard nomenclature.

As a result of the move to the RxNorm drug nomenclature, CMS has identified drug records that were contained on the CY 2009 FRF that will be absent from the CY 2010 file. These deletions are primarily due to the elimination of duplicate codes that represent the same drug product or the removal of inactive or obsolete codes, and thus, do not represent a reduction in the number of unique drug entities appearing on the file. CMS posted a draft version of the CY 2010 FRF in the HPMS formulary submission module to enable Part D plan sponsors to process the new file and provide feedback on its content. The final version is now available in HPMS and on the CMS website. The CMS website also includes materials explaining the use of the FRF and why CMS changes to the reference file will continue to occur annually in order to keep the file current.

Specialty Tier Threshold

We continue to analyze and evaluate the specialty tier for very high cost and unique drugs that are exempt from tiering exceptions. For contract year 2010, we will maintain the $600 threshold for drugs on the specialty tier. Thus, only Part D drugs with negotiated prices that exceed $600 per month may be placed in the specialty tier in accordance with section 30.2.4 of Chapter 6 of the Medicare Prescription Drug Benefit Manual.

As part of our formulary review process, we will continue to carefully evaluate sponsors' formularies to ensure that they do not discourage enrollment by certain classes of beneficiaries. We encourage ongoing dialogue regarding our specialty tier policy and will evaluate whether further notice-and-comment rulemaking in this area is warranted.

Formulary Exceptions Tier

Part D sponsors have the flexibility to determine what level of cost-sharing will apply for all non-formulary drugs approved under the exceptions process. As provided in section 30.2.2 of Chapter 18 of the Prescription Drug Benefit Manual, CMS generally requires Part D sponsors to apply only one level of cost sharing from an existing formulary tier to all approved formulary exceptions. However, Part D sponsors may also elect to apply a second less expensive level of cost sharing for approved formulary exceptions for generic drugs, so long as the second level of cost sharing is associated with an existing formulary tier and is uniformly applied to all approved formulary exceptions for generic drugs.

Transition Notices in Long Term Care Settings

A successful transition process is contingent upon informing enrollees and their caretakers about their options for ensuring that enrollees' medical needs are safely accommodated within a Part D sponsor's formulary. This is particularly important in situations when a beneficiary resides in a long term care (LTC) facility where his/her medical needs may change quickly and require rapid modifications in drug therapy. With this in mind, for contract year 2010, we are permitting Part D sponsors the option of sending required transition fill notices to network long term care pharmacies. In addition to sending enrollees residing in LTC facilities a model transition notice via U.S. mail within 3 business days of the transition fill, Part D sponsors may elect to send the beneficiary transition notice to the LTC pharmacy serving the beneficiary's LTC facility. The LTC pharmacy must then ensure delivery of the notice to the beneficiary within 3 business days of the fill.

Part D sponsors electing this option must update their existing transition policy to specifically address that:

1. The sponsor maintains documentation of the LTC pharmacies' willingness to be delegated transition notice responsibilities; and

2. The sponsor maintains a fully functional electronic communication process with the LTC pharmacy once a transition fill has occurred (within three business days).

3. The LTC pharmacy will maintain a process that demonstrates notice has been provided to the beneficiary (or his/her representative) within the 3-day period.

This option must be in place prior to the start of the 2010 contract year; otherwise, the Part D sponsor must continue to provide notice directly to the beneficiary (or his/her designated representative) via U.S. mail.

Transition Across Contract Years

Section 30.4.5 of Chapter 6 of the Prescription Drug Benefit Manual describes our transition requirements with regard to formulary changes for current enrollees across contract years. Per that guidance, sponsors have two options for effectuating an appropriate and meaningful transition for enrollees whose drugs are no longer on the formulary in a subsequent contract year.

We clarify that these transition requirements apply both to drugs that are removed from a sponsor's formulary from one contract year to the next, as well as to formulary drugs that remain on formulary but to which a new prior utilization or step therapy restriction is added from one contract year to the next. Thus, for example, sponsors must effectuate a meaningful transition for a current enrollee whose Drug X is no longer on the formulary the following contract year, as well as for a current enrollee whose Drug Y, which previously had no prior authorization restriction on its use, has a prior authorization restriction added for the following contract year. This clarification ensures that the transition requirements for current enrollees across contract years are consistent with those for new enrollees.

Utilization Management Criteria

For contract year 2010, drugs identified on a Part D sponsor's formulary flat file with prior authorization (PA) or step therapy must have corresponding utilization management (UM) criteria reflected in HPMS. To ensure this occurs, Part D sponsors will again be required to submit a complete PA and step therapy UM file to CMS via HPMS, utilizing a standardized template. However, to achieve greater efficiency in the review of sponsors' 2010 submissions, any new 2010 or modified 2009 UM criteria will be required to be clearly marked in HPMS so CMS can focus its review on those changes identified. Further operational details associated with the upload of UM criteria will be released as part of the CY 2010 Formulary Submission Module and Reports Technical Manual in March 2009.

We note that, during the 2009 UM review, we identified a number of common errors associated with submission of Part D sponsors' UM criteria. To ensure a streamlined formulary submission in 2010, Part D sponsors must familiarize themselves with the following issues to remain compliant with our guidance:

1. P&T Committee Review

   Part D sponsors are reminded that the P&T committee must review the utilization management criteria submitted to CMS for clinical appropriateness. Those sponsors that submit criteria that are not consistent with widely used treatment guidelines or which contain significant quality control issues will have their submission returned and may be subject to a focused audit to ascertain if the P&T committee actually reviewed the criteria prior to CMS submission.

2. Lack of access to FDA labeled indications

   Generally, sponsors must cover formulary drugs for all FDA approved indications not otherwise excluded from Part D. In 2009, some Part D sponsors attempted to limit access to drugs by implementing prior authorization criteria that only covered certain labeled indications. Such UM criteria are generally not permitted. If we identify sponsors attempting to limit access of formulary drugs to only certain indications, those sponsors will have their criteria returned and will be asked to submit clinical justification supporting the necessity of such an approach. In the absence of any reasonable justification, the criteria will be rejected.

3. Use of "off-label" indications

   Part D sponsors will not be permitted to require an enrollee to try and fail drugs supported only by an off-label indication (an indication only supported in the statutory compendia) before providing access to a drug supported by an FDA approved indication (on-label indication) unless the off-label indication is supported by widely used treatment guidelines or clinical literature that CMS considers to represent best practices. Generally, CMS requires such authoritative guidelines to be endorsed or recognized by United States government entities or medical specialty organizations. We remind Part D sponsors of the definition of a medically-accepted indication outlined in Chapter 6 of the Medicare Prescription Drug Benefit Manual, section 10.6.

4. Non-specific or vague criteria will not be accepted

   Part D sponsors must provide for a level of detail in their UM criteria that allows a prescriber to readily understand what criteria must be satisfied to permit access to the identified formulary drug. Non-specific or vague criteria will not be accepted. For example, Part D sponsors must not submit UM criteria requiring "laboratory values" without specifying the exact laboratory values considered as a component of the assessment. Furthermore, broad policies are not acceptable, such as "new drug PAs" or "alternate dosage form PAs" which cover a range of drugs, classes and/or categories. These policies are insufficiently specific for prescribers and beneficiaries to understand and will be returned to the sponsor for correction.

5. Overly burdensome criteria

   Part D sponsors must not submit overly burdensome UM criteria. For example, Part D sponsors should not generally maintain prior authorization criteria that require trial and failure of more than two formulary alternatives in advance of providing access to the prescribed drug. Any exceptions must be supported by clinical literature, such as situations where drugs are third or fourth line therapy.

6. Administrative Submission Errors

   Part D sponsors must follow the technical instructions regarding submission of UM criteria and ensure quality control of their work prior to submission. Part D sponsors with a high number of initial errors or those who fail to follow our guidance above will have their UM criteria returned without review. As a result, the Part D sponsor may fail to meet formulary submission timelines.

While we will focus our review on new and/or modified UM criteria relative to the prior year, CMS plans to continuously evaluate the Part D sponsors' UM criteria against a number of reported measures (e.g., exceptions and appeal statistics and beneficiary complaints) to ensure they reflect current medical practice and provide for appropriate access to Part D drugs. As has been our practice in previous contract years, on a case-by-case basis, we will reach out to specific sponsors and ask for revisions when necessary.

New Website Posting Requirement

In addition to posting PA criteria on plan websites in 2010, Part D sponsors must also post quantity limit restrictions and step therapy requirements. Accordingly, Part D sponsors will need to ensure that all UM applied to formulary drugs, including quantity limit amount, quantity limit days supply, prior authorization criteria and step therapy criteria, are available on their formulary websites for display by November 15, 2009. While Part D sponsors may make minor modifications on plan websites with regard to the HPMS prior authorization and step therapy criteria to address issues such as abbreviations and/or grammatical truncation, Part D sponsors will be expected to display all of the information contained within the HPMS files.

PACE Plan Formularies

PACE plans are not required to use a formulary to offer prescription drug coverage. However, we clarify that, if a PACE plan elects to use a formulary to offer its prescription drug coverage in 2010, the submitted formulary must meet all of our formulary requirements. We appreciate the frail nature of PACE enrollees; however, the uniqueness of this population will not automatically exempt the submitted PACE formulary from any of our formulary review checks. Similar to other Part D sponsors, clinical justifications for failure to meet our requirement are permissible where appropriate, but the justification cannot rest solely on the nature of the PACE enrollee population.

III. PART D BENEFITS

Beneficiary Understanding of Part D Benefits and Labeling of Part D Benefit Designs

Given the complexity of the Part D benefit, we continue to explore ways of conveying information about Part D plan benefit designs in ways that are meaningful and understandable to beneficiaries in order to promote informed decision-making. Opportunities for more clearly conveying information are present in terms of both pre- and post-enrollment communications, as discussed below.

Pre-Enrollment Provision of Benefits Information

In establishing the Part D program, CMS defined four benefit types in regulation – defined standard (DS) benefits, actuarially equivalent (AE) standard benefits, basic alternative (BA) benefits, and enhanced alternative (EA) coverage – in order to describe permissible benefit variations. These terms were intended to provide explicit guidance on permissible benefit design parameters for plan sponsors and actuaries. The first three benefit types are considered basic prescription drug coverage, and are actuarially equivalent to the defined standard benefit established in statute. These basic benefit designs vary only in terms of whether cost sharing tiers are applied versus one level of coinsurance, the deductible is lowered or eliminated, and the initial coverage limit is increased. However, there are a number of other benefit design features that are not captured by these actuarial distinctions (e.g., whether particular drugs are on the plan's formulary or a beneficiary's preferred pharmacy is included in a plan's network) that are critically important to beneficiary decision-making. In fact, our research has shown that the plan

features that are important to beneficiaries are whether a plan offers basic or basic plus supplemental benefits (particularly gap coverage), and what the premium, deductible, cost sharing, formulary, and pharmacy network offered by a particular plan are. The variations in those features among plans cannot be meaningfully captured in the foregoing four categories.

CMS provides some information about the various local MA plan and PDP options available to beneficiaries in the health plan charts included in the annual Medicare & You publication. However, because there are practical limitations to the display of detailed comparative information in a print format, CMS provides comparative plan information through other vehicles. We post landscape files to our web site (see http://www.cms.hhs.gov/PrescriptionDrugCovGenIn/) that provide more detailed comparative information, such as information about benefit type (basic versus enhanced and also specific DS, AE, BA, or EA plan types), whether the plan has a $0 premium with full LIS subsidy, and a description of any gap coverage provided. However, this information is geared more toward beneficiary advocates and researchers than beneficiaries.

No static description of plan benefits design features can suffice to allow meaningful comparisons between plans. However, CMS designed and maintains the Medicare Prescription Drug Plan Finder (MPDPF) web tool to allow beneficiaries to customize their comparisons based on their particular needs and thus compare plan benefit packages in a meaningful way. For example, the MPDPF allows beneficiaries or their representatives to develop customized comparisons that are sensitive to a beneficiary's drug regimen, as well as tolerance for generic and therapeutic substitutes.

We continue to attempt to strike a balance between providing beneficiaries with more information and providing them with information that is useful in making an appropriate plan choice. For example, in 2008, CMS created an automated process to standardize the externally reported descriptions of Part D sponsors' levels of gap coverage. Previously, sponsors had self-identified their gap coverage descriptions, which resulted in descriptions that were not necessarily uniform or meaningful to beneficiaries. Our new process describes any gap coverage offered by plans using the labels identified in the table below. Each label – "all," "many," "some," "few" or "no" drugs – is associated with a certain percentage of formulary drugs covered in the gap. These gap coverage descriptions will be used to illustrate the degree of coverage for drugs labeled as generics and/or drugs labeled as brands on the HPMS formulary submissions. We used this new labeling process to describe gap coverage in the CY 2009 Medicare & You health plan charts listing coverage options in beneficiaries' areas of residence. Several commenters requested clarification regarding what the denominator should be when determining the percentage of covered drugs within the coverage gap. For CY 2010, plans will determine their unique denominator when determining gap coverage levels. We will consider the comments regarding the calculation of gap coverage levels for future plan years.

Gap Coverage Level Descriptions Applied to Gap Coverage for CY 2009

Level	Percent of Formulary Drugs Covered in Gap

All	100%
Many	≥65% to <100%
Some	≥10% to <65 %
Few	>0% to <10% (and must also be >15 products covered through the gap)
No Gap Coverage	0% (or ≤15 products covered through the gap).

Beginning in CY 2010, sponsors will be required to identify their gap coverage offerings for both generic and brand drugs in the plan benefit package (PBP) software using CMS-defined standardized thresholds. These thresholds represent the proportion of unique HPMS formulary drug entities (i.e., unique clinical drug component and dosage form) that are covered through the gap for drugs described on the formulary as generic and for drugs described as brand (as specified by the drug type label). Generic and brand gap coverage level determinations should be derived separately (e.g., *Many Generic drugs and Few Brand drugs*) and should not represent a combined coverage level for both brand and generic labeled formulary drug entities. Gap coverage descriptions for both brand and generic drugs will be communicated to beneficiaries through the Summary of Benefits (SB) and possibly other marketing and information dissemination materials.

Post-Enrollment Provision of Benefits Information

We believe it is equally important for beneficiaries to understand their plan's benefits, and particularly their own experience relative to those benefit design features, once they select and enroll in a plan. To this end, in 2008, CMS significantly revised the model explanation of benefits (EOB) plan sponsors use to convey information to enrollees about their year-to-date TrOOP and total drug spend balances. We had not updated the model since 2005, and our revisions – which were consumer tested in early stages of development – were focused on providing more tailored and better information for plan enrollees. We believe the new model, which was implemented in mid-2008, allows plan sponsors to provide a more nuanced understanding of each beneficiary's progression through a plan's particular benefit design, including for LIS eligible enrollees who, as a result of low-income cost sharing subsidies, experience a different benefit design than non-LIS eligibles enrolled in the same plan. Recently, CMS provided further guidance for sponsors further clarifying the use of the model for a variety of benefit designs, as well for enrollees with secondary coverage. In addition, we incorporated certain elements in response to requests from advocates for customization for LIS members. We continue to solicit comments regarding how plan benefit information can be best conveyed to beneficiaries after they enroll in a plan, particularly via the EOB.

Plan Corrections

CMS expects that with the experience gained over the last four years of bid submissions, sponsors' requests for plan corrections for CY 2010 will be minimal. As required by 42 C.F.R. § 423.265(c)(3) and 42 C.F.R. § 423.505(k)(4), sponsors' submission of their final actuarial certifications and bid attestations serve as documentation that the sponsor has verified the final bid submission and attests that it is complete and accurate at the time of submission. A request for a plan correction indicates the bid is inaccurate and/or incomplete and calls into question an organization's ability to submit correct bids and the validity of the sponsors' final actuarial certifications and bid attestations. Please be advised that CMS considers sponsors making plan correction requests to be out of compliance with the Part D program's bid submission and certification requirements.

The plan corrections module will be available in HPMS for CY 2010 benefits for a limited period, from early September until October 1, 2009. Consistent with marketing and open enrollment coordination, Part D sponsors will not be able to request plan corrections for CY 2010 benefits packages after the October 1, 2009 deadline. This will ensure that correct bid information will be available for review on the Medicare Prescription Drug Plan Finder in time for the open enrollment start date of November 15, 2009. It is important to note that only changes to the PBP that are supported by the BPT are allowed during the plan correction period.

Medication Therapy Management Program Requirements

Since the inception of the Part D program, CMS has stated that Medication Therapy Management (MTM) programs must evolve and become a cornerstone of the Medicare Prescription Drug Benefit. We required plans to report various details on their respective MTM programs and to proactively collect additional data on MTM. CMS intended to use these data to identify best practices that will improve MTM and achieve the statutory goal of improving therapeutic outcomes.

In 2008, we performed an extensive analysis and evaluation of MTM programs being offered by Part D sponsors to identify common practices. This review included analysis of Part D MTM program applications, plan-reported data, exploratory research on MTM, informal interviews with a number of Part D sponsors, and other relevant literature or data. Our review focused on enrollment methods, targeting mechanisms, eligibility criteria, interventions, and outcomes. In examining these areas and identifying best practices, we sought to maximize access to MTM and reduce eligibility restrictions. We want to promote greater consistency and raise the level of the MTM interventions offered to positively impact medication use. Based upon the results of our review, CMS is revising its existing MTM program requirements for 2010 by establishing more specific enrollment, targeting, intervention and outcomes-reporting requirements.

Beginning in 2010, Part D sponsors will be required to implement MTM programs that:

1. Enroll targeted beneficiaries using an opt-out method of enrollment only;

2. Target beneficiaries for enrollment at least quarterly during each year;

3. Target beneficiaries who:

    a. Have multiple chronic diseases; and

        - In defining multiple chronic diseases, sponsors cannot require more than 3 chronic diseases as the minimum number of multiple chronic diseases and sponsors must target at least four of the following seven core chronic conditions:

            1. Hypertension;
            2. Heart Failure;
            3. Diabetes;
            4. Dyslipidemia;
            5. Respiratory Disease (such as Asthma, Chronic Obstructive Pulmonary Disease (COPD), or Chronic Lung disorders);
            6. Bone Disease-Arthritis (such as Osteoporosis, Osteoarthritis, or Rheumatoid Arthritis);
            7. Mental Health (such as Depression, Schizophrenia, Bipolar Disorder, or Chronic and disabling disorders).

    b. Are taking multiple Part D drugs; and

        - In defining multiple Part D drugs, sponsors cannot require more than 8 Part D drugs as the minimum number of multiple covered Part D drugs.

    c. Are likely to incur annual costs for covered Part D drugs that exceed a predetermined level as specified by the Secretary.

        - The existing cost threshold, $4000, will be lowered to $3000, and sponsors' targeting criteria should be adjusted accordingly.

4. Offer a minimum level of MTM services including interventions for both beneficiaries and prescribers, an annual comprehensive medication review for the beneficiary, which includes a review of medications, interactive, person-to-person consultation, and an individualized, written summary of interactive consultation, and quarterly targeted medication reviews; and

5. Measure and report details on the number of comprehensive medication reviews, number of targeted medication reviews, number of prescriber interventions, and the change in therapy directly resulting from the interventions.

All Part D sponsors must establish a MTM program per these requirements. The MTM requirement does not apply to MA Private Fee for Service (MA-PFFS) organizations. However, considering MA-PFFS organizations have an equal responsibility to provide a quality Part D

product, CMS encourages MA-PFFS organizations to establish an MTM program to improve quality for Medicare beneficiaries.

Opt-out Enrollment

Opt-out approaches have become the preferred method among sponsors and increase the number of beneficiaries offered MTM. Fewer than 15% of MTM programs in 2008 implemented an opt-in method of enrollment. In 2010, sponsors will be required to enroll targeted beneficiaries into MTM programs using only an opt-out method. A beneficiary that meets the targeting criteria would be auto-enrolled and considered to be enrolled unless he/she declines enrollment. The enrolled beneficiaries may refuse or decline individual services without having to disenroll from the program. This requirement will allow Medicare beneficiaries to have more access to MTM services and increase member compliance and enrollment into these programs. Part D sponsors are reminded that if an enrollee chooses to opt-out of the plan's MTM program, they must continue to apply their existing drug utilization management program to ensure the beneficiary receives high quality prescription drug coverage.

Targeting Frequency

Most MTM programs (over 95% in 2008) are already identifying targeted beneficiaries at least quarterly. Beginning 2010, sponsors will be required to target beneficiaries for enrollment at least quarterly during the year to allow more Medicare beneficiaries to have access to the MTM program earlier in the year. For example, daily, weekly, monthly, or quarterly targeting frequencies would meet this requirement.

CMS also expects Part D sponsors to promote continuity of care by performing an end-of-year analysis that identifies current MTM program participants who will continue to meet the eligibility criteria for the next program year for the same Plan. This targeting could be done to auto-enroll eligible beneficiaries in the plan's MTM program early in the next program year in order to provide MTM interventions with less interruption.

Targeting Criteria

Based on analysis of plan-reported data, a lower than anticipated number of plan enrollees have been eligible for MTM. In 2007, 13% of beneficiaries enrolled in Plans with an MTM program met the Plan's MTM program criteria (10% in 2006). Part D MTM programs must target beneficiaries who have multiple chronic diseases, are taking multiple Part D drugs, and are likely to incur annual costs for covered Part D drugs that exceed a predetermined level as specified by the Secretary. CMS is further refining these targeting criteria to increase the number of beneficiaries eligible to receive MTM services and ensure that MTM programs manage the medication use for beneficiaries with the most prevalent health conditions affecting the Medicare population. The Part D sponsors may not include discriminatory exclusion criteria. If an enrollee meets all three of the required criteria as defined by the sponsor, the enrollee should be targeted for enrollment. CMS will monitor sponsors' movement to more restrictive criteria.

Multiple Chronic Diseases

Almost 85% of MTM programs in 2008 already targeted beneficiaries with a minimum of 2 or 3 chronic diseases. Beginning in 2010, sponsors cannot require more than 3 chronic diseases as the minimum number of multiple chronic diseases. Therefore, sponsors may set this minimum threshold at 2 or 3 and target beneficiaries with at least 2 chronic diseases or target beneficiaries with at least 3 chronic diseases.

Part D sponsors may continue to choose to target beneficiaries with any chronic diseases or limit enrollment in their MTM program to beneficiaries having specific chronic diseases. .However, at a minimum, sponsors must target at least 4 of the 7 core chronic diseases described previously in 3a. These are very prevalent conditions in the Medicare population based on the analysis of the RxHCC Risk Adjustment model, pose a risk to the Medicare Trust Fund, and are already the most common diseases targeted by Part D MTM programs.

Part D sponsors may target any chronic diseases in addition to the core diseases, but all Part D MTM programs must target at least 4 of these 7 diseases. Sponsors are encouraged to consider targeting additional diseases to meet the needs of their patient populations and improve therapeutic outcomes. In applying the criterion, the targeted beneficiary could have any combination of the chronic diseases targeted by the sponsor. As an example, if a sponsor targets beneficiaries with at least two chronic diseases and targets all seven of the core diseases plus five additional diseases, a beneficiary would meet these criteria by having at least two of these twelve diseases in any combination.

Multiple Part D Drugs

In 2008, over 85% of MTM programs already targeted beneficiaries with a minimum threshold of 8 or fewer Part D drugs. Beginning in 2010, in targeting beneficiaries who are taking multiple Part D drugs, sponsors cannot require more than 8 Part D drugs as the minimum number of multiple Part D drugs. Therefore, sponsors may set this minimum threshold at any number equal to or between 2 and 8.

Dollar Cost Threshold

The existing cost threshold will be revised to $3000. Therefore, sponsors must target beneficiaries who meet the other two criteria and who are likely to incur annual costs for Part D drugs of at least $3000. This change will improve access to MTM.

MTM Services

For 2010, Part D sponsors must offer interventions to the enrolled beneficiary and his/her prescriber. The beneficiary and prescriber interventions may be provided independently or in combination to promote coordinated care. Approximately 90% of MTM programs in 2008 already target interventions to both beneficiaries and prescribers.

Part D sponsors must offer a minimum level of MTM services that include an interactive component of MTM as well as continued monitoring and follow-up. These services may be furnished by pharmacists or other qualified providers. Sponsors may incorporate passive or ‘lower touch’ interventions, such as educational newsletters, drug utilization review (DUR) edits,

refill reminders, and medication lists into their MTM programs, but these cannot be the sole offerings. Very few MTM programs currently provide only passive and "lower touch" interventions (less than 2% in 2008). Most MTM programs already offer an annual comprehensive medical review (CMR), and there is industry consensus that this is an essential element of MTM services to improve outcomes.

As stated above, the enrolled beneficiaries may refuse or decline individual services without having to disenroll from the program. At a minimum, Part D sponsors must offer MTM services that include the following:

1. Offer a CMR by a pharmacist or other qualified provider at least annually to all targeted beneficiaries enrolled in the MTM program by a pharmacist or other qualified provider. A CMR is a review of a beneficiary's medications, including prescription, over-the-counter (OTC) medications, herbal therapies and dietary supplements, that is intended to aid in assessing medication therapy and optimizing patient outcomes. While initial preparations to assess medication use and identify medication-related problems before the patient interaction may be conducted 'behind the scenes', they are only one piece of the overall comprehensive medication review. CMS recognizes the importance of offering an interactive, person-to-person consultation with the beneficiary for a complete assessment of the beneficiary's needs to improve medication use or outcomes.

This includes three components:

   a. Review of medications to assess medication use and identify medication-related problems. This may be conducted person-to-person or 'behind the scenes' by a qualified provider and/or using computerized, clinical algorithms.

   b. Offering to provide to each targeted beneficiary enrolled in the MTM program an interactive, person-to-person consultation performed by a qualified provider. This real-time interaction may be face-to-face or through other interactive methods such as the telephone. This interaction may include further assessment of the beneficiary's medication history and use (could enable sponsors to collect information from the beneficiary, such as OTC medications or supplements, that is outside of the claims data they have access to), health status, clinical information, adverse events, or other issues that could affect medication use or outcomes.

   c. Implementation of a systematic process to summarize the interactive consultation and provide an individualized written "take-away" to the beneficiary such as a personal medication record, reconciled medication list, action plan, recommendations for monitoring, education, or self-management, etc.

2. For ongoing monitoring, perform targeted medication reviews for all beneficiaries enrolled in the MTM program, no less often than quarterly, to assess medication use since the CMR, monitor whether any unresolved issues need attention, new drug therapy problems have

arisen, or if the beneficiary has experienced a transition in care. Part D sponsors must assess the findings of these reviews to determine if a follow-up intervention is necessary and if the intervention is warranted for the beneficiary and/or prescriber. These assessments could be person-to-person and/or system generated. The follow-up interventions should be interactive, if possible, but may be delivered via the mail or other means.

3. Offer interventions targeted to prescribers to resolve medication-related problems or other opportunities to optimize the targeted beneficiary's medication use. These interactions may be passive (e.g. faxed, mailed) or interactive when determined necessary.

For targeted beneficiaries enrolled in the MTM program that are in a LTC setting, sponsors are not required to offer the interactive CMR component, but still must perform quarterly medication reviews and offer interventions targeted to the beneficiaries' prescribers.

CMS expects that sponsors will have procedures in place to drive participation and follow-up with beneficiaries that do not respond to initial offers for MTM services. In addition, sponsors are expected to consider using more than one approach when possible to reach all eligible patients who may wish to receive MTM services.

Outcomes Measurement

At the beneficiary level, Part D sponsors must measure and report to CMS through our reporting requirements the number of comprehensive medication reviews (CMRs), the number of targeted medication reviews, number of prescriber interventions, and the change(s) in therapy directly resulting from the MTM interventions. Sponsors are expected to analyze and evaluate their MTM programs and make changes to continuously improve their programs. An MTM Monitoring contract was recently awarded through 2010 to assist CMS in monitoring and evaluating Part D sponsors' MTM programs. These efforts, along with the efforts of the Pharmacy Quality Alliance (PQA) and other industry stakeholders may also assist CMS in identifying additional standardized measures that could be measured or reported by all Part D sponsors.

In the future, sponsors may be required to measure program process, output and/or outcomes in the following areas:

- Drug utilization (e.g., drug interactions, polypharmacy, and adverse drug events)
- Beneficiary health (e.g., clinical indicators and medical utilization)
- Financial impact (e.g., pharmacy cost and medical cost change)
- Customer satisfaction (e.g., usefulness of information provided)

Reference-Based Pricing

Since the program's implementation in 2006, we have allowed Part D sponsors to incorporate reference-based pricing, a commercial practice used to promote generic substitution, into their benefit designs. Under these programs, sponsors may require enrollees to pay a defined cost sharing amount plus supplemental cost sharing based on the differential in cost between the drug being dispensed and a lower-cost preferred alternative such as a generic equivalent. In contract year 2009, fewer than 10% of Part D contracts used reference-based pricing.

Although reference-based pricing is a legitimate utilization management tool, issues remain with respect to this practice in the Part D program. Moreover, given the complexity of reference-based pricing formulas, it is very difficult to accurately convey the extent of expected out-of-pocket spending for formulary drugs subject to reference-based pricing. For this reason, we have been unable to have the Medicare Prescription Drug Plan Finder (MPDPF) calculate correct pricing for drugs subject to reference-based pricing, which may distort projections of out-of-pocket expenditures for some beneficiaries (who do not select generic substitution) and significantly affect their ability to compare cost sharing obligations under different plans and choose the plan that best meets their needs.

Based on our experience and the increased complexity we have observed with these programs, we will eliminate the option of reference-based pricing in the Part D PBP for CY2010. Therefore, sponsors – including employer plans – may not utilize this cost-sharing design. The basis for this decision is our goal of improving transparency with regard to expected beneficiary cost sharing under Part D. We believe that Part D sponsors can (and should) employ alternative utilization management strategies (e.g., tiering and closed formularies) that are more transparent and equally effective in encouraging the use of preferred formulary products.

Bundling of Part D Home Infusion Drugs Under a Part C Supplemental Benefit

Please refer to Section A, Subsection II (Benefit Design), of this Call Letter for more information.

Cost Contract Drug Benefits

Please refer to Section A, Subsection XII (Section 1876 Cost Plans), of this Call Letter for more information.

IV. PHARMACY ACCESS

Pharmacy Access during a Federal Disaster or Other Public Health Emergency

CMS appreciates Part D sponsors' prompt and efficient response to the federal disasters that occurred in 2008 such as the Midwest floods and Hurricane Ike. While we believe enrollees residing in, or displaced from, these disaster areas received appropriate access to their Part D benefits, we want to reinforce that Part D sponsors should guarantee immediate refills of Part D

medications to any enrollee located in an "emergency area," as defined in Chapter 5 of the Prescription Drug Benefit Manual, section 50.12. Furthermore, we clarify that Part D sponsors may consider lifting edits in advance of an impending disaster. We also clarify that Part D sponsors may exercise some operational discretion as to how edits are lifted during a disaster as long as access to Part D drugs is provided at the point-of-sale. For instance, Part D sponsors could implement an edit that is readily resolvable at the point-of-sale through the use of a pharmacist override code. Consequently, if a displaced beneficiary presents at the pharmacy for a refill, and identifies him/herself as an affected enrollee, the pharmacist would be free to use the override code and provide the emergency refill without having to contact the sponsor (or PBM).

In our ongoing conversations with sponsors on this issue, we have become aware of sponsors' difficulties in determining the closure of a major disaster declared by the President or a U.S. Department of Health and Human Services (DHHS) declared public health emergency. We remind Part D sponsors that they must continuously monitor both the Federal Emergency Management Agency (FEMA) Web site (http://www.fema.gov/) and the DHHS Web site (http://www.dhhs.gov/) for updates, changes and/or closures of existing emergency declarations. In general, public health emergencies terminate when either the Secretary declares an emergency no longer exists, or upon the expiration of the 90-day period beginning from the initial declaration, whichever occurs first.

For major disasters declared by the President, Part D sponsors should pay particular attention to the closure of disaster incident periods listed in the Disaster Federal Register Notice section on FEMA's web site. In circumstances in which the incident period has not closed 30 days from the initial Presidential declaration, Part D sponsors may consider re-implementation of their edits. However, sponsors must remain prepared to work closely with enrollees who indicate they are still displaced or otherwise impacted by the disaster and need access to their Part D benefits. This extends to continuing to guarantee out-of-network (OON) pharmacy access to those enrollees who cannot reasonably access a network pharmacy (i.e., the locality is so badly impacted by the disaster that prescription drugs are only available through a severely limited distribution chain), as provided in Chapter 5 of the Prescription Drug Benefit Manual, section 60.1. CMS may contact individual plan sponsors to extend disaster edits or OON pharmacy access, as necessary, based on information from Federal, State, or local officials.

V. ENROLLMENT

Mandatory Use of the Online Enrollment Center (OEC)

Please refer to Section A, Subsection VI (Enrollment), of this Call Letter for more information.

VI. LOW-INCOME SUBSIDY POLICY

Reassignment of Low-Income Subsidy Eligible Individuals

CMS does not expect to make significant changes to its reassignment process for contract year 2010. Thus, we anticipate again reassigning certain low-income subsidy (LIS) eligible beneficiaries from PDPs with premiums that exceed the LIS benchmark in 2010 to PDPs with premiums at or below the benchmark, effective January 1, 2010. We will continue to provide

mailings to affected individuals. However, we are continuing to study this issue and welcome constructive suggestions consistent with the existing statute for improving the reassignment process. We will continue to work with plans that are losing members to identify appropriate ways to reach out to these members to explain how they can remain in their current plan and what their premium liability will be if they choose to do so.

Retroactive Auto-Enrollment of Full-Benefit Dual Eligible Individuals

Beginning on January 1, 2010, CMS intends to implement a demonstration in which it will assign new full-benefit dual eligible individuals with retroactive coverage to a single contractor for those retroactive periods. The contractor will pay for all claims for retroactive auto-enrollment periods plus immediate need point-of-service claims for unenrolled LIS eligibles. We will modify our auto/facilitated enrollment process, so that all individuals with retroactive effective dates are assigned to the demonstration contractor for those retroactive periods, but continue to be randomly auto/facilitated for prospective periods to standard LIS PDPs. We are currently conducting a competitive solicitation to select this contractor. This process will not affect individuals who are already enrolled in a Part D plan before they obtain dual eligibility. CMS will provide more detailed information about the demonstration after a contractor has been selected.

VII. GRIEVANCES/COVERAGE DETERMINATION, AND APPEALS

Please refer to Section A, Subsection VIII (Grievances, Organization Determinations, and Appeals), of this Call Letter for more information.

VIII. CLAIMS PROCESSING

New Medicare Secondary Payer (MSP) Edits

For 2010, Part D sponsors will receive new data elements related to Workers' Compensation Medicare Set-aside Arrangements (WCMSAs), but the requirements for Coordination of Benefits (COB) in all MSP situations will remain the same.

Existing requirements related to MSP are addressed in §50.13 of chapter 14 of the Medicare Prescription Drug Manual. In this section, we note that Part D sponsors should not immediately reject claims when they are secondary. Rather, for Workers' Compensation (WC), Black Lung (BL), and No-Fault or Liability coverage, the Part D sponsor must make conditional primary payment and then recover any mistaken payments where it should only have paid secondary -- unless the sponsor is already aware that the enrollee has WC/BL/No-Fault/Liability coverage and has previously established that a certain drug is being used exclusively to treat a related injury.

Section 111 of the Medicare, Medicaid, and SCHIP Extension Act of 2007 (MMSEA Section 111) added mandatory reporting requirements with respect to Medicare beneficiaries who have coverage under group health plan (GHP) arrangements, as well as for Medicare beneficiaries who receive settlements, judgments, awards or other payment from non-GHP insurers including liability insurance (including self-insurance), no-fault insurance, or workers' compensation. The purpose of the data collection under the Section 111 MSP reporting is to permit Part D sponsors

and other Medicare payers to correctly pay for covered items and services furnished to Medicare beneficiaries by determining primary versus secondary payer responsibility. GHP and non-GHP insurers must submit data for both on-going claims processing and for MSP recovery actions, where applicable. These data will be reported to the CMS Coordination of Benefits Contractor (the COBC) that will manage the process. The implementation dates for the new reporting are January 1, 2009, for GHP arrangement information and July 1, 2009, for the non-GHP insurer information.

One method of protecting Medicare's interest in a Workers' Compensation (WC) situation is a WCMSA, which allocates a portion of the WC settlement for future medical treatment costs and future prescription drug expenses. "Future medical treatment costs and future prescription drugs" are those services and items provided after the final WC settlement. CMS reviews WCMSA proposals for Medicare beneficiaries with WC settlements greater than $25,000 and for individuals who are within 30 months of Medicare entitlement and possess a WC settlement greater than $250,000. WCMSA funds are administered by either the claimant or a professional administrator employed by the workers' compensation employer, carrier or the claimant. CMS keeps a record of the WCMSA amount determined by CMS to be adequate to protect Medicare's interests with regard to the claimant's future medical treatment and/or prescription drug expenses.

By the end of 2009, CMS will begin including costs related to prescription drugs in its settlements and reporting the WCMSAs under a distinct non-GHP MSP code on the COB file. The record will include the Administrator name and telephone number, WCMSA settlement date, and an indicator specifying whether prescriptions drug costs are included in the WCMSA amount.

In 2010, if the COB file record received from CMS indicates prescription drugs are included in the WCMSA, Part D sponsors must continue to make conditional primary payment under Part D and promptly contact the administrator to determine which claims should not be paid for under Part D. Once the Part D sponsor establishes that a certain drug is included in the set-aside, the sponsor should set appropriate point-of-sale edits, deny payment and reject the claim for billing to the primary payer.

At this time, CMS is not clear on the most efficient methodology for handling any retroactive payment recoveries on the part of the Part D plan. Multiple options exist concerning how recoveries should be calculated, who should handle recoveries and how recoveries might be distributed. Therefore, we propose at the next opportunity, to provide for public notice and comment rulemaking. Through rulemaking, we can present the options CMS has considered and solicit feedback on the best approach. In the meantime, sponsors must continue to comply with the COB requirements specified in Chapter 14 and handle recoveries on their own.

Claims for Drugs Prescribed by Excluded Providers

CMS wants to clarify the follow-up actions that Part D sponsors should take upon discovering that payment has been made for a drug prescribed by a provider (i.e., an individual or entity) who has been excluded from participation in the Medicare program. The existing requirement, as stated in 42 CFR 1001.1901, is that Medicare payment may not be made for items or services

prescribed by a physician or other authorized individual who is excluded. Therefore, Part D sponsors should regularly update their systems with the most current information on sanctioned providers. Lists of the excluded providers are available at: http://oig.hhs.gov/fraud/exclusions/exclusions_list.asp and https://www.epls.gov/.

Also, sponsors must have processes in place to identify and prevent payment of Part D claims at point-of-sale (POS) when such claims have been prescribed by providers who have been excluded by either the Department of Health and Human Services Office of Inspector General or General Services Administration. To support the identification of excluded providers at POS, sponsors should request that network pharmacies obtain prescribers' national provider identifier (NPI) (when prescribers have one). We believe the majority of prescribers will have an NPI available. When sponsors identify these claims at POS, the claims should be denied.

If a Part D sponsor discovers that, due to timing issues associated with identifying excluded providers (such as those related to the timing of updates to the lists of excluded providers or to sponsor systems), any such claims have been submitted and paid:

- The Sponsor should follow the guidance in section 50.2.6.3.3 of Fraud, Waste and Abuse Chapter (9) of the Prescription Drug Manual. Therein, we state that the sponsor should investigate to determine whether other claims have been submitted for items prescribed by the excluded provider and report the claims to the Medicare Drug Integrity Contractor (MEDIC).

- The Sponsor should not reverse the claims, and no adjustment to the prescription drug event (PDE) data is required.

- However, the sponsor should immediately notify the beneficiary and their network pharmacies that further prescriptions from this prescriber, including refills on existing prescriptions written after the prescriber's exclusion, will not be filled because the prescriber has been excluded from participation in the Medicare program. CMS will develop a model letter for sponsors to use in these situations to notify the beneficiary, and will explore options for communicating with all Medicare beneficiaries concerning excluded providers. We will also work with the industry through the National Council for Prescription Drug Programs regarding electronic messaging that can be used to inform the pharmacies.

Coordination of Benefits (COB) Notification

As provided in the MMA, beneficiaries are legally obligated to report information about other prescription drug coverage or reimbursement for prescription drug costs that the beneficiaries have or expect to receive; any material misrepresentation of such information by a beneficiary may constitute grounds for termination of coverage from a Part D plan. Currently, Part D sponsors must survey their enrollees regarding any other prescription drug coverage they may have within 30 days of the date the sponsor processes a beneficiary's enrollment and annually thereafter. Section 50.2 of the chapter 14 of the Prescription Drug Manual, released on September, 26, 2008, provides guidance on the COB survey process and specifies the requirements for following up with non-responding beneficiaries.

Since the implementation of Part D, the number of other payers participating in voluntary data sharing agreements with CMS has grown, improving the volume and quality of the other payer information available to Part D sponsors on the COB file. In 2009, implementation of the new MSP reporting for group health plan and non-group health plan insurers, including liability (including self-insurance), no-fault insurance, and workers' compensation, will further expand the other payer information available for COB.

Given these developments, we are revising the Part D beneficiary COB survey requirements. Beginning in 2010, in lieu of a survey, Part D sponsors will be required to notify each beneficiary of his/her other payer information as reflected in the COB file from CMS and request the beneficiary to review the information and report back only updates (that is, corrections to existing information and new coverage information) to the sponsor. The new process will continue to be required within 30 days of the date the sponsor processes a beneficiary's enrollment and annually thereafter. Beneficiary notification will be required even in situations when there is no other coverage information in the file; thus enabling the beneficiary, when appropriate, to report other coverage. Absent a report of corrected or new information from the beneficiary, sponsors can assume the existing information or the absence of data, is correct and there will be no need for follow-up. CMS believes this new process, which provides for periodic review and correction of the CMS COB data, will further enhance the quality of the data available to Part D sponsors for COB.

Although this new process will be required in 2010, sponsors may elect to substitute the new approach sooner and are encouraged to do so. Sponsors electing to use the new approach in 2009 may substitute the new process for all beneficiaries or may use the new process for beneficiaries who failed to respond to the sponsor's current COB survey. In either situation, routine sponsor follow-up will not be required.

CMS is working on improvements to the process for sponsors to notify the COB Contractor via the Electronic Correspondence Referral System (ECRS) of updated COB information and for COB Contractor validation of the information submitted. We recognize that the new approach may require sponsors to implement systems changes and we intend to issue details on these improvements as early as possible.

Finally, these requirements are specific to Part D plans. As noted in Section A of the call letter, further guidance on the Part C MSP survey will be provided in the final 2010 Payment Announcement. Please see the Advance (Payment) Notice for Calendar Year 2010 dated February 20, 2009, where we explain our proposal to eliminate the requirement for the MSP survey that has been used to compute the Part C MSP payment factor. We will respond to comments and provide further guidance on that survey when we release the final 2010 Payment Announcement on April 6, 2009.

Coordination of Benefits (COB) User Fees

CMS is authorized to impose user fees on Part D sponsors for the transmittal of information necessary for benefit coordination between sponsors and other entities providing prescription drug coverage. CMS may review and update this user fee annually to reflect the costs associated with COB activities. For contract year 2009, the Part D COB user fee was significantly

increased, and we undertook some major projects – automated TrOOP balance transfer, mandatory reporting of Medicare secondary payer information, and the de-linking of the enrollment and payment modules in MARx – to improve the quality reliability and timeliness of COB-related data. Upon review of the incremental ongoing costs of COB activities in 2010, the Part D COB user fee can be decreased to $1.89 per enrollee per year for contract year 2010. This COB user fee will be collected at a monthly rate of $0.21 for the first 9 months of the coverage year (for an annual rate of $0.16 per enrollee per month) for a total user fee of $1.89 per enrollee per year. Part D sponsors should account for this COB user fee when developing their 2010 bids.

IX. QUALITY AND PERFORMANCE MEASURES

New Part D Reporting Requirements for CY 2010

New Part D reporting requirements will be implemented for CY2010. CMS expects to propose the addition of the following reporting sections: network pharmacy support of electronic prescribing; prompt payment to pharmacies; fraud, waste and abuse compliance programs; enrollment, and employer/union-sponsored group health plan sponsors. CMS will also propose changes to current reporting sections. Examples of proposed changes include revising the MTM reporting section to collect specific data related to enrollment, targeting, intervention and outcomes, and streamlining some of the data elements listed in the grievance reporting section. We posted the first draft of the CY2010 reporting requirements in the Federal Register for public comment in January 2009.

Quality Assurance Requirements

As outlined in Section 20 of Chapter 7 of the Prescription Drug Benefit Manual, Part D sponsors must establish quality assurance measures and systems to reduce medication errors and adverse drug interactions and improve medication use. To further the quality of care provided to Part D enrollees, we are adding new expectations and further details to the following sections of Chapter 7:

1. Section 20.3: Concurrent Drug Utilization Review (cDUR)

   Part D Sponsors should maintain written cDUR policies and procedures that explain the level of the cDUR checks (pharmacy and/or plan level), system logic, established thresholds, and accompanying pharmacy messaging. These policies should detail how the aforementioned elements were established (i.e., thresholds that are based upon relevant clinical and drug information references), validated, and revised. Sponsors' cDUR polices should also address pharmacy requested overrides and detail how pharmacy override requests are evaluated and approved. Moreover, sponsors' policies should explain how trends in override requests (both approved and unapproved) are monitored and considered in ongoing formulary management.

   Part D Sponsors should be able to demonstrate how information obtained from their cDUR program is used in their overall quality assurance system and improves their enrollees' quality of care.

2. Section 20.4: Retrospective Drug Utilization Review (rDUR)

   Part D sponsors should maintain a written rDUR policy that establishes clear objectives and identifies the relevant claims data proposed for review, the evaluation period, criteria used in the evaluation, and proposed interventions. The policy should also include a periodic assessment that determines the success of the proposed objectives, interventions, findings and outcomes.

   Part D sponsors should be innovative in improving the quality of care provided to enrollees through application of rDUR. For example, Part D sponsors may want to apply rDUR upon FDA issuance of a new drug safety warning to ensure enrollees and/or physicians are aware of alternative therapies. Alternatively, Part D sponsors may consider application of rDUR for purposes of ensuring appropriate Part B versus Part D payment by working to obtain additional information after the point-of-sale adjudication.

3. Section 20.5: Medication Error Identification and Reduction (MEIR)

   The Part D sponsor's internal MEIR process should be fully documented and identify what types of medication errors will be collected internally. For example, Part D sponsors may receive calls or letters from enrollees containing a broad range of issues, including medication errors. Other operational functions may also receive and report medication errors, such as the sponsor's exceptions and appeal group, the clinical division involved in processing prior authorization forms, or the electronic prescribing group involved in the resolving issues with the implementation of new e-prescribing standards. As a result, appropriate sponsor staff should be trained to identify potential reportable medication errors and understand how to evaluate, resolve, document, and, if necessary, report to the appropriate authority (i.e., FDA, DEA).

   As a component of the sponsor's error reduction program, a periodic evaluation of the medication errors should be completed looking for trends and patterns that require the sponsor's attention and resolution. Additionally, when appropriate, reported medication errors should be shared and discussed with downstream contractors to ensure that corrective actions are implemented and future errors are prevented.

We believe these new expectations and clarifications will enhance Part D sponsors' existing quality systems and ensure Medicare beneficiaries receive the highest quality prescription drug coverage available in the marketplace.

Consumer Assessment Health Providers Survey (CAHPS) Administration

Please refer to Section A, Subsection IV (Quality and Performance Measures), of this Call Letter for more information.

X. COMPLIANCE/MONITORING

Prompt Payment of Retail Pharmacy Claims and Submission of LTC Pharmacy Claims

We remind Part D sponsors that MIPPA established new requirements with respect to Part D network pharmacy claims. Effective January 1, 2010, CMS' contract with Part D sponsors must include a provision requiring sponsors to issue, mail, or otherwise transmit payment for all clean claims submitted by network pharmacies – except for mail-order and long-term care pharmacies – within specified timeframes. Also effective on January 1, 2010, CMS' contract with Part D sponsors must include provisions such that LTC pharmacies have not less than 30 days, nor more than 90 days, to submit claims to the sponsor for reimbursement. Sponsors must also include these prompt payment and long-term care pharmacy claims submission requirements in their contracts with pharmacies or other providers, first tier, downstream, and related entities. For more detail about these requirements, please refer to our September 18, 2008 interim final rule with comment (CMS 4138-F) implementing a number of the new MIPPA requirements.

Response to Complaint Tracking Module (CTM) Complaints

To ensure that Medicare Part D enrollees receive the highest quality of service in a timely manner, CMS will expand case resolution time standards with respect to CMS recorded complaints within the Health Plan Management System (HPMS) Complaints Tracking Module (CTM) in 2010.

Currently, all Part D plan sponsors are required to resolve at least 95% of "immediate need" complaints entered into CTM within 2 calendar days. Effective January 1, 2010, Part D sponsors will be required to resolve at least 95% of CTM complaints designated as "urgent" within seven days, and 95% of CTM complaints without an issue level within 30 days. The table below defines and summarizes these resolution time requirements.

Designation	Part D Definition	Resolution Time
Immediate Need	Defined as a complaint that is related to the beneficiary's need for medication when the beneficiary has 2 or less days of medication left.	At least 95% of cases resolved within 2 calendar days of receipt.
Urgent Need	Defined as a complaint that is related to the beneficiary's need for medication when the beneficiary has 3 to 14 days of medication left.	At least 95% of cases resolved within 7 calendar days of receipt.

Unclassified	Any other CTM complaints.	At least 95% of cases resolved within 30 calendar days of receipt.

CMS continues to reserve the right to reclassify any complaint that does not fit the above definitions as "immediate need" or "urgent" at our discretion.

Should a Part D sponsor not meet the aforementioned 95% thresholds, CMS will consider these organizations out of compliance with one or more Part D requirements, including, but not limited to, requirements related to enrollment; coverage determinations, appeals, and formulary exceptions; and claims processing.

Audit Approach

Please refer to Section A, Subsection V (Compliance and Monitoring), of this Call Letter for more information

Part C and Part D Data Validation

Please refer to Section A, Subsection V (Compliance and Monitoring), of this Call Letter for more information.

Compliance with CMS' Requirements for Processing Out-of-Network Reimbursement Requests

Under 42 CFR 423.568(b), when a party makes a request for payment of an out-of-network reimbursement request, the Part D sponsor is required to notify the enrollee of its determination no later than 72 hours after receipt of the request. The intent of the existing 72-hour timeframe for processing reimbursement requests is to ensure that enrollees receive prompt responses to requests for payment. In practice, however, we have found that this deadline generally does not provide Part D sponsors a reasonable amount of time to process these payment requests particularly in situations involving out-of-network pharmacies. Sponsors have generally been unable to identify these requests among their incoming mail, transfer the requests to the appropriate department, manually enter and process the claims in the online adjudication systems, and then make reasoned and accurate determinations within the 72-hour timeframe for making a coverage determination. As a result, in many cases plan sponsors either are making negative coverage determinations in order to meet the 72-hour timeframe, or they are auto-forwarding the request to the Part D IRE based on their inability to make a timely determination. Although these steps achieve technical compliance with the existing requirement, we do not believe they serve the best interests of enrollees, who are in effect forced to resolve their requests in the appeals process, often in situations where a full review by the sponsor would result in favorable resolution at the coverage determination level. Even if the appeals process does result in a favorable decision, the enrollee may receive consecutive, conflicting notices on the case, which has a strong potential for creating confusion.

While we consider options for resolving this issue, we believe the best approach for addressing this problem is to exercise our enforcement discretion to decline to bring an enforcement action for non-compliance with the 72-hour deadline in 42 CFR 423.568 if the plan sponsor processes a reimbursement request and submits reimbursement (when appropriate) within 14 calendar days after receipt of the request (or auto-forward a request that cannot be processed timely). In other words, beginning January 1, 2009, sponsors that make a determination, and either send payment or the standard denial notice to the enrollee within 14 calendar days after receipt of the request will not have any enforcement actions taken against them for non-compliance with the 72-hour deadline in 42 CFR 568(b). However, if a plan sponsor notifies the enrollee of its favorable determination within 72 hours, the sponsor will still have 30 calendar days to mail the payment. We believe this short-term approach will strike a balance between affording plans sufficient time to make accurate coverage determinations and ensuring that enrollees are reimbursed for their out-of-network claims timely. While Part D sponsors will be afforded more time, if needed, to process enrollees' out-of-network reimbursement requests and enrollees may wait longer than 72 hours for decisions in such cases, enrollees will receive reimbursement in half the time than the current rules require when the decisions are favorable.

We emphasize that this enforcement approach is an interim measure only, and we intend to develop a permanent regulatory solution to this issue through notice-and-comment rulemaking as soon as possible.

Auto-Enrollment Readiness Audits

Based on our experience with auto-enrollments in the Part D program, we have identified several requirements that are critical to making sure that a plan's auto-enrolled dual eligible population receives effective drug coverage. To adequately protect Medicare beneficiaries, we are obligated to ensure that PDP sponsors receiving reassignees, auto-enrollees, and facilitated enrollees are fully prepared to accept these enrollments. To that end, we will conduct Auto-Enrollment Readiness Audits in late August and early September of 2009. Sponsors will be selected for audits based on a variety of factors, including whether they will qualify for auto-enrollments for the first time in 2010, whether they will be expanding the number of regions in which they will qualify to receive these enrollees in 2010, or whether the sponsor is operating under an existing corrective action plan (CAP) or is experiencing performance problems.

The critical functions that will be part of the Readiness Audit may include, but are not limited to: 4Rx data; LIS matching; call center performance; beneficiary notifications; transition policy; point-of-sale claims adjudication; systems testing; and best available evidence.

CMS may audit these functions through either an on-site audit or a self-audit request. Sponsors will be notified of their selection for an audit roughly 1 week prior to the audit team's arrival onsite. Sponsors selected for a self-audit will be notified at the same time as sponsors selected for an onsite audit and provided a deadline for their self-audit report (approximately 2 weeks). Based on the results of these audits, any organization that is not fully prepared to undertake this important role will be excluded from receiving reassignees and/or auto and facilitated enrollments. Also, CMS will require the sponsor to complete a CAP through which it must demonstrate that it meets the requirements associated with the autoenrollment process. CMS

will close the CAP only after the sponsor meets the requirements and has begun to accept autoenrollments.

XI. SPAP GUIDANCE

Prohibition of Mid-Year Enrollment by State Pharmaceutical Assistance Programs (SPAPs)

CMS has received a significant number of complaints from Part D sponsors about SPAPs performing mass mid-year plan enrollment changes. Sponsors have found that substantial disenrollment from one plan, followed by mass enrollment into another during the calendar year significantly impacts the financial operations of the Part D sponsor. Since the funding of the Part D benefit is uniform over the entire plan year, plans that lose beneficiaries mid-year are more likely to take losses, and plans that acquire beneficiaries mid-year from other Part D plans are more likely to experience gains. Specifically, plans that have beneficiaries early in the year are likely to incur expenses attributable to the initial coverage period, the portion of the benefit that includes 75% coverage. Plans that have beneficiaries later in the year are more likely to have beneficiaries during the coverage gap portion of the benefit, which requires 100% beneficiary cost sharing and no plan obligation.

In addition, aside from the financial disparities that may occur, we believe that re-enrollment into a new plan mid-year disrupts the continuity of care the beneficiary is accustomed to under his/her current Part D plan.

For these reasons, CMS will be monitoring this situation closely. We strongly discourage state pharmaceutical assistance programs (SPAPs), when authorized to enroll in Part D plans on behalf of beneficiaries, from performing substantial volumes of disenrollments and re-enrollments other than on a calendar year basis. If we learn that any SPAP is continuing to undertake substantial mid-year enrollment changes to Part D plans, we may determine that the SPAP has failed to meet the definition of state pharmaceutical assistance program set forth in Section 1860D-23(b) of the Act. Note that individual members of qualified SPAPs (or the State, acting as the authorized representative of members) will continue to have SEPs, as provided in the current CMS guidance, for case-by-case enrollment actions. (See Section 20.3.8, #9 of the PDP Guidance on Eligibility, Enrollment, and Disenrollment.)

XII. LICENSURE AND SOLVENCY

Licensure and Solvency Waivers

PDP Sponsors with expiring licensure waivers that have not obtained licenses before April 1, of the year in which the waiver expires, will be notified in April that CMS has determined that they are not qualified to be a PDP sponsor in the following contract year in any regions that include States for which a license is not held. These notices will also afford the sponsors the opportunity to complete a CAP prior to August 1st (the date by which CMS must issue non-renewal notices for the following contract year). (42 CFR 423.507(b)(2)(i), 423.642(d)). Sponsors that fail to complete a CAP (i.e., obtain risk-bearing licenses) will have their contracts non-renewed for any regions that include States for which a license is not held prior to August 1, of the current year.

Specific reporting requirements and deadlines related to the PDP sponsor's actions taken to obtain State licensure are specified in Appendix III.

In situations when the State cannot approve a license before the waiver expires because of State requirements that are beyond the PDP sponsor's ability to meet (e.g., a "seasoning" requirement or the need for a state to complete an audit report and the state has not scheduled an audit), CMS will allow the PDP sponsor to apply for a waiver extension. To qualify for such a waiver extension, the sponsor will need to submit documentation from the State explaining why the state has not been able to license the PDP sponsor. If the sponsor has contributed to the State's inability to approve the license application submitted to a State during the current licensure waiver period, then a CMS waiver extension will not be granted.

XIII. ELECTRONIC PRESCRIBING (E-PRESCRIBING)

CMS and HHS continue to encourage and support the utilization of electronic prescribing (e-prescribing) within the Part D program. We believe the migration to e-prescribing has the potential to result in programmatic cost-savings through reduction of administrative inefficiencies involved in handwritten prescriptions and may result in improved outcomes for beneficiaries through the reduction of adverse events that occur in the current prescribing environment.

In order to monitor the uptake of e-prescribing in the Part D program, CMS will require Part D sponsors to obtain the Prescription Origin Code via the NCPDP Telecommunication Standard 5.1 (see section 50.3 of Chapter 7 of the Prescription Drug Benefit Manual for more information on the standards for e-prescribing) option field 419 DJ beginning in 2010 and report this code on their prescription drug event (PDE) submissions. A corresponding Prescription Origin Code field already has been added to the PDE record file layout and PDE return file layout at field number 41. Field 41 is optional for 2009 but CMS strongly recommends that Part D sponsors work with their network pharmacies to voluntarily begin using the NCPDP Telecommunication Standard 5.1 option field 419 DJ in 2009.

In the draft Call Letter, CMS stated that we expected to require the Prescription Origin Code on all PDEs, not just PDEs for new prescriptions. Based upon industry comment, we now plan to require the Prescription Origin Code (using alphanumeric values 1 – 4) only on PDEs for new prescriptions submitted in Standard format (currently Standard format is NCPDP Telecommunication Standard 5.1). The Prescription Origin Code will remain optional for all PDEs for refills submitted in the Standard format and for all PDEs submitted in the Non-Standard Format. Further, the Part D sponsor has the option to report "blank" for PDEs for refills and Non-Standard format PDEs.

We believe this approach avoids any 2010 point-of-sale issues associated with refills, while not requiring any changes for future years. We will consider further industry input on this approach prior to releasing final operational guidance through HPMS early this summer.

XIV. EMPLOYER AND UNION-SPONSORED GROUP PLANS

Employer and Union Direct Contracts - Mutual Termination

CMS issues guidance each year for all sponsors seeking to non-renew their contract with CMS. It has come to our attention that some employers and unions that contract with CMS directly as PDP sponsors ("Direct Contractors") have failed to follow the non-renewal procedures, and instead have requested that CMS terminate their contracts by mutual consent after the non-renewal deadline established for the provision of sponsor-initiated contract non-renewal notices to CMS has passed. CMS has not waived the non-renewal deadline for such plans. Failure to comply with non-renewal procedures results in a failure to provide adequate notification to beneficiaries regarding their change in group coverage. CMS will not approve terminations by mutual consent as a substitute for the non-renewal process except under unusual circumstances as determined by CMS.

Section C - MARKETING/BENEFICIARY COMMUNICATIONS

This section applies to both MAOs and PDP Sponsors

Marketing Requirements Oversight

Marketing is the primary means for organizations to attract people with Medicare to their products – accuracy and timeliness in data file submissions and exchanges, compliance with systems requirements, and timely and reliable outreach are essential to helping inform people with Medicare about their choices. In addition, organizations are responsible for making sure that brokers or others authorized to represent an organization's plan or plans operate according to all guidance and requirements related to marketing, including those stated in our marketing guidance, the marketing chapters of the Managed Care and Part D manuals and the program requirements for Part C and, if offering a Medicare prescription drug benefit, Part D (Parts 422 and 423, respectively, of Title 42 of the Code of Federal Regulations).

CMS has taken many actions over the past few years to strengthen marketing requirements and oversight, particularly of agent and broker conduct. It appears that despite our efforts to ensure the protection of Medicare beneficiaries and preserve the integrity of the Medicare Managed Care program, some of our contractors and related third-party entities attempt to find ways to circumvent our rules and guidelines. CMS will not accept any continued attempts by some in the industry to avoid complying with our marketing requirements and guidance. CMS will take very strong action against any entity attempting to circumvent our rules.

Payment of Agents for Enrollments in 2009

CMS has received a number of questions about whether organizations offering MA plans or PDPs can withhold payments to agents until the report identifying new enrollments is released by CMS. The preamble of the compensation regulation (CMS-4138-IFC2) states that "for enrollments with effective dates in 2009, the MA or PDP plan initially pays the renewal compensation amount to the broker or agent enrolling an individual. Several times in 2009, we will run a report identifying those beneficiaries enrolled in an MA plan or PDP who were newly entitled or enrolled from original Medicare. Organizations can use the report to identify the agents or brokers who are entitled to an initial compensation amount" and adjust their payment accordingly. This policy does not require plans to wait to pay agents until the report is released. Rather, CMS thinks that it would be prudent to pay agents the renewal rate and then adjust the payment once the report is released. (Note that per our regulation, in 2009 plans may pay agents and brokers that enroll beneficiaries in their ICEP in a MA or PDP at the initial compensation rate without waiting for the enrollment report from CMS.)

Payment of Referral Fees to Agents

CMS has received and verified reports of Part C and D marketing activities that appear to be intentionally designed to attempt to circumvent the limits on agent compensation in our new agent/broker compensation regulations (CMS-4138-IFC2). Specifically, following the imposition of the limits on agent compensation in CMS-4138-IFC2, organizations offering Part C and D have begun for the first time, to offer exorbitant fees to agents for making a referral that

in some cases exceed regulatory limits that apply to compensation paid in connection with the sale of a Part C or Part D plan. We discovered that these fees are being paid in addition to compensation paid to the agent who ultimately enrolls the beneficiary in the plan. While historically referral fees have been of a nominal amount, such as $25-$100, in some cases we are finding that referral fees offered under these new referral fee programs exceed the total compensation that can be paid to agents under Medicare rules (the national fair market value cut-off amount released in the January 16, 2009, HPMS memo). Organizations must cease this practice immediately as it is not compliant with our regulation and guidance. The total compensation amount paid to agents for an enrollment including any referral fees paid in connection with that enrollment may not exceed the limits set forth in the agent compensation regulations and implementing guidance. The amount paid to the agent who enrolls the beneficiary thus may not, when combined with any referral fee paid in connection with the enrollment, exceed these limits.

Presumably, the referral fee programs that have been put in place subsequent to the imposition of the new limits on agent compensation are based on an erroneous belief that referrals are not governed by our new regulations and January 16th, 2009 guidance. However, new §§422.2274 and 423.2274 in CMS-4138-IFC2 specify that compensation "includes pecuniary and non-pecuniary remuneration of any kind relating to the sale or renewal of a policy including, but not limited to, commissions, bonuses, gifts, prizes, awards and finder's fees." Referral fees are equivalent to finder's fees, and therefore are governed by CMS regulations. We clarify that these requirements apply to referral fees paid to independent agents only when the referral leads to an actual enrollment.

Multiple Organization Marketing Pieces Created by Agents

This year CMS is providing specific guidance with respect to agents/brokers that create customized advertising materials that include plan information for multiple organizations. The Medicare Marketing Guidelines require that all marketing materials be submitted to CMS via HPMS for approval or File & Use prior to use in the marketplace. In addition, CMS is reminding organizations that third party marketing materials, including materials created by agents/brokers must also be submitted to the MAO or PDP sponsor prior to use for review and approval. Under certain circumstances agents/brokers that create customized materials will not be required to submit to the MAO or PDP sponsor for CMS review. Essentially, materials that are generic in nature and do not discuss content specific to plan benefits, cost sharing or include the plan names will not require review and approval. Generic materials may reference the different product types (e.g., MA plan, MA-PD, Cost Plan, PDPs) offered by the agent.

Standardization of Plan Name Type

Section 103 of MIPPA requires both MAOs and PDP sponsors to include the plan type of the given plan in the plan name, using standard terminology as developed by the Secretary. This requirement is in effect for plan years beginning on or after January 1, 2010.

MAOs and PDP sponsors enter and maintain their plan names in HPMS. The plan name is used by internal CMS systems and in standardized marketing tools, including, but not limited to: the

Summary of Benefits (SB), Medicare Options Compare and Medicare Prescription Drug Plan Finder on www.medicare.gov, and the *Medicare & You* Handbook.

To ensure the consistent use of standardized plan-type terminology across all organizations, HPMS will auto-populate the plan type label at the end of each plan name beginning in Contract Year 2010. For instance, an HMO plan named "Golden Medicare Plan" would appear as follows: Golden Medicare Plan (HMO). The auto-generated plan type label will **not** count toward the 50 character maximum length reserved for the plan name field.

The following table outlines the standardized plan type terminology to be generated for each active HPMS plan type:

Standardized Plan Type Terminology	
Plan Type	**Plan Name with Standardized Plan Type Label**
HMO	Plan Name (HMO)
PPO	Plan Name (PPO)
HMOPOS	Plan Name (HMOPOS)
ESRD II	Plan Name (HMO-POS)
PSO	Plan Name (PSO)
MSA	Plan Name (MSA)
MSA Demo	Plan Name (MSA)
RFB PFFS	Plan Name (PFFS)
PFFS	Plan Name (PFFS)

Standardized Plan Type Terminology	
Plan Type	**Plan Name with Standardized Plan Type Label**
1876 Cost	Plan Name (Cost)
1833 Cost	Plan Name (Cost)
PACE	Plan Name (PACE)
PDP	Plan Name (PDP)
Regional PPO	Plan Name (Regional PPO)
Employer PDP	Plan Name (Employer PDP)
Employer PFFS	Plan Name (Employer PFFS)
RFB HMO	Plan Name (HMO)
RFB HMO-POS	Plan Name (HMO-POS)
RFB Local PPO	Plan Name (PPO)
RFB PSO	Plan Name (PSO)
CCRC	Plan Name (HMO-POS)

NOTE: HPMS cannot accommodate further differentiation among plan types this year; however, we will consider further refinement in future years. We note that in addition to standardizing the terminology in HPMS, organizations will need to display the plan name and plan type in the same format on all marketing materials, including advertising materials (i.e., banner ads, outdoor advertising, television, print ads, Internet ads and radio ads). Plans that have incorporated the standardized plan type in a position other than at the end of their plan name

must also place the plan type at the end on printed marketing materials. Plans should submit marketing materials with the plan name corrections on a flow basis recognizing that all materials intended to be used for the 2010 marketing season must contain the standardized plan type terminology. CMS will provide further clarity on this policy through training.

Part D Marketing Materials

CMS will be making minor modifications to the Part D marketing model materials and requirements for contract year 2010. We expect to release updated model materials, separate from the 2010 Call Letter, in the spring of 2009. Following are some of the process and model changes we anticipate for contract year 2010:

- **Changes to Printed Formularies**. Beneficiaries have a legitimate expectation that they will have access to the Part D drugs included on marketed formularies. While Part D sponsors can readily update their online formularies, the same is not true for printed formularies provided to plan enrollees. Given the potential perception of "bait and switch" related to mid-year non-maintenance formulary changes (defined in section 30.3.3.3 of Chapter 6 of the Prescription Drug Benefit Manual), beginning in contract year 2010, Part D sponsors will be expected to update all impacted abridged and comprehensive printed formularies with any CMS approved non-maintenance formulary changes. Part D sponsors may make any necessary changes via errata sheets mailed to beneficiaries; however, Part D sponsors retain the flexibility to utilize other processes for notifying beneficiaries of non-maintenance changes to their printed formularies. We clarify that this new requirement does not extend to mid-year maintenance changes defined in section 30.3.3.2 of Chapter 6 of the Prescription Drug Benefit Manual. Changes to previously printed formularies resulting from mid-year maintenance changes may be made at the time of the next printing.

- **OTC Drugs on Formularies**. Part D sponsors will be permitted to indicate any OTC drugs for which they pay as a Part D administrative expense in a new OTC section of their comprehensive or abridged formularies.

- **E-Prescribing Indicator on Pharmacy and Provider Directories.** For CY 2010, we are requesting that Part D sponsors indicate which of their network pharmacies support e-prescribing in their pharmacy directories. In addition, we request MAOs indicate which of their participating physicians or physician practices support e-prescribing.

- **Exceptions Cost Sharing in the Evidence of Coverage (EOC) and Summary of Benefits (SB).** Part D sponsors will be required to indicate in their EOC and SB which of their formulary cost sharing tiers is designated as their "exceptions tier" - in other words, the formulary tier cost share at which they will adjudicate all formulary exceptions. This is consistent with a change to the PBP software that we will be implementing for contract year 2010. Although CMS generally allows Part D sponsors to apply only one level of cost sharing from an existing formulary tier to all approved formulary exceptions, sponsors may also elect to apply a second less expensive level of cost sharing for all approved formulary exceptions for generic

drugs, so long as this second level is also associated with an existing formulary tier and is uniformly applied to all approved formulary exceptions for generic drugs. When designating the exceptions tier in a PBP submission, sponsors can enter only one level of cost sharing for contract year 2010. Thus, a sponsor that has established a second (less expensive) level of cost sharing should indicate the more expensive cost-sharing level of the two tiers as its exceptions tier. The more expensive cost-sharing level of the two tiers will appear on their marketing material, as well as on the Medicare Prescription Drug Plan Finder, as a sponsor's exceptions tier.

- **Beneficiary Notice for Transfer of Prescriptions to Mail-Order**. Given previous beneficiary complaints that sponsors are transferring their prescriptions from network retail pharmacies to network mail-order pharmacies without their explicit consent, we will require sponsors to notify their affected enrollees prospectively of any such transferred prescriptions. We intend to provide a new model notice for this purpose.

New Model Explanation of Benefits (EOB)

We are aware that the transition to our new Part D EOB requirements in mid-2008 required a number of programming changes for sponsors and that there was a general need for additional guidance regarding CMS' expectations around the summary of year-to-date Medicare prescription drug costs in the EOB model, in particular. Although we provided additional guidance, including a number of examples using different benefit designs and beneficiary LIS status, via a February 9, 2009 HPMS memorandum, we received comments that additional guidance is needed relative to the examples provided. Commenters were also concerned about the timing of implementing the changes specified in the guidance. Please be aware that CMS expects to issue additional guidance this spring and will respond to concerns at that time regarding implementation timeframes for changes necessary so that EOB information is being conveyed consistently.

CMS Surveillance of Marketing Activities

In 2008, CMS issued final regulations designed to protect Medicare beneficiaries from deceptive or high-pressure marketing tactics by private insurance companies and their agents. In an effort to ensure compliance with these new marketing requirements and prohibitions, CMS initiated a comprehensive surveillance program that began during the 2008 Annual Election Period (AEP), and will continue through the end of the Medicare Advantage Open Enrollment Period (i.e. March 31, 2009). This surveillance strategy significantly expands on previously conducted surveillance activities. For example, CMS attended over 1,000 "secret shopping" marketing events, more than triple the number conducted in 2007. CMS also significantly expanded the scope of secret shopping to encompass at least one secret shopping event for each contracted Medicare Advantage (MA) and Prescription Drug Plan (PDP) parent organization in each of the 50 States. Further, CMS is focusing increased resources on high risk geographic areas and organizations by allocating additional surveillance resources to these MAOs and regions.

In addition to secret shopping, CMS also deployed a number of additional surveillance activities, including:

- **Use of a clipping service** to scan local media for advertisements to assess accuracy of marketing content and whether organizations are reporting all marketing events to CMS.

- **Secret shopping call centers** to test both the accuracy and understandability of CSR responses, as well as automated call center analyses such as hold times and disconnect rates.

- **Outbound calling** to selected recently enrolled beneficiaries to ensure that their enrollments were conducted properly.

- **Review of recorded enrollment calls** to determine if enrollments occurred appropriately or if there were instances of high-pressure marketing tactics employed, particularly for organizations identified as outliers in other surveillance activities.

- **Review of relevant data** for potential evidence of marketing violations, including data contained in CMS' complaints tracking module (marketing misrepresentation category).

- **Online readiness assessment** to assess organizations' readiness on implementation of the new marketing requirements and prohibitions. Organizations were asked to attest to their readiness, as well as provide feedback to CMS on implementation of best practices.

- **Regional Office surveillance** to obtain ground-level feedback on organizations' performance, gathering tips from local and state-government partners, and for conducting additional secret shopping.

CMS tracked the performance of all contracted organizations across the various surveillance activities. As a result of these efforts, CMS issued over 40 compliance letters at the end of the Annual Election Period to organizations that were found to be outliers in performance or that were found to be out of compliance with CMS' marketing requirements. Organizations that were specifically found to be outliers related to high rates of marketing misrepresentation complaints were required to report on their performance by investigating and reporting on their response to these complaints on a monthly basis. All other organizations were put on notice to improve performance or risk further compliance and/or enforcement actions. CMS continues to monitor performance of all organizations through the OEP and will take further actions, as warranted.

Due to continued concerns with the marketing activities of some MAOs and the brokers and agents who are marketing their products, CMS expects to continue to devote considerable efforts to similar surveillance activities in the future, and reminds MAOs that repeated violations that demonstrate a pattern of misconduct will be considered more substantial violations than those that merited initial noncompliance notices and warning letters this past AEP.

Section D – Appendices

APPENDIX I: CMS OVER-THE-COUNTER (OTC) LIST

In the body of the call letter we have presented the basic principles governing a supplemental, Part C, packaged OTC list. The table below presents a detailed list of categories of items. The following principles will facilitate correct usage of the list:

- Categories vs. items: The table below lists categories of items. MA plans should not steer enrollees to particular brands of items. For example, if an MA plan Part C OTC list includes headache medications, it must allow all brands of headache medications;

- Enrollee vs. Family: The plan must explicitly notify enrollees in its plan materials that OTC items may only be purchased for the plan enrollee. The plan must instruct enrollees that it is prohibited to purchase OTC items for family members and friends. The plan is responsible for ensuring that the Part C OTC benefit is properly used;

- Categories not on the list: Each MA plan must publish, on its plan website, or in catalogs or other marketing materials, the categories of items that a plan enrollee may purchase. The MA plan list need not be identical to the list below however the MA plan list may not include as eligible any items marked below as non-eligible. Should the plan wish to include categories of items not listed on the CMS list below – that is, the item is not listed in either the eligible, dual purpose, or non-eligible sections – it must first obtain permission from CMS;

- Three eligibility categories: The list has three types of items. The type is listed in the first column of the chart below:

    - Eligible items: These, if listed on the MA plan OTC list, may be purchased by the enrollee without further action. However, each MA plan, at its own discretion, may require written notes for purchase of OTC items;

    - Non-eligible items: The MA plan OTC list must specify all non-eligible items included in the CMS list. Enrollees must be instructed that non-eligible items, if purchased, will not be covered by the plan;

    - Dual Purpose items: These, if listed on the plan OTC list, may be purchased but the plan must, in its marketing materials, advise enrollees that prior to purchase (1) the enrollee must have appropriate conversations with the enrollee's personal provider, and (2) the enrollee's personal provider orally recommends the OTC item for a specific diagnosable condition. CMS does not require written recommendations. However, MAOs may require written recommendations for purchase of dual purpose or eligible items.

- Debit card linkages: If the plan provides a supplemental, Part C OTC benefit paid by a debit card then it should be aware of differences between its own MA plan Part C OTC list and the official list of items electronically linked to the debit card. The following three examples illustrate the situations that plans must formulate instructions for:

    - Dual Purpose: Many electronically linked cards do not allow purchase of dual purpose items. Consequently the plan must explicitly provide instructions to enrollees on how to purchase such dual purpose items, for example vitamins and minerals;

    - Acne / Sunscreen: Certain items – for example, acne treatment or sunscreen lotion– are classified as eligible on the CMS list, but are classified as dual-purpose or non-eligible on lists of items electronically linked to debit cards. In this case (should the plan for example, wish to cover acne treatment or sunscreen lotion) the plan must notify the enrollee that acne treatment or sunscreen lotion may only be purchased through a catalog or direct reimbursement; and

    - Baby Items: Many electronically linked cards allow purchase of baby items. The plan must explicitly notify enrollees of those categories of items which are prohibited, even if they are electronically linked to the plan debit card.

Eligibility Type	Category	Sub-categories	Exceptions
Dual Purpose	Minerals	Includes both multi-vitamins, individual vitamins and minerals.	
Dual Purpose	Vitamins	Includes both multi-vitamins, individual vitamins and minerals.	
Dual Purpose	Diagnostic Equipment	Equipment diagnosing: blood pressure, cholesterol, diabetes, colorectal screenings, HIV, etc.	Thermometers are eligible items not dual eligible; scales are non-eligible. Pregnancy diagnosis items are non-eligible.
Dual Purpose	Hormone replacement	Phytohormone, natural progesterone	

Eligibility Type	Category	Sub-categories	Exceptions
Dual Purpose	Weight loss items	Phenermine, FucoThin, Alli, Hoodia	Any OTC foods, such as protein shakes, even if heavily supplemented by nutrients, may not be offered as an OTC benefit
Eligible	Fiber supplements		Fiber supplements which are primarily food with fiber added are excluded.
Eligible	First Aid supplies	Includes: Bandages, dressings, non-sport tapes.	Flashlights are non-eligible.
Eligible	Incontinence supplies		
Eligible	Medicines, ointments and sprays with active medical ingredients that cure, diminish or remove symptoms	For examples see footnote #1.	Homeopathic and alternative medicines including botanicals, herbals, probiotics, dry skin lotions, and neutraceuticals are non-eligible. For further exceptions see footnote #2.
Eligible	Sunscreen lotion		
Eligible	Support items	Compression hosiery, rib belts, braces, orthopedic supports,	Arch and insoles are non-eligible.
Eligible	Teeth-related items / Dentures /	Toothbrushes, toothpaste, floss, denture adhesives, OTC items that treat gum	Mouthwashes, bad breath items, and teeth-whiteners

Eligibility Type	Category	Sub-categories	Exceptions
	Mouth care	problems, thrush, mouth sores	are non-eligible.
Non-eligible	Alternative medicines	Includes botanicals, herbals, probiotics and neutraceuticals	Vitamins and minerals are dual eligible
Non-eligible	Baby items		
Non-eligible	Contraceptives		
Non-eligible	Convenience (non medical) items	Scales, fans, magnifying glasses, ear plugs, foot insoles, gloves	
Non-eligible	Cosmetics	For examples see footnote #3.	Sun-tan lotions are eligible Medicated soaps, hand sanitizers, therapeutic shampoos, shampoos to fight dandruff are non-eligible.
Non-eligible	Food Supplements	Sugar / salt supplements, energy bars, liquid energizers, protein bars, power drinks, Ensure, glucema.	Vitamins and minerals are dual eligible. Probiotics are non-eligible. Fiber products are eligible unless they are primarily foods with fiber added.
Non-eligible	Replacement items, attachments, peripherals.	Includes: Hearing aid batteries, contact-lens containers, etc. when not factory packaged with	

Eligibility Type	Category	Sub-categories	Exceptions
		original item.	

NOTES:

1. Each item in the following alphabeticized list is either a medicine, ointment or spray, or a condition which is addressed by a medicine, ointment or spray, which has active medical ingredients: acne, allergy, analgesics (which reduce pain, inflammation), anti-acid, anti-arthritics, antibiotics, antiradicals, anti-diarrheas, anti-fungals, anti-gas, anti-histamines, anti-inflammatory, anti-insect, anti-itch, anti-parasitic, antiseptics, antipyretics (fever reducing), arthritis, asthma, blood clotting, bruises, burns, calluses, corns, colds, cold sores, cough, diabetes, flu, decongestants, dermatitis, eczema, digestive aids, ear drops, expectorants (mucus), eye drops, gastro-intestinal, hay fever, headaches, hemorrhoidal, incontinence, influenza, laxatives, (medicated) lactose intolerance products, lice, (medicated) lip products, menopausal, menstrual, sinus, motion sickness, nasal, osteoporosis, pain, psoriasis, pediculicide, rash, respitory, scars, sleep, smoking, snoring, sore throat, stomach problems, travel sickness, steroids, sunscreen, thrush, wart, worms, wounds.

2. The following are not eligible: Baby medicines are non-eligible. Dehydration drinks are non-eligible. Dry skin lotions (e.g. Eucerin, Aquaphor) are non-eligible. For Food supplements see below. Contraceptives are non-eligible. Dairy Care is non-eligible (it is non-medicated). Lactaid milk is a food (not a medicine) and non-eligible. Certain smoking cessation aides may be covered under Part B. Certain diabetic supplies may be covered under either Part B or Part D. Shampoos to fight dandruff are non-eligible. Hair-loss products are non-eligible.

3. Lip balm, deodorants, facial cleansers, feminine products, grooming devices, hair conditioners, hair removal, hair bleaches, moisturizers, perfumes, anti-perspirants, shampoos, shaving and men's grooming, and soaps.

APPENDIX II – Risk Adjustment Implementation

1. Risk Adjustment Data Submission Schedule

Table 1. Risk Adjustment Implementation Calendar (below) provides the updated submission schedule for all diagnosis data submitted for all risk adjustment models. This includes data for both the Part C CMS-HCC and ESRD models and the Part D Drug risk adjustment model.

Table 1. Risk Adjustment Implementation Calendar

CY	Dates of Service	Initial Submission Deadline*	First Payment Date	Final Submission Deadline
2008	July 1, 2006 through June 30, 2007	September 7, 2007	January 1, 2008	N/A**
2008	January 1, 2007 through December 31, 2007	March 7, 2008	July 1, 2008	January 31, 2009
2009	July 1, 2007 through June 30, 2008	September 5, 2008	January 1, 2009	N/A**
2009	January 1, 2008 through December 31, 2008	March 6, 2009	July 1, 2009	January 31, 2010
2010	July 1, 2008 through June 30, 2009	September 4, 2009	January 1, 2010	N/A**

2010	January 1, 2009 through December 31, 2009	March 5, 2010	July 1, 2010	January 31, 2011
2011	July 1, 2009 through June 30, 2010	September 3, 2010	January 1, 2011	N/A**
2011	January 1, 2010 through December 31, 2010	March 4, 2011	July 1, 2011	January 31, 2012

*March and September dates reflect the first Friday of the respective month.

**All risk adjustment data for a given payment year (CY) must be submitted by January 31st of the subsequent year.

Changes in payment methodology for 2010, including Part C and Part D payment and risk adjustment, are described in the February 20, 2009, *Advance Notice of Methodological Changes for Calendar Year (CY) 2010 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies* and the April 6, 2009, *Announcement of CY 2010 MA Capitation Rates and MA and Part D Payment Policies* (which will be available at http://www.cms.hhs.gov/MedicareAdvtgSpecRateStats/).

2. Part A Risk Adjustment Factor Options

Determinations of Risk Status

As stated in the April 3, 2006 Announcement of Calendar Year (CY) 2007 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies (available at http://www.cms.hhs.gov/MedicareAdvtgSpecRateStats/), plans subject to risk adjusted payments have the option of treating beneficiaries with 12 months of Part A data but less than 12 months of Part B enrollment in a data collection year.

Table 2. Which Risk Adjustment Factors to Apply to Payment*

Time Period Beneficiary Has Been Enrolled in Part B Medicare**	**Time Period Beneficiary Has Been Entitled to Benefits under Part A Medicare****	
	0 – 11 months	**≥ 12 months**
0 – 11 months	New enrollee factors	Plan's option: New enrollee or full risk adjustment factors
≥ 12 months	Full risk adjustment factors	Full risk adjustment factors

*Applies to Part C and D payments for MA plans, demonstrations, and PACE organizations. Note that MA enrollees must be entitled to benefits under Part A and enrolled in Part B.

**During data collection period (previous calendar year).

Table 2. *Which Risk Adjustment Factors to Apply to Payment* (above) illustrates that beneficiaries with 12 or more months of Medicare Part B enrollment during the data collection period (previous calendar year) are considered full risk enrollees. The new enrollee factors do not apply.

Beneficiaries with less than 12 months of entitlement to benefits under Part A and less than 12 months of Part B enrollment during the data collection period will be treated as new enrollees, as they are now.

Currently beneficiaries with 12 or more months of entitlement to benefits under Part A and less than 12 months of Part B enrollment during the data collection period (referred to as "Part A-only" enrollees) are considered new enrollees for the purpose of risk adjusted payments. Because of concerns expressed by some sponsors of demonstration plans that "Part A only" enrollees are always considered to be new enrollees, CMS has created an option for how the risk adjustment payments for this category of enrollees are determined. Effective as of 2006 payments, organizations may elect to have CMS determine payments for all "Part A-only" enrollees using either new enrollee factors or full risk adjustment factors. The organization's decision will be applied to all "Part A-only" enrollees in the plan. Plans may not elect to move some eligible "Part A-only" enrollees into risk adjustment, while retaining others as new enrollees.

Option to Elect Full Risk Option for "Part A-only" Enrollees

Effective as of 2006 payments, organizations may elect to have CMS determine payments for all "Part A-only" enrollees using either new enrollee factors or full risk adjustment factors. If an organization elects to have CMS determine payment factors; (i.e., new enrollee factors or full risk adjustment factors) for all "Part-A only" enrollees, then:

- The decision will be applied to all "Part-A" only enrollees in the plan;
- The option elected will remain turned in effect until CMS is otherwise notified prior to August 31st of any successive year.

This option is also available to §1876 Cost HMOs/CMPs offering Part D coverage for individuals who have been entitled to Part A for 12 or more months and who have been entitled to Part B for 11 or fewer months at the time of their enrollment in the Cost-PD plan. In such cases, the Part D payment will be risk–adjusted (new enrollee or full risk adjustment factor) based on the plan's election. In the absence of an election, the Part D payment will be risk-adjusted using the new enrollee factor.

Plans interested in electing this option for 2010 must contact: Henry Thomas, CMS, at henry.thomas@cms.hhs.gov by August 31, 2009.

3. Risk Adjustment Implementation

MA organizations must review the following:

- Changes in payment methodology for 2010 including Part C and Part D payment and risk adjustment, are described in the February 20, 2009, *Advance Notice of Methodological Changes for Calendar Year (CY) 2010 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies* and the April 6, 2009, *Announcement of CY 2010 MA Capitation Rates and MA and Part D Payment Policies* (which will be available at http://www.cms.hhs.gov/MedicareAdvtgSpecRateStats/).
- Two important risk adjustment memoranda dated November 27, 2007, which were published via HPMS on November 28, 2007:
  - CMS implementation of ICD-9 diagnosis codes for 2009
  - Medicaid status for Part C and D risk adjustment and Part D cost sharing; and

CMS implementation of ICD-10 diagnosis codes has been postponed until October 2013. CMS will provide plans with an opportunity for testing with ICD-10 diagnoses. More information will be forthcoming as CMS progresses with the development and implementation of changes to accept and process the new ICD-10 diagnosis codes.

For additional information on risk adjustment, see 42 CFR §422.310.

4. Impact of Hospital Acquired Conditions under the Inpatient Prospective Payment System on Diagnoses Reporting for Risk Adjustment

For purposes of risk adjustment, MA organizations are required to submit discharge diagnoses from hospital inpatient settings. To the extent that any ICD-9 codes attributable to the eight selected hospital acquired conditions (surgical site infections, blood incompatibility, air embolism, object left in surgery, catheter associated urinary tract infections, pressure ulcers, hospital acquired injuries, or vascular catheter associated infection) appear in the discharge diagnoses, these codes may be submitted for risk adjustment payment.

5. National Provider Identifier (NPI)

The January 23, 2004 final rule (69 FR 3434*), HIPAA Administrative Simplification: Standard Unique Health Identifier for Health Care Providers*, established the standard for a unique identifier for health care providers and adopted the National Provider Identifier (NPI) number as that standard. The National Provider System (NPS) was established to assign unique NPI numbers to health care providers. The NPS was designed to be used by other Federal and state Agencies as well as by private health plans, if deemed appropriate, to enumerate health care providers that did not participate in Medicare. Consequently, the NPI can not be used to determine whether a provider is a Medicare certified provider.

On May 23, 2007, CMS implemented the use of the NPI, for claims submitted to Fee-For-Service (Original) Medicare and discontinued issuing the Medicare Provider Identifier Numbers (legacy or OSCAR numbers). In the past, Medicare plans could use the legacy number to verify that a provider was a Medicare provider and that the provider was an acceptable source for diagnosis data for the CMS risk adjustment process. Implementation of the NPI necessitates that Medicare plans that had been using the legacy Medicare provider numbers to verify the source of diagnoses submitted for risk adjustment purposes establish new methodologies for determining: 1) that providers are Medicare certified and 2) that diagnosis sources are acceptable. Implementation of the NPI does not change the requirement for Medicare plans to verify that the diagnosis data submitted to the CMS for risk adjustment are from Medicare certified providers and from acceptable data sources.

6. Testing Requirements

Submitter testing is required to ensure the proper flow of data from the submitter to the Risk Adjustment Processing System (RAPS). Testing also ensures the data submitted is valid and formatted correctly.

If you would like to send data in a test format, please contact the Customer Service and Support Center (CSSC) Help Line at (877) 534-2772. By calling the CSSC Help Line prior to transmission of your first production or test file, a CSSC representative will be able to give you information on how to properly submit a test and/or production file. Information regarding the CSSC and the Risk Adjustment Processing System (RAPS) is available on the CSSC web site at http://www.csscoperations.com/.

7. Acceptable Provider Types and Physician Data Sources

For purposes of risk adjustment, MA organizations must collect data from the following provider types:

- Hospital inpatient facilities
- Hospital outpatient facilities
- Physician

In addition, only those physician specialties and other clinical specialists identified in Table 3 – Acceptable Physician Data Sources of the Medicare Advantage, Medicare Advantage-Prescription Drug Plans CY 2007 Instructions (dated April 4, 2006) are acceptable for risk adjustment. To obtain a copy of this document, please visit the CMS web site at http://www.cms.hhs.gov/healthplansgeninfo/downloads/Rev%20MA-MAPD%20call%20letter%20final.pdf. Note that registered nurses, licensed practical nurses, and nursing assistants are not included in Table 3 – Acceptable Physician Data Sources as they are unacceptable physician data sources.

MA organizations are responsible for ensuring that the data they collect and submit to CMS for payment comes from acceptable provider types and physician data sources. The collection of physician data relevant for risk adjustment is associated with the physician's specialty. That is, all ICD-9-CM diagnoses that are in the risk adjustment model and rendered as a result of a visit to a physician must be collected by the MA organization. This includes data collected from non-network as well as network providers. Therefore, CMS requires MA organizations to filter and submit risk adjustment data in accordance with the appropriate provider types and acceptable physician data sources as approved by CMS.

8. Integrity of RAPS Submissions

Although a plan may designate another entity to submit claims on its behalf to CMS, the plan remains responsible for data submission, accuracy and content. If your MA organization needs assistance or is experiencing data submission issues, please contact our Customer Service and Support Center (CSSC) at 1-877-534-2772 or http://www.csscoperations.com/.

9. IT Technical Assistance Outreach

The purpose of the IT Technical Assistance Outreach program is to provide MA organizations with the IT support to perform the required Risk Adjustment data submissions skills and to understand the roles that data play in relationship to payment. This outreach will enable MA organizations to collect and submit the appropriate data in accordance with CMS requirements; thereby, this assistance's expected outcome seeks to provide a positive impact on "the correct payment." The outreach program contains two components: IT Participant User guides and IT User Group sessions.

IT Participant User Guides

CMS offers three user guides: Risk Adjustment, Enrollment and Payment, and Prescription Drug Event Data. These guides are structured in an interactive training format. They address the enrollment, payment, and data collection and submission provisions of Titles I and II of the MMA of 2003 as related to risk adjustment, drug risk adjuster, drug and low income subsidies, out-of-pocket costs, reinsurance and risk corridors. The guides are designed for employees of organizations responsible for the submission and maintenance of risk adjustment data, prescription drug event data and enrollment data. This designation also includes the staff of MA and MA-PD organizations' third party submitters, providers' training staff and demonstration programs. The expected objectives and outcomes are for the user to demonstrate a working knowledge of the fundamentals of payment provisions and methodologies for Parts C and D; enrollment, reenrollment and disenrollment; and the collection and submission of diagnostic health status data and prescription drug data events through applying information learned from real-life problem solving situations for Parts C and D. The IT guides may be found at www.csscoperations.com. CMS anticipates updating these materials annually sometime after April 2009.

IT User Groups

The Medicare Part C risk adjustment user groups are designed to provide a forum for identification, discussion and resolution of the operational and supporting components of the Part C payment provisions, data collection and submission and to provide feedback to CMS. The sessions are conducted monthly via teleconference, and extend from October, 2008 through September, 2009. The participants include MA organizations, PACE, other demonstrations and specialty programs, MA industry association representatives, CMS Contractors, and other CMS approved interested parties. Registration for the outreach sessions are located at http://www.TARSC

APPENDIX III – Part D Licensure Waivers-Reporting and Filing Deadlines

For PDP Sponsors With Licensure Waivers Expiring on December 31, 2009

Deadline	Action
2/27/2009	Deadline for submitting a waiver extension request from Part D sponsors with expiring state licensure waivers on 12/31/2009 that were unable to become licensed because of state requirements that are beyond the Part D sponsor's ability to meet. (Note that CMS issued notice of this deadline in early February 2009 to affected sponsors through an e-mail to their compliance officers).
4/1/2009	CMS will notify Part D sponsors that they are not qualified to offer Part D benefits during 2010 in the Part D sponsor regions where a licensure waiver will expire on 12/31/09. Part D sponsors will be afforded an opportunity to complete a CAP, either by obtaining licenses from all states for which a waiver will expire 12/31/2009 or reducing their service area.
4/1/2009	Part D sponsor will be requested to submit an exit plan* for each region which contains an unlicensed (waivered) state where the waiver will expire on 12/31/2009.
7/30/2009	Last day for Part D sponsors to obtain state licensure in states for which they have 2008 expiring waivers or to reduce their service areas, and not receive a notice of non-renewal from CMS.
7/31/2009	Non-renewals for contract year 2010 issued as appropriate
9/1/2009	Part D sponsor implements service area exit plans as appropriate.
12/31/09	Contract non-renewal or service area reduction becomes effective.

* Exit Plan – Must address the steps/schedule for ensuring the timely transfer of any data or files. Sponsor should indicate whether it wants to issue notices instead of CMS.

For Sponsors With Licensure Waivers Expiring on December 31, 2010

Deadline	Action
4/15/2009	Part D sponsor must submit confirmation from each state for which its licensure waiver will expire in 2010, that the state is in possession of a substantially complete application and expects to be able to approve or disapprove before 4/1/2010, or the state provides the earliest date on which it will accept an application if seasoning is an issue.
2/2010	Deadline for submitting a waiver extension request from Part D sponsors with expiring state licensure waivers on 12/31/2010 that were unable to become licensed because of state requirements that are beyond the Part D sponsor's ability to meet.
4/1/2010	CMS will notify Part D sponsors that they are not qualified to offer Part D benefits during 2011 in the Part D sponsor regions where a licensure waiver will expire on 12/31/10. Part D sponsors will be afforded an opportunity to complete a CAP, either by obtaining licenses from all states for which a waiver will expire 12/31/2010 or reducing their service area.
4/1/2010	Part D sponsor will be requested to submit an exit plan* for each region which contains an unlicensed (waivered) state where the waiver will expire on 12/31/2010
7/31/2010	Last day for Part D sponsors to obtain state licensure for states with 2010 expiring waivers or to reduce their service area, and not receive a notice of non-renewal.
8/1/2010	Non-renewals for contract year 2010 issued as appropriate
9/1/2010	Part D sponsor implements service area exit plans as appropriate.
12/31/10	Contract non-renewal or service area reduction becomes effective.

* Exit Plan – Must address the steps/schedule for preparing notifications to beneficiaries, the public and network providers, and for ensuring the timely transfer of any data or files.

April 6, 2009

NOTE TO: All Medicare Advantage Organizations, Prescription Drug Plan Sponsors, and Other Interested Parties

SUBJECT: Announcement of Calendar Year (CY) 2010 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies

In accordance with section 1853(b)(1) of the Social Security Act (the Act), we are notifying you of the annual Medicare Advantage (MA) capitation rate for each MA payment area for 2010, and the risk and other factors to be used in adjusting such rates. The capitation rate tables for CY 2010 are posted on the Centers for Medicare & Medicaid Services (CMS) web site at http://www.cms.hhs.gov/MedicareAdvtgSpecRateStats/ under Ratebooks and Supporting Data. The spreadsheet that shows the statutory component of the regional benchmarks is also posted at this website.

Attachment I shows the final estimates of the increases in the National Per Capita MA Growth Percentages for 2010. These growth rates will be used to update the 2010 rates, except for the ESRD State rates, which are subject to a 2 percent minimum increase under Section 1853(a)(1)(H). As discussed in Attachment I, the final estimate of the increase in the National Per Capita MA Growth Percentage for combined aged and disabled beneficiaries is 0.81 percent. Attachment II provides a set of tables that summarizes many of the key Medicare assumptions used in the calculation of the National Per Capita MA Growth Percentages.

Section 1853(b)(4) of the Act requires CMS to release county-specific per capita fee-for-service (FFS) expenditure information on an annual basis, beginning with March 1, 2001. In accordance with this requirement, FFS data for CY 2007 are being posted on the above website.

Attachment III presents responses to comments on the Advance Notice of Methodological Changes for CY 2010 MA Capitation Rates and Parts C and Part D Payment Policies (Advance Notice). We received 66 submissions in response to CMS' request for comments on the Advance Notice, published on February 20, 2009. Three of the comments were from advocacy groups, three were from Congress (members or agencies of Congress), seven were from associations, nine were from consultants, and forty-four were from health plans.

Attachment IV contains tables with the Part D benefit parameters.

Key Changes from the Advance Notice

Attachment I provides the final estimates of the National MA Growth Percentages (growth trends) and information on deductibles for MSA standard and demonstration plans, and on the maximum out-of-pocket amount for MSA demonstrations plans.

Attachment III, Section E announces the policy decision on the MA coding pattern differences adjustment for 2010. After consideration of comments, CMS has modified the methodology proposed in the Advance Notice. Section D includes the Budget Neutrality factor for 2010. Attachment IV announces the final version of the update to the Part D Benefit Parameters.

As in past years, policies proposed in the Advance Notice that are not modified or retracted in the Rate Announcement become effective in the upcoming payment year, as set forth in the Advance Notice. Clarifications in the Announcement supersede materials in the Advance Notice.

Proposals Adopted as Issued in the Advance Notice:

Frailty Adjustment Transition for PACE organizations. Frailty adjustment scores will be applied to payment to PACE organizations using the transition schedule published in the 2008 Announcement (published April 2, 2007). PACE frailty scores for payment year 2010 will be calculated using a blend of 50% of the frailty factors in use prior to 2008 and 50% of the recalibrated frailty factors implemented in 2009.

Frailty Adjustment Transition for Certain Demonstrations. Frailty adjustment scores will be applied to payment to the following MA plan types using the phase-out schedule published in the 2008 Announcement (published April 2, 2007): Social Health Maintenance Organizations (S/HMOs), Minnesota Senior Health Options (MSHO)/ Minnesota Disability Health Options (MnDHO), Wisconsin Partnership Program (WPP) and Massachusetts Senior Care Options (SCO) plans. The phase out schedule for 2010 is 25% of the pre-2008 frailty factors. 2010 will be the final year in the phase out for these MA plan types.

Normalization Factors. Normalization factors for 2010 are as follows:

- The final 2010 normalization factor for the aged-disabled model is 1.041.
- The final 2010 normalization factor for the ESRD dialysis model is 1.039.
- The final 2010 normalization factor to be applied to the risk scores of enrollees in functioning graft status is 1.072.
- The final 2010 normalization factor for the RxHCC model is 1.146.

ESRD Payment. For payment year 2010, CMS' payments for ESRD dialysis and transplant enrollees will be based on State rates calculated using a blend of 25% of the old State ratebook (in use through 2007) and 75% of the revised State ratebook (implemented in 2008).

IME Phase Out. For 2010, CMS will begin phasing out indirect medical education (IME) amounts from MA capitation rates (including ESRD).

Location of Network Areas for PFFS Plans in Plan Year 2011. The list of network areas for plan year 2011 can be downloaded from the following website: http://www.cms.hhs.gov/PrivateFeeforServicePlans/ The list has not changed since the publication of the Advance Notice.

Continuation of Clinical Trial Policy. In 2010, we will continue the policy of paying on a fee-for-service basis for clinical trial items and services provided to MA plan members that are covered under the relevant National Coverage Determinations on clinical trials.

Adjustment to FFS Per Capita Costs for VA-DOD Costs. For payment year 2010, OACT concludes that there is insufficient evidence to incorporate any VA adjustment into the rate making process.

Calculation and Source Data of MSP Factor. For payment year 2010, CMS no longer requires that MA organizations conduct, nor will we use the results of, plan surveys conducted in 2009. Rather, CMS will adjust for MSP status using Coordination of Benefits (COB) data.

Reporting Drug Costs When Contracting with a Pharmacy Benefit Manager (PBM). In accordance with the January 12, 2009 Final Rule with Comment, "Medicare Advantage and Prescription Drug Benefit Programs: Negotiated Pricing and Remaining Revisions", Part D sponsors must use the amount paid to the pharmacy (or other dispensing provider) when calculating beneficiary cost sharing, developing their Part D bids, and reporting drug costs to CMS. For Part D sponsors that contract with a PBM, amounts paid to the PBM for Part D drugs that exceed the amounts paid to the pharmacy (or other dispensing provider) must be included in the administrative expense component of the bid. Starting in 2010, Part D sponsors will not be required to submit an Attestation of Pricing Approach.

Reinsurance Payment Demonstration Plans. 2010 is the last scheduled year for the Part D Reinsurance Payment Demonstration. CMS will not accept any new or expanded applications for reinsurance demonstration plans to be offered in 2010. Reinsurance demonstration plans which were offered in 2009 may continue through 2010. The budget neutrality offsets applied to the capitated reinsurance payments for these plans will be $10.77 per member per year for contract year 2010.

Payment Reconciliation. The 2010 risk percentages and payment adjustments for Part D risk sharing are unchanged from contract year 2009. The risk percentages for the first and second thresholds remain at 5% and 10% respectively of the target amount for 2010. The payment adjustments for the first and second corridors are 50% and 80% respectively.

Questions can be directed to:

Paul Spitalnic at (410-786-2328) or Paul.Spitalnic@cms.hhs.gov for Attachments I and II

Deondra Moseley at (410) 786-4577 or Deondra.Moseley@cms.hhs.gov, Rebecca Paul at (410) 786-0852 or Rebecca.Paul@cms.hhs.gov, or Meghan Elrington at (410)786-8675 or Meghan.Elrington@cms.hhs.gov for Attachments III and IV.

/ s /
Jonathan D. Blum
Acting Director
Center for Drug and Health Plan Choice

/ s /
Paul Spitalnic, A.S.A., M.A.A.A.
Director
Parts C & D Actuarial Group
Office of the Actuary

Attachments

Attachment I. Final Estimate of the Increase in the National Per Capita MA Growth Percentages for 2010

The first table below shows the National Per Capita MA Growth Percentages (NPCMAGP) used to determine the minimum update percentages for 2010. Adjustments of 1.99 percent, 0.64 percent, 1.23 percent and 1.76 percent for aged, disabled, ESRD, and combined aged and disabled, respectively, are included in the NPCMAGP to account for corrections to prior years' estimates as required by section 1853(c)(6)(C). The combined aged and disabled increase is used in the development of the ratebook.

The second table below shows the monthly actuarial value of the Medicare deductible and coinsurance for 2009 and 2010. In addition, for 2010, the actuarial value of deductibles and coinsurance is being shown for non-ESRD only, since the plan bids will not include ESRD benefits in 2010. These data were furnished by the Office of the Actuary.

Increase in the National Per Capita MA Growth Percentages for 2010

	Prior Increases	Current Increases			NPCMAGP for 2010 With §1853(c)(6)(C) adjustment[1]
	2003 to 2009	2003 to 2009	2009 to 2010	2003 to 2010	
Aged	38.97%	41.74%	−0.97%	40.36%	1.00%
Disabled	46.87%	47.81%	−0.67%	46.82%	−0.04%
ESRD[2]	15.44%	16.86%	−0.95%	15.76%	0.28%[3]
Aged+Disabled	39.94%	42.40%	−0.93%	41.07%	0.81%

[1]Current increases for 2003 to 2010 divided by the prior increases for 2003 to 2009.
[2]Starting in 2008, increases for ESRD reflect an estimate of the increase for dialysis-only beneficiaries.
[3]The NPCMAGP for ESRD for 2010 will be the minimum 2 percent increase.

Monthly Actuarial Value of Medicare Deductible and Coinsurance for 2009 and 2010

	2009	2010	Change	2010 non-ESRD
Part A Benefits	$37.94	$40.31	6.2%	$38.34
Part B Benefits[4]	$97.97	$100.01	2.1%	$93.98
Total Medicare	$135.91	$140.32	3.2%	$132.32

[4]Includes the amounts for outpatient psychiatric charges.

Medical Savings Account (MSA) Plans. The maximum deductible for current law MSA plans for 2010 is $10,600. For MSA demonstration plans, the 2010 minimum deductible amount is $2,200, the maximum out-of-pocket amount is $10,600, and the minimum difference between the deductible and deposit is $1,000.

Attachment II. Key Assumptions and Financial Information

The USPCCs are the basis for the National Per Capita MA Growth Percentages. Attached is a table that compares the published United States Per Capita Costs (USPCC) with current estimates for 2003 to 2010. In addition, this table shows the current projections of the USPCCs through 2012. We are also providing an attached set of tables that summarizes many of the key Medicare assumptions used in the calculation of the USPCCs. Most of the tables include information for the years 2003 through 2012.

All of the information provided in this enclosure applies to the Medicare Part A and Part B programs. Caution should be employed in the use of this information. It is based upon nationwide averages, and local conditions can differ substantially from conditions nationwide.

None of the data presented here pertain to the Medicare prescription drug benefit.

Comparison of Current Estimates of the USPCC with Published Estimates

PART A:

Calendar Year	Aged			Disabled			Aged and Disabled		
	Current Estimate	Published Estimate	Ratio	Current Estimate	Published Estimate	Ratio	Current Estimate	Published Estimate	Ratio
2003	$301.42	$290.50	0.964	$250.04	$234.89	0.939	$293.87	$282.50	0.961
2004	$321.21	$326.78	1.017	$268.86	$271.69	1.011	$313.24	$318.43	1.017
2005	$343.27	$348.28	1.015	$286.31	$291.45	1.018	$334.31	$339.49	1.015
2006	$352.70	$351.38	0.996	$309.67	$295.15	0.953	$345.97	$342.67	0.990
2007	$363.56	$370.34	1.019	$317.49	$318.17	1.002	$356.07	$362.06	1.017
2008	$388.02	$385.61	0.994	$342.42	$344.31	1.006	$380.69	$379.02	0.996
2009	$410.78	$414.22	1.008	$362.11	$378.40	1.045	$402.88	$408.50	1.014
2010	$415.28	$415.28	1.000	$366.83	$366.83	1.000	$407.38	$407.38	1.000
2011	$429.04			$380.50			$421.12		
2012	$446.59			$400.33			$439.13		

PART B:

Calendar Year	Aged			Disabled			Aged and Disabled		
	Current Estimate	Published Estimate	Ratio	Current Estimate	Published Estimate	Ratio	Current Estimate	Published Estimate	Ratio
2003	$250.81	$232.24	0.926	$246.76	$211.58	0.857	$250.26	$229.47	0.917
2004	$276.49	$263.39	0.953	$274.57	$252.74	0.920	$276.22	$261.89	0.948
2005	$296.64	$281.90	0.950	$293.34	$272.79	0.930	$296.16	$280.58	0.947
2006	$319.09	$311.28	0.976	$311.80	$316.82	1.016	$318.00	$312.09	0.981
2007	$336.19	$334.02	0.994	$331.91	$343.76	1.036	$335.54	$335.47	1.000
2008	$354.57	$354.44	1.000	$352.88	$343.26	0.973	$354.31	$352.75	0.996
2009	$371.93	$358.03	0.963	$372.21	$357.10	0.959	$371.97	$357.89	0.962
2010	$359.82	$359.82	1.000	$362.57	$362.57	1.000	$360.25	$360.25	1.000
2011	$365.13			$369.74			$365.85		
2012	$375.68			$381.49			$376.58		

PART A & PART B:

Calendar Year	Aged			Disabled			Aged and Disabled		
	Current Estimate	Published Estimate	Ratio	Current Estimate	Published Estimate	Ratio	Current Estimate	Published Estimate	Ratio
2003	$552.23	$522.74	0.947	$496.80	$446.47	0.899	$544.13	$511.97	0.941
2004	$597.70	$590.17	0.987	$543.43	$524.43	0.965	$589.46	$580.32	0.984
2005	$639.91	$630.18	0.985	$579.65	$564.24	0.973	$630.47	$620.07	0.984
2006	$671.79	$662.66	0.986	$621.47	$611.97	0.985	$663.97	$654.76	0.986
2007	$699.75	$704.36	1.007	$649.40	$661.93	1.019	$691.61	$697.53	1.009
2008	$742.59	$740.05	0.997	$695.30	$687.57	0.989	$735.00	$731.77	0.996
2009	$782.71	$772.25	0.987	$734.32	$735.50	1.002	$774.85	$766.39	0.989
2010	$775.10	$775.10	1.000	$729.40	$729.40	1.000	$767.63	$767.63	1.000
2011	$794.17			$750.24			$786.97		
2012	$822.27			$781.82			$815.71		

Comparison of Current Estimates of the USPCC with Published Estimates−continued

PART A:

	All ESRD				Basis for Growth Percentage	
Calendar Year	Current Estimate	Published Estimate	Ratio	Current Cumulative Trend	Adjustment Factor for Dialysis-only*	Adjusted Current Cumulative Trend
2003	1,854.38	1,596.58	0.861			
2004	1,690.26	1,685.25	0.997	0.9115		0.9115
2005	1,735.53	1,759.90	1.014	0.9359		0.9359
2006	1,807.19	1,717.97	0.951	0.9746		0.9746
2007	1,891.18	1,874.54	0.991	1.0198		1.0198
2008	2,015.22	1,843.42	0.915	1.0867	1.0067	1.0940
2009	2,112.67	1,885.71	0.893	1.1393	1.0134	1.1546
2010	2,133.76	2,133.76	1.000	1.1507	1.0202	1.1739
2011	2,200.43			1.1866	1.0271	1.2187
2012	2,299.34			1.2400	1.0340	1.2820

PART B:

	All ESRD				Basis for Growth Percentage	
Calendar Year	Current Estimate	Published Estimate	Ratio	Current Cumulative Trend	Adjustment Factor for Dialysis-only*	Adjusted Current Cumulative Trend
2003	2,021.41	1,847.53	0.914			
2004	2,161.14	2,552.18	1.181	1.0691		1.0691
2005	2,297.12	2,739.99	1.193	1.1364		1.1364
2006	2,297.76	2,454.98	1.068	1.1367		1.1367
2007	2,356.60	2,470.81	1.048	1.1658		1.1658
2008	2,446.23	2,887.38	1.180	1.2102	0.9709	1.1749
2009	2,533.58	2,371.73	0.936	1.2534	0.9426	1.1815
2010	2,523.56	2,523.56	1.000	1.2484	0.9152	1.1426
2011	2,581.94			1.2773	0.8886	1.1350
2012	2,608.15			1.2903	0.8627	1.1131

PART A & PART B:

	All ESRD				Basis for Growth Percentage	
Calendar Year	Current Estimate	Published Estimate	Ratio	Current Cumulative Trend	Adjustment Factor for Dialysis-only*	Adjusted Current Cumulative Trend
2003	3,875.79	3,444.11	0.889			
2004	3,851.40	4,237.43	1.100	0.9937		0.9937
2005	4,032.65	4,499.89	1.116	1.0405		1.0405
2006	4,104.95	4,172.95	1.017	1.0591		1.0591
2007	4,247.78	4,345.35	1.023	1.0960		1.0960
2008	4,461.45	4,730.80	1.060	1.1511	0.9871	1.1362
2009	4,646.25	4,257.44	0.916	1.1988	0.9748	1.1686
2010	4,657.32	4,657.32	1.000	1.2016	0.9633	1.1576
2011	4,782.37			1.2339	0.9523	1.1751
2012	4,907.49			1.2662	0.9430	1.1940

* Starting in 2008, increases for ESRD reflect an estimate of the increase for dialysis-only beneficiaries

Summary of Key Projections Under Present Law[1]

Part A

Year	Calendar Year CPI Percent Increase	Fiscal Year PPS Update Factor	FY Part A Total Reimbursement (Incurred)
2003	2.2	3.0	3.6
2004	2.6	3.4	8.8
2005	3.5	3.3	8.9
2006	3.2	3.7	6.2
2007	2.9	3.4	5.6
2008	4.3	3.3	8.2
2009	−1.0	2.7	9.1
2010	1.7	−0.9	3.1
2011	2.3	2.6	5.3
2012	2.7	4.9	7.4

Part B[2]

Calendar Year	Physician Fee Schedule		Part B Hospital	Total
	Fees	Residual[3]		
2003	1.7	4.5%	5.4%	6.9%
2004	1.5	5.9%	10.0%	9.7%
2005	1.5	3.2%	9.8%	6.9%
2006	0.2	4.6%	4.1%	5.9%
2007	0.0	3.5%	8.4%	4.3%
2008	0.5	3.6%	3.8%	4.4%
2009	1.1	2.6%	6.1%	4.4%
2010	−21.5	8.1%	5.8%	−3.8%
2011	−5.6	2.8%	6.1%	1.7%
2012	−5.3	2.9%	6.3%	2.4%

[1]Percent change over prior year.
[2]Percent change in charges per Aged Part B enrollee.
[3]Residual factors are factors other than price, including volume of services, intensity of services, and age/sex changes.

Medicare Enrollment Projections Under Present Law (In Millions)

Non-ESRD

Calendar Year	Part A		Part B	
	Aged	Disabled	Aged	Disabled
2003	34.428	5.929	33.027	5.187
2004	34.835	6.249	33.282	5.458
2005	35.241	6.576	33.609	5.747
2006	35.892	6.657	33.962	5.987
2007	36.432	7.068	34.445	6.187
2008	37.264	7.133	34.979	6.335
2009	37.768	7.318	35.503	6.485
2010	38.473	7.500	36.065	6.645
2011	39.371	7.679	36.752	6.798
2012	40.657	7.813	37.806	6.922

ESRD Part A

Calendar Year	Part A			
	Aged	Disabled	299I[1]	Total
2003	0.160	0.126	0.096	0.383
2004	0.167	0.132	0.100	0.399
2005	0.174	0.137	0.104	0.415
2006	0.182	0.141	0.107	0.430
2007	0.190	0.143	0.110	0.443
2008	0.198	0.144	0.113	0.455
2009	0.206	0.146	0.116	0.467
2010	0.212	0.149	0.118	0.478
2011	0.218	0.151	0.120	0.489
2012	0.226	0.154	0.121	0.501

ESRD Part B

Calendar Year	Part B			
	Aged	Disabled	299I	Total
2003	0.161	0.120	0.088	0.370
2004	0.168	0.125	0.089	0.382
2005	0.175	0.130	0.092	0.396
2006	0.183	0.133	0.095	0.411
2007	0.190	0.135	0.098	0.423
2008	0.198	0.135	0.100	0.433
2009	0.205	0.137	0.102	0.444
2010	0.211	0.140	0.103	0.454
2011	0.217	0.142	0.105	0.464
2012	0.225	0.144	0.106	0.475

[1] Individuals who qualify for Medicare based on ESRD only.

Part A Projections Under Present Law [1]

Calendar Year	Inpatient Hospital		SNF		Home Health		Managed Care		Hospice: Total Reimbursement (in Millions)	
	Aged	Disabled	Aged	Disabled	Aged	Disabled	Aged	Disabled	Aged	Disabled
2003	2,657.65	2,861.53	419.92	150.13	132.41	71.96	522.55	218.64	5,446	287
2004	2,775.49	3,005.59	469.88	173.01	143.46	78.03	569.16	236.85	6,506	342
2005	2,885.13	3,139.82	513.88	193.18	151.60	82.67	675.68	299.94	7,618	401
2006	2,830.27	3,212.38	541.17	211.94	151.48	85.64	823.25	516.26	8,866	467
2007	2,776.45	3,147.05	574.84	227.61	154.16	87.70	981.74	659.27	9,991	526
2008	2,861.37	3,285.05	608.19	245.18	160.79	93.02	1,160.89	812.33	11,094	584
2009	2,930.10	3,400.83	638.32	261.85	164.90	96.90	1,340.39	922.44	12,032	633
2010	2,904.68	3,413.61	658.25	275.22	165.52	98.95	1,402.32	950.92	12,667	667
2011	3,017.84	3,557.11	678.55	287.01	166.81	100.58	1,437.67	965.70	13,515	711
2012	3,154.87	3,743.18	693.61	298.78	171.29	104.73	1,498.52	1,014.58	14,480	762

[1]Average reimbursement per enrollee on an incurred basis, except where noted.

Part B Projections Under Present Law[1]

Calendar Year	Physician Fee Schedule		Part B Hospital		Durable Medical Equipment	
	Aged	Disabled Non-ESRD	Aged	Disabled Non-ESRD	Aged	Disabled Non-ESRD
2003	1,263.11	1,190.84	378.19	470.64	182.20	302.52
2004	1,393.34	1,311.08	429.21	545.45	180.99	301.09
2005	1,451.27	1,354.77	482.59	602.99	181.31	303.92
2006	1,456.82	1,327.97	498.14	614.52	181.80	307.02
2007	1,428.28	1,313.39	527.81	655.89	178.26	305.51
2008	1,430.09	1,329.54	536.91	678.15	184.97	323.44
2009	1,459.42	1,364.59	561.03	716.66	188.65	336.77
2010	1,200.72	1,134.42	589.34	759.93	190.54	344.55
2011	1,158.11	1,095.03	632.20	815.49	200.34	364.09
2012	1,123.10	1,048.67	677.78	874.11	212.59	387.26

Calendar Year	Carrier Lab		Other Carrier		Intermediary Lab	
	Aged	Disabled Non-ESRD	Aged	Disabled Non-ESRD	Aged	Disabled Non-ESRD
2003	76.42	79.72	337.18	349.92	60.27	80.00
2004	82.36	86.53	362.39	394.84	65.27	88.18
2005	86.70	91.41	370.65	416.71	67.44	91.99
2006	89.75	94.92	375.76	379.88	67.62	92.56
2007	94.76	104.06	378.16	389.56	67.22	95.21
2008	97.95	113.14	374.00	405.60	66.12	96.53
2009	106.24	124.29	389.94	436.29	69.37	102.38
2010	109.81	129.63	399.97	448.65	67.96	101.27
2011	110.54	130.59	425.25	476.82	67.19	100.23
2012	117.25	138.33	452.30	505.73	70.51	105.07

Calendar Year	Other Intermediary		Home Health		Managed Care	
	Aged	Disabled Non-ESRD	Aged	Disabled Non-ESRD	Aged	Disabled Non-ESRD
2003	179.80	138.02	139.32	117.11	481.20	199.56
2004	205.81	165.80	159.56	133.66	537.12	233.86
2005	227.10	178.95	183.00	154.37	624.09	291.73
2006	232.17	193.37	206.78	175.63	835.76	529.27
2007	241.88	213.35	236.25	205.17	1,006.33	676.72
2008	245.10	220.65	252.04	217.40	1,197.45	823.14
2009	259.41	240.62	258.15	226.98	1,308.34	889.44
2010	246.99	240.31	259.86	231.77	1,392.73	932.58
2011	263.00	259.80	263.03	235.76	1,406.65	930.81
2012	278.68	278.67	271.14	245.27	1,451.31	965.53

[1]Average reimbursement per enrollee on an incurred basis.

Claims Processing Costs as a Fraction of Benefits

Calendar Year	Part A	Part B
2003	0.001849	0.011194
2004	0.001676	0.010542
2005	0.001515	0.009540
2006	0.001245	0.007126
2007	0.000968	0.006067
2008	0.000944	0.006414
2009	0.000944	0.006414
2010	0.000944	0.006414
2011	0.000944	0.006414
2012	0.000944	0.006414

Approximate Calculation of the USPCC and the National MA Growth Percentage for Aged Beneficiaries

The following procedure will approximate the actual calculation of the USPCCs from the underlying assumptions for the contract year for both Part A and Part B.

Part A:
The Part A USPCC for aged beneficiaries can be approximated by using the assumptions in the tables titled "Part A Projections Under Present Law" and "Claims Processing Costs as a Fraction of Benefits." Information in the "Part A Projections" table is presented on a calendar year per capita basis. First, add the per capita amounts for the aged over all types of providers (excluding hospice). Next, multiply this amount by 1 plus the loading factor for administrative expenses from the "Claims Processing Costs" table. Then, divide by 12 to put this amount on a monthly basis. The last step is to multiply by .97035 to get the USPCC for the aged non-ESRD. This final factor of .97035 is the relationship between the total and non-ESRD per capita reimbursements in 2010. This factor does not necessarily hold in any other year.

Part B:
The Part B USPCC can be approximated by using the assumptions in the tables titled "Part B Projections Under Present Law" and "Claims Processing Costs as a Fraction of Benefits." Information in the "Part B Projections" table is presented on a calendar year per capita basis. First, add the per capita amounts for the aged over all types of providers. Next, multiply by 1 plus the loading factor for administrative expenses and divide by 12 to put this amount on a monthly basis. Then multiply by .96240 to get the USPCC for the aged non-ESRD.

The National Per Capita MA Growth Percentage:
The National Per Capita MA Growth Percentage for 2010 (before adjustment for prior years' over/under estimates) is calculated by adding the USPCCs for Part A and Part B for 2010 and then dividing by the sum of the current estimates of the USPCCs for Part A and Part B for 2009.

Attachment III. Responses to Public Comments

Section A. Estimate of the National Per Capita MA Growth Percentage for Calendar Year 2010

As mentioned in Attachment I, the final estimate of the 2010 MA growth trend for combined aged and disabled beneficiaries is 0.81 percent, which is 0.3 higher than the preliminary estimate of 0.5 percent announced February 20, 2009 in the Advance Notice. The President's Budget current-law baseline was used for the preliminary estimate, and a more recent baseline was used for the final estimate. The primary reason for the higher final estimate is that the more recent baseline is based on a different set of economic assumptions. In addition, some additional program data and assumption modifications had nearly offsetting impacts.

Comment: Many commenters contend that, if rates are reduced, MA organizations will have trouble maintaining their provider networks, because they will have to pay providers less, and will have to raise premiums, increase copays and deductibles, especially in rural areas, Puerto Rico, in the case of Special Needs Plans (SNPs), PACE plans, and plans that are in direct competition with cost plans.

Response: Plans prepare bids that reflect their revenue requirements. If plan costs grow at a faster rate than increases in benchmarks, plans may choose to reduce their margins or benefits or increase premiums and copays from prior levels. Our intent here is not to hurt providers, beneficiaries or plans, but to update the rates in a way that is consistent with longstanding practice and current law.

Comment: Many commenters felt that the growth trend was underestimated, especially compared to other recent estimates. Some commenters argued that, based on the USPCCs published in the 2009 Payment Rate Announcement and the trend restatements published in the 2010 Advance Notice, trends have been running approximately 5% for the past 4 years. The −1.1% trend for 2010, they say, is materially lower than these trends.

Other commenters contended that the estimate of the Medicare growth in the Advance Notice does not track with other estimates of healthcare cost increases. On average, over the last decade, they say, Medicare spending has increased 5.8 percent annually. CMS' estimate of negative growth in the Advance Notice is significantly lower than other estimates, including other CMS estimates, such as the April 2008 announcement of MA rates (3.8%), the 2008 Medicare Trustees Report (4.6%), and a 2/24/09 *Health Affairs* Article (2.5%) written by CMS actuaries among others.

Therefore, commenters asked for more information on the calculation of the growth trend, especially in terms of projected trends in other Medicare expenditures (hospital inpatient and imaging, for instance), as well as utilization projections that may be relevant to explaining the low growth percentage.

Response: While the estimate for the national growth percentage has been succeeded by the final national growth percentage as announced in this notice, we provide the following rough derivation of the estimate announced in the Advance Notice.

In last year's rate announcement, we provided an estimate of the 2010 per capita growth rate of 3.8 percent. At that time, the relative reduction in physician fees for 2010 was expected to be 5 percent. Subsequent legislation amended the law to provide for roughly a 20 percent cut in physician fees beginning in January 2010. The difference between the originally expected cut of 5 percent and the cut of approximately 21 percent provided for under current law accounts for roughly a 3 percentage point reduction in the USPCC growth rate.

In addition, OACT has updated their databases since last year's estimates to account for new utilization and intensity trends. The updating of historical databases accounts for roughly another 1 percent change in the USPCC growth rate. The remainder of the difference between last year's estimate of 3.8 percent and the estimate of −1.1 percent is due to different economic assumptions which lead to lower provider market baskets, CPI, and other price indices used for updating payments to Medicare providers.

Some commenters pointed out what they suggested were inconsistencies in various published CMS growth rates for 2010. The 3.8 percent per capita growth rate in last year's announcement was based on the 2008 Trustees Report. The 4.6 percent cited in some comments was also from the 2008 Trustees Report. However, the 4.6 percent includes Part D expenditures whereas the 3.8 percent includes just Parts A and B. The 2.5 percent cited from the 2/24/09 Health Affairs article is also based on the 2008 Trustees Report. The 2.5 percent is growth in total expenditures, not per capita. In addition, the 2.5 percent was adjusted to account for the legislation that modified the physician fee increase for 2010, but it does not include any of the changes made from the updating of the historical data bases.

Some commenters have asked for more information on the growth trend. As has always been the practice, CMS provides detailed information on assumptions and trends in the final announcement of the payment rate update. See attachment II of this Notice.

Comment: Several commenters asked that OACT revisit several assumptions used in the growth trend. Commenters asked CMS to review economic assumptions that are utilized in the preliminary estimates in light of continuing increases in health care spending as well as the projected economic impact of the stimulus package. Other commenters wanted to better understand the analytic support behind the suggested lagged effect of a slowing economy on medical trends, specifically in the Medicare environment. Commenters said they did not believe that the slowing economy would result in reduced utilization of medical services by the Medicare population. Two commenters indicated that their MA plans have not experienced a drop in utilization of Part B drugs. One questioned whether the change in the trend is driven by a real decrease in part B drug utilization across Medicare or if it is an artifact of enrollment shifts from traditional FFS into MAPD plans, where hospital cost sharing is limited. Another has found that while unit costs are falling, utilization has continued to grow at a high rate. As a result, this commenter says, cost trends overall appear to have moderated in the past several years, but there have been no significant decreases in per member Part B drug costs.

Response: When OACT stated that new economic assumptions are one reason for a lower estimated per capita growth rate for 2010, they were specifically referencing the effect of the economic assumptions on projected unit costs. The lower economic growth rates affect various price indices such as the CPI, the hospital market basket, etc., which in turn affect projected unit costs. Utilization and intensity trends are developed from historical trends using the latest Medicare claims data available. For the latest budget baseline projections, OACT had fairly complete data for 2007 and about one-half year's data for 2008. For one service in particular, Part B physician administered drugs, the latest data showed much lower utilization compared to prior estimates. Our current data shows residual growth rates of about 7 percent per capita compared to prior estimates of about 16 percent per capita. We used this later data in developing the historical base and in developing the lower projected trend rates. Prior projections graded the trend down to about 7 percent. We now project a flat 7 percent residual factor. These trends are measured on a per capita basis, so they are not an artifact of enrollment shifts from traditional FFS into managed care plans as one commenter suggested.

Comment: Several commenters thought that CMS should follow what the commenters believed to be the assumptions in the President's Budget, and in the *Health Affairs* online article published 2/24/09, and assume in its estimate of the Medicare growth percentage that the 21% reduction in the physician fee schedule will not be implemented as provided for under current law. The assumptions in the President's Budget and the *Health Affairs* article would, in the opinion of these commenters, be a more reasonable predictor of the actual growth in Medicare expenditures considering Congress's historical actions on the issue of physician rates. Commenters suggested that CMS take historical patterns into account in making its estimate for the current year. Alternatively, commenters asked that CMS provide a citation to any provision of law that would prevent CMS from reflecting assumptions other than the reduction in the SGR provided for under current law in the development of the trend. One commenter recommends that OACT adjust utilization and coding factors in their model so that total physician reimbursement per beneficiary would be the same as if the physician schedule were increased as the commenter believes will happen, even while incorporating the reduction in the SGR provided for under current law. Other commenters suggested a transition to ensure a smooth transition to the new rates.

Response: The President's Budget and the *Health Affairs* online article both show current law projections that assume roughly a 21 percent cut in physician fees. While it is true that each shows an additional illustration of an adjustment to current law if physician fees were held constant, this is not the current law scenario. CMS's consistent interpretation and longstanding practice has been to base the projected growth percentage on the law as it exists on the date of the announcement of the payment rate update. The statute requires that the growth percentage reflect the Secretary's estimate of the projected per capita rate of growth in expenditures "under this title." We believe that the best read of this statutory language is that the growth percentage should be based on the provisions of "this title" (Title XVIII) as of the date that the rates are announced. As a result, every ratebook to date has been based on a USPCC increase estimated under the then current law. Changes to the Medicare statute are a fairly common occurrence. There have been a number of years where Medicare expenditures were expected to be reduced by pending legislative action. In those years, if we had anticipated the legislative changes in the projections, payments to Medicare Advantage plans would have been reduced. By following current law as the basis for the projection, any judgment regarding the likelihood or implications

of unknown possible law changes is removed. Plans have sometimes benefited from this practice and other times been disadvantaged by it. In each case, the advantage or disadvantage has been temporary, affecting only the first contract year following the change in law.

Comment: One commenter asked how the 2010 rates will be adjusted if Congress acts to stop the 21% physician pay cut. Commenters asked that we make efforts to incorporate the approach at another time before the 2010 contract year, such as through the bidding process. Forecasting a decrease in the current year and allowing for a correction in the future will cause unnecessary benefit cuts or premium increases.

Response: We are required by law to release the CY2010 ratebook on April 6, 2009. We expect that this will be the ratebook that will be used in the CY2010 bid preparation and plan payment. If Congress acts to override the physician pay cut, CMS will work with Congress to explore viable options for incorporating any changes in physician pay into the MA payments for CY 2010.

Comment: Several commenters asked for our legal basis for not giving MA organizations a 2% minimum increase.

Response: Section 5301 of the Deficit Reduction Act of 2005 (DRA) added §1853(k) of the Act to create a single rate book for calculating Medicare Advantage (MA) payments and applicable adjustments. The DRA also modified the methodology for updating the MA payment rates by adding §1853(k)(1)(B) of the Act. Beginning in 2007, the statute requires that the previous year's benchmarks be updated annually using the national per capita MA growth percentage as described in §1853(c)(6) of the Act. Since the statute, as revised by the DRA, no longer provides for the 2 percent minimum update, CMS cannot apply it to the 2010 MA rates. The 2 percent minimum update still applies to the end stage renal disease MA update because the statute at §1853(a)(1)(H) provides that ESRD rates are to be calculated in a manner consistent with the way those rates were calculated "under the provisions of [section 1853] as in effect before the date of enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003." The pre-2003 version of section 1853 of the Act included the 2 percent minimum update.

Comment: One commenter suggested that PACE needs its own rate book because it cannot charge premiums or deductibles and therefore cannot respond to a decrease in the rate book.

Response: PACE rates are determined in accordance with §1894(d) of the Act. PACE plans already have their own rate book in the sense that, unlike all other MA plan payment rates, IME payments are not carved out of PACE rates. Under current law, CMS does not have authority to apply a different growth percentage to the rates for PACE plans.

Comment: One commenter asked that we publish an explanation of how each kind of payment amount is determined. The commenter would especially like an explanation of which fields on the MMR are used to establish payment for an ESRD case, which fields in the bid tool are the drivers for the fields in the MMR, etc.

Response: CMS is in the process of drafting a Medicare Manual Chapter with this information. We will seek comment on the revision in the near future.

Comment: We received two comments on the Bid Pricing Tool and one regarding payments to physicians.

Response: The subject of the Advance Notice is payment to Medicare Advantage organizations. These comments are not relevant to the subject of the Advance Notice. We will respond to these comments in the appropriate forums. We will respond to comments on the Bid Pricing Tool during our Actuarial Bidding Calls this Spring.

Section B. Frailty Adjustment

Comment: One commenter believed that the current risk adjustment system does not adequately account for limitations of daily living for those MA enrollees who live in the community despite being at an institutional level of care. The commenter encouraged CMS to make changes to address payment adequacy for this population. One commenter was concerned that the revised frailty adjustment model in combination with the CMS-HCC risk adjustment model does not fully account for Medicare costs for beneficiaries comparable to those enrolled in PACE. The commenter encouraged CMS to accelerate efforts to assure that the risk adjustment model and frailty adjustment accurately reflect costs incurred by a PACE-eligible population.

Response: CMS is continuing to study ways to predict the expenditures of high cost beneficiaries enrolled in MA and PACE plans. By statute, CMS must adjust payment to PACE organizations for frailty, and has historically made a separate adjustment to PACE rates under this authority. By law, CMS must pay all MA plans, including SNPs, using the same risk adjustment methodology.

Comment: One commenter asked if the reference to the 2008 HOS-M was a typographical error and if we instead meant the 2009 HOS-M.

Response: The commenter is correct; CMS will use the 2009 HOS-M as the source of ADL distribution for the 2010 frailty scores.

Section C. Normalization Factors for the Rx Hierarchical Condition Category (RxHCC) Model

Comment: Several commenters expressed concerns that normalizing the Part D risk scores based on Part D enrollees instead of Part D eligible beneficiaries would increase premiums and be disruptive to Part D beneficiaries. Two commenters variously estimated that the proposed 2010 Part D normalization factor of 1.146 would increase monthly beneficiary premiums by amounts ranging from $2 to $9. One commenter indicated that the proposed Part D normalization factor will result in a significant reduction to the 2010 Part D risk scores that will exceed the risk score trends compared to the 2008 base year. The commenter stated that this reduction in 2010 Part D risk scores will shift costs from the federal government to Medicare beneficiaries in a way that will cause Part D premiums to increase faster than prescription drug costs.

Response: We expect that the methodology change will increase beneficiary Part D premiums, but by a relatively modest amount ($1-$2). This change is necessary to help ensure that the beneficiary premium is equal to 25.5 percent of aggregate plan payments as specified in statute.

Comment: We received a couple of comments suggesting that CMS maintain the current methodology and develop the Part D normalization factor based on Part D eligible beneficiaries. The commenters expressed concerns that the proposed methodology would result in the decreased enrollment of healthy beneficiaries. One commenter indicated that normalizing the Part D risk scores based on Medicare Part D enrollees would increase the possibility of an upward spiral in premiums and a downward spiral in enrollment as healthy beneficiaries drop out or choose not to enroll in the Medicare Part D program in the first place.

Response: We disagree with the commenters. Using the risk scores of Part D enrollees to develop the Part D normalization factor will help to ensure that the beneficiary premium remains at the appropriate proportion of aggregate plan payment: approximately 25.5 percent from beneficiary plan premiums and 74.5 percent from the government as intended by Congress. We do not expect that the increase in Part D beneficiary premiums will be large enough to create a significant disincentive for the enrollment of healthy beneficiaries, nor that it will create an upward spiral in beneficiary premiums.

Comment: Several commenters recommended that CMS phase in the proposed change in methodology to create a smooth transition from the current methodology to the proposed methodology. Commenters recommended phasing-in this proposed change over 2, 3, or 4 years to provide Part D sponsors with sufficient time to adapt to this change and reduce disruption to Part D beneficiaries. One commenter stated that implementing a transition period for this change in methodology would be consistent with the phasing in of other significant changes such as the changes to the frailty factors and the low-income subsidy (LIS) benchmarks.

Response: We do not believe that an additional transition period is needed to phase-in the new methodology for determining the Part D normalization factor. The change in our methodology for computing the Part D normalization factor is intended to ensure that the beneficiary premium remains at the appropriate proportion of aggregate plan payment. We also note that to the extent that the Part D normalization factors for contract years 2008 and 2009 were developed based on the risk scores for Part D eligible beneficiaries the normalization factors were lower than they would have been if the normalization factor had been based upon Part D enrollees. As a result, these years were, in effect, a transition period before the implementation of a Part D normalization factor based upon Part D enrollees.

Comment: One commenter recommended that CMS synchronize the proposed change to the methodology for normalizing the Part D risk scores with the development of a new RxHCC model based on historical medical and prescription drug data. The commenter indicated that both changes would significantly affect beneficiaries and therefore, should be implemented during the same contract year to minimize disruption to beneficiaries.

Response: While we appreciate the concerns expressed by the commenter, we believe that the transition to normalizing based on Part D enrollees should not be delayed an additional year.

Comment: One commenter stated that the proposed methodology does not consider the risk scores of newly enrolled or newly eligible beneficiaries and recommended that CMS adjust the Part D normalization factor to account for these enrollees. Another commenter indicated that the composition of the Medicare Part D enrollee population could change under current financial conditions due to Medicare Part D eligible beneficiaries losing their employer group benefits. The commenter asserted that the proposed 2010 Part D normalization factor could be lower if there is an increase in the number of younger (and healthier) beneficiaries who seek to enroll in Medicare Part D due to loss of employer coverage.

Response: The risk scores for newly enrolled individuals were included when determining the 2010 Part D normalization factor. We believe that it would be inappropriate to make an adjustment to the 2010 Part D normalization factor based on current financial conditions since CMS cannot accurately determine how Part D enrollment will be affected. For example, while there may be an increase in the number of healthy beneficiaries who enroll due to the loss of employer benefits, there could just as likely be a significant increase in the number of LIS-eligible beneficiaries who enroll in Medicare Part D for the same reason.

Comment: We received a couple of comments suggesting that CMS include individuals receiving drug coverage under the Retiree Drug Subsidy program in the base of Part D enrollees used to normalize the Part D risk scores. The commenters asserted that these individuals are participants in the Medicare drug program under the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) and therefore, should be included as Part D enrollees. One commenter also recommended including Part D eligible individuals enrolled in employer plans when determining the Part D normalization factor.

Response: Part D beneficiaries enrolled in employer group/union-only waiver plans (EGWPs) were included when determining the Part D normalization factor. We disagree with the commenters' recommendation that CMS include individuals receiving drug coverage under the Retiree Drug Subsidy program when determining the Part D normalization factor. These individuals are not affected by Part D risk adjustment and are explicitly excluded from the Part D payment calculations including the national average monthly bid amount and the regional LIS benchmarks. Thus, we believe it would also be inappropriate to consider these individuals when determining the Part D normalization factor.

Section D. Budget Neutrality

The Deficit Reduction Act (DRA) of 2005 specifies the components that CMS must include in the estimate of budget neutral (BN) risk adjustment factor, and codifies the phase-out of the BN factor. As in prior years, the BN factor was estimated as the difference between aggregate payments to plans using 100 percent demographic payments and aggregate payments to plans using 100 percent risk adjustment payments, expressed as a percent of risk adjusted payments. For purposes of the calculation, CMS assumes that risk payments to plans will be at the local benchmarks, adjusted for each plan's risk score. CMS calculates a single BN factor for all MA plan enrollees.

The BN factor estimate for 2010 is 0.10%. This factor was calculated based on a full BN factor of 2.0%, multiplied by the BN phase-out percentage of 5 percent. 2010 is the fourth and final year of the phase-out required by the DRA, and 5 percent of the full BN factor is applied to the rates, as the same percentage for all counties.

Section E. Adjustment for MA Coding Pattern Differences

In the Advance Notice, we proposed a coding difference adjustment of 3.74%. This adjustment was based on adjusting for three years of differential coding between MA and FFS, i.e., from 2007 to 2010. This adjustment factor was calculated based on beneficiaries who were enrolled for seven months or more in any given year, using data for three cohorts (2004-2005, 2005-2006, and 2006-2007). In the Notice, we stated our intention to update the adjustment factor with data for an additional cohort (2007-2008) for the Rate Announcement.

Our analysis of the 2007-2008 cohort showed that coding pattern differences have accelerated and this finding has strengthened our conclusion that coding pattern differences between MA and FFS are having a notable impact on payment. Because this is the first year that CMS is implementing this MA coding adjustment under the provisions of the DRA, however, CMS is taking a conservative approach and implementing an adjustment factor using a coding difference factor based on the earliest three cohorts (2004-2005, 2005-2006, and 2006-2007). CMS will consider the 2007-2008 data and later cohort data for future MA coding pattern difference factors.

CMS received a number of comments suggesting that the stayer percentage and enrollment duration factor used to calculate the MA coding pattern difference adjustment factor should be based only on beneficiaries who are enrolled in MA for a full 12 months in any given year, rather than seven months or more. CMS concurs with these comments; in finalizing the 2010 MA coding pattern difference adjustment factor, CMS is basing the stayer percentage and enrollment duration factor on 12 months of continuous MA enrollment.

Based on these changes in methodology, the final 2010 MA coding intensity adjustment will be 3.41%. Table 1 summarizes the calculation of the adjustment.

Table 1: Calculation of Difference Factor

Calculation of difference factor for 2010 Cohorts between 2004 and 2007 EDF = 2.38 Stayer percentage = 81.8%	
Weighted average of Year 2 MA risk scores	0.9806
Weighted average differences in disease score growth	0.0171
Difference factor as a percent of risk score	1.75%
Apply EDF to obtain adjustment factor (2.38)	4.16%
Adjust for percent of stayers to allow application of adjustment factor to all enrollees' risk scores (81.8%)	3.41%

Comment: A number of commenters offered CMS strong support for our determination in the Advance Notice that we were required to apply a coding pattern difference adjustment in 2010. Several commenters cited several reasons why the adjustment was appropriate. They agreed with CMS that the adjustment will improve payment accuracy, reduce unnecessary Medicare expenditures, and better assure financial neutrality between FFS and MA. Some commenters opined that the adjustment was long overdue. Commenters noted that MA organizations had an incentive to identify and code diseases, whether the diseases were treated or not, and that as a result unadjusted risk scores show MA enrollees to be sicker than they actually are. Several commenters noted that the increased MA payments resulting from coding pattern differences are in addition to the 14% payment differential resulting from MA benchmarks being set above Medicare FFS levels. One commenter noted that because physicians in FFS do not have a financial incentive to code as intensely, MA plan risk scores can increase at a greater rate than FFS risk scores, making MA enrollees look less healthy and more costly without any change in their actual health status.

Response: We concur with these comments.

Comment: Several commenters argued that the coding pattern difference adjustment was being made on the assumption that coding observed in the FFS program is accurate, and argued that CMS should not penalize MA organizations for differing from FFS coding patterns if, in fact, these FFS patterns were somehow inaccurate or inadequate. One commenter expressed concern that the adjustment would penalize many organizations for doing what CMS and Congress intended when they implemented risk adjustment payments (invest resources to improve data collection and educate providers on proper documentation). One commenter contended that a significant differential should be expected between FFS and SNPs for SNPs that code accurately. Another commenter claimed that risk scores of beneficiaries in Original Medicare are depressed by the inadequate coding of chronic conditions on FFS claims. One commenter does not believe that it is in keeping with Congressional intent for CMS to make a negative adjustment to all plans regardless of whether improper or inaccurate coding has been identified; another commenter thought that an across-the-board adjustment conflicted with Congressional intent to adjust payments for "differences resulting from inaccurate coding."

Response: As we stated in the 2009 Advance Notice, we do not assume that the coding pattern differences that we found in our study are the result of improper coding. As documented in the 2009 Announcement, CMS believes that the statutory language in the DRA provision at issue provides for a payment adjustment if CMS establishes that there are "differences in coding patterns between Medicare Advantage plans and providers under part A and B."

Given the fact that the MA payment methodology is based on fee-for-service payments, and that the risk adjustment methodology is designed to compare the risk scores of MA plan enrollees to other plan enrollees and beneficiaries not enrolled in MA plans, for this comparison to be valid, MA plans must code the way Medicare Part A and B providers do in order for risk adjustments to be valid. This means that MA organizations are coding "accurately" when they are coding in a manner similar to fee-for-service coding used on the beneficiaries to whom MA plan enrollees are being compared. In this sense, "differences" in coding patterns, regardless of the source, would make the MA plan coding "inaccurate" for purposes of implementing risk adjustment.

This reading of the word "inaccurate" is supported by floor statements made by Senator Grassley, Congressman Barton, and Congressman Thomas. Senator Grassley made the following floor statement; the other two committee chairs made very similar statements:

> "Section 5301 and the joint statement which accompanied the conference report in the Senate requiring adjustments for differences in coding patterns is intended to include adjustments for coding that is inaccurate or incomplete for the purpose of establishing risk scores that are consistent across both fee-for-service and Medicare Advantage settings, even if such coding is accurate or complete for other purposes. This will ensure that the goal of risk adjustment—to pay plans accurately—is met."

Comment: One commenter argued that, since CMS did not make adjustments in 2008 and 2009, this necessarily must mean that data available to CMS as late as April 2008 did not demonstrate that the changes in risk scores were the result of differences in coding patterns, and that CMS accordingly should not apply an adjustment based on 2007 to 2008 data. Under this argument, CMS cannot now state that a change in risk score trends can be conclusively attributed to differences in coding patterns based on pre-April, 2008 dates. This commenter argued that CMS can adjust the capitation rates only to compensate for that one year of differential. In other words, the commenter argued that CMS implicitly had previously found that prior years of risk score trends can be explained based on factors other than coding patterns, and thus should not rely on the data to make an adjustment. Another commenter opined that the information in the 2010 Advance Notice fails to present substantive new evidence free of technical concerns.

Response: While, in previous years, CMS has delayed the application of a coding patterns difference adjustment in order to conduct further research, this did not mean that we had concluded that risk score trends were caused by factors other than coding pattern. Our most recent analysis – discussed below – has resulted in our decision to apply a coding pattern differences adjustment in 2010. We believe that, having concluded that the differences we have observed are in fact attributable to differences in coding patterns, it is appropriate to use data from the beginning of the program, as deemed necessary to better ensure appropriate and accurate payments.

Comment: Several commenters, noting that CMS had indicated in last year's Announcement that we would use the results from the risk adjustment data validation (RADV) audits to inform our assessment of whether risk score differences were driven by coding pattern differences, rather than by the health status of MA enrollees, inquired about our findings and how they supported the coding pattern difference adjustment. A number of commenters were concerned that CMS would be making an adjustment twice for the same coding effects if it applied both a coding pattern difference adjustment and made adjustments as a result of its RADV audits. Several commenters expressed concern that a prospective coding intensity adjustment in combination with future 2010 risk score audits could result in duplicate adjustments. A few commenters asked if CMS was adjusting the 2007 risk scores used in developing the MA coding pattern difference adjustment factor for adjustments made as a result of the RADV audits. Some commenters suggested that, instead of implementing a coding pattern difference adjustment, we rely on the RADV audits. They contended that the current risk score validation audit process was the appropriate system to determine coding accuracy and payments should only be adjusted for the subset of plans in which coding problems can be documented.

Response: CMS' strategy for determining the correct MA coding pattern difference for 2008 and 2009 was to ensure that we thoroughly understood the dynamics behind the coding pattern differences between MA and FFS. In this spirit, we agreed to assess whether the new annual medical record audits would be able to inform our study of MA coding pattern differences. Medical record audits serve the purpose of determining whether diagnosis codes submitted to CMS for risk adjustment payment purposes have a basis in the documented medical record, while our study of MA coding pattern differences has resulted in a better understanding of the differential growth in the number of diagnosis reported by MA plans and FFS providers. The results of the medical record audits supported our approach to calculating the MA coding pattern differences adjustment by failing to show a systematic correlation between coding pattern differences and errors in the reporting of documented coding.

Comment: Several commenters argued that CMS was not authorized to make a retroactive coding pattern difference adjustment. Another commenter asked if the adjustment would be used for 2010 alone, or would also be used to make retroactive adjustments. Several commenters opined that the DRA did not require a retroactive adjustment and that, since the MA payment methodology is fundamentally a prospective system, that absent an explicit statutory direction to impose a retroactive adjustment, CMS should not apply adjustments it now deems appropriate for 2008 and 2009 into 2010 payments. A couple commenters argued that the DRA established coding intensity to be a single annual adjustment made for each coverage year, if supported by the data, and felt that the MA coding pattern difference adjustment described in the Advance Notice was intended to retroactively apply an adjustment for 2008 and 2009. One commenter felt that this was not the intent of Congress and the other commenter felt that this adjustment would be made for years when CMS found that it did not have adequate information to justify an adjustment.

Response: CMS is not making a retroactive adjustment. We estimated the cumulative coding pattern difference in MA and FFS stayers' disease scores in 2010. We calculated this adjustment by applying a three-year enrollment duration factor (EDF) to the annual average difference in disease score growth, essentially calculating the adjustment to account for three years of coding pattern differences. As a result, the coding adjustment is an estimate of how much lower risk scores would be in 2010 if they rose at the same rate as FFS risk scores over the period 2007-2010. We note that some commenters supported using six years (2004-2010) in the calculation based, taking into account all measured differences since risk adjusted payments were begun.

Comment: One commenter believed that using a 2-year stayer cohort captures a large proportion of MA stayers that are new to MA with no coding history in year-one with potentially larger coding increases in the second year as the plan gains accurate diagnosis data. Another commenter opined that the calculation of the adjustment does not seem to acknowledge a trend observed by MA organizations in which a beneficiary's risk score increases more quickly during the second year that the beneficiary is enrolled in an MA plan and that, therefore, the enrollment effect that the agency attempts to isolate may be larger than assumed in the notice. One commenter suggested studying 3−and 4-year stayer cohorts; they also recommend that CMS study the cohort of individuals that would not qualify as stayers due to being in MA or FFS for only a single year over the examined time period.

Response: The method by which CMS constructs its two-year stayer cohorts ensures that the experience of beneficiaries newly enrolled in MA are not included in the difference measurement. Requiring enrollees to have been enrolled for thirty months results in first-year disease scores that were coded exclusively by either MA plans or FFS providers and, thus, CMS is comparing year-after-year disease scores that were coded exclusively by a single sector. These cohorts will capture some enrollees' second and third years in MA, but it will also capture differential disease score changes for enrollees who have been enrolled in either sector for longer periods of time. Therefore, the difference factor is calculated over all beneficiaries who have been enrolled in a sector over varying periods of time, thereby obtaining an average difference across all continually-enrolled beneficiaries.

The use of cohorts over more than two years would result in smaller cohorts of non-representative beneficiaries in that they were alive much longer and they were enrolled in their respective sector for longer than beneficiaries in the two-year cohorts. For example, beneficiaries who are in MA for at least 3 or 4 years are not identical to those who are enrolled for at least two years. Two-year cohorts capture the information needed while keeping the largest number of enrollees in the cohorts.

Comment: One commenter stated that, since CMS acknowledges that a significant portion of Medicare beneficiaries who join MA plans are switching from FFS, and that the vast majority of beneficiaries joining FFS are newly eligible and have very low risk scores, basing an adjustment of risk scores on a comparison of FFS to MA enrollees will overstate the differences between the two groups.

Response: CMS constructs the cohorts in such a way that "joiners" and "leavers" – beneficiaries who switch from one sector to the other – are excluded from the population on whom we calculate the difference factor. The cohorts only include beneficiaries who have been in MA or FFS for several years – at least 30 months.

Comment: A couple commenters expressed interest in having CMS recognize that MA plans' effort to "catch up" with FFS in the coding pattern difference adjustment factor. One commenter felt that changes in coding due to "catch up" fell outside the purview of the DRA and strongly suggested that the agency consider changes to the calculation of the adjustment to exclude "catch up" to more directly address the statutory requirement. Another commenter felt that, after seeking to take "catch up" into account last year, CMS should recognize it in the 2010 adjustment factor. One commenter offered an example of a way to adjust for "catch up" that involved applying a ratio of the amount by which the average MA risk score was below the FFS 1.0 when risk adjusted payments started, relative to the amount by which the average MA risk score was greater than the FFS 1.0 in later years.

Response: While we are using cohorts starting with 2004-2005 to calculate the average difference factor, we are only taking into account three years of experience in the enrollment duration factor (EDF). Any catch up occurring in the first three years (2004-2007) of risk adjusted payments is not factored into the duration factor and, therefore, not included in the coding pattern difference adjustment. In other words, by adjusting the annual average difference by the average enrollment over the past three years, CMS is only adjusting 2010 risk scores by

the cumulative effect of coding pattern differences over three years, and not over all six years since the start of risk adjusted payments.

Comment: One commenter stated that the enrollment duration factor (EDF) seems intended to reflect the number of beneficiaries to whom a coding intensity adjustment would have been appropriately applied in 2008 and 2009 (if the agency had made a determination to apply such an adjustment in time to affect payments in those years) and prospectively in 2010. Another commenter questioned why CMS was using an enrollment duration factor and felt that an adjustment based on the disease scores would take differences into account. This commenter argued that CMS had not established that there was a link between length of MA enrollment and higher risk scores or explained how the EDF meets with the intent of the DRA.

Response: The enrollment duration factor (EDF) is used to adjust the annual difference factor in order to approximate the experience of stayers in 2010. In other words, the EDF creates a single year, prospective estimate of cumulative difference between MA and FFS disease scores (not just the marginal growth in the difference from the previous year). A less nuanced way to calculate the cumulative difference would simply be to multiply the average annual difference (the difference factor) times the number of years being taken into account. The EDF allows CMS to adjust the annual average difference by the estimated enrollment experience of the beneficiaries in MA during the payment year.

Comment: Several commenters recommended that the adjustment incorporate an analysis of coding pattern differences in four cohorts available at the time the Announcement is published: 2004-2005, 2005-2006, 2006-2007, and 2007-2008. They felt that doing so would permit the agency to more precisely determine the appropriate magnitude of the adjustment while considering data from the 2004-2005 data collection year, when risk adjustment was first a significant component of MA plan payments. One commenter felt that, since the coding difference experience seems to be volatile and unpredictable, using four cohorts would add some stability to the calculation. They cited OACT's use of 5-year moving averages of the ratio of the county FFS per capita costs to national per capita costs when estimating the FFS costs in each county.

Response: Because 2010 is the first year that CMS is applying the MA coding pattern difference factor under the provisions of the DRA, we have decided to take a conservative approach and calculate the difference factor using only the first three cohorts, as described in the Advance Notice. After applying the new enrollment duration factor (EDF) (see below), the MA coding pattern difference factor for 2010 is 3.41.

Comment: Several commenters disagreed with the use of seven months enrollment in the prior year to determine whether someone is a stayer for purposes of the enrollment duration factor (EDF) and felt that twelve months would be a more appropriate measure. Commenters contended that an MA organization needed at least one full year of enrollment experience with a beneficiary to credibly calculate a member's risk score and that 12 months was in alignment with the idea that the adjuster should be applied to "stayers." One commenter understood that the EDF makes the assumption that the adjustment factor would be the same for members with between 7 and 30 months of plan membership, and believed that this was highly unlikely, and that the effect of relative coding intensity are likely to increase over time. One commenter asked

how CMS had validated that a 7 month time period is sufficient to capture the HCC diagnoses for a member.

Response: The objective of the enrollment duration factor (EDF) is to capture the average number of years a population of enrollees has had their diagnoses submitted by the MA sector; for this factor, we are not trying to capture change in disease score, but exposure to MA coding patterns. In response to industry concerns regarding the adequacy of seven months of enrollment in capturing and reporting enough diagnoses codes to establish a pattern, CMS will use twelve months in previous years as a criteria for calculating the EDF. Using twelve months, applied to the same time period as in the Advance Notice – 2007-2010 – the EDF that CMS will use in calculating the adjustment factor will be 2.38.

Comment: One commenter noted that plans with more turnover will have lower EDFs. Other commenters asked if an analysis had been done to see how much variance there is in enrollment duration from plan to plan.

Response: CMS recognizes that enrollment duration may differ among plans. Because we have determined that it is most appropriate to apply an industry-wide adjustment, the EDF used in the calculation will, by its construct, be an industry average.

Comment: One commenter wanted CMS to use the same definition of "stayer" when determining the stayer percentage as we do when developing the cohorts used for measuring the coding pattern difference (30 months of continuous enrollment).

Response: Because CMS will apply the adjustment to all enrollees' risk scores, not just stayers, we need to reduce the adjustment proportionately so that the aggregate effect is the same, whether we applied the adjustment to stayers only or to all enrollees. To calculate the actual adjustment to use in payment, we reduce it by the proportion of stayers in MA for the most current period available. In applying the twelve month enrollment criteria in calculating previous-year enrollment for the EDF, we also changed the calculation of the stayer percentage that we will use to reduce the adjustment factor for application in payment. The stayer percentage we will use is 81.8%.

Comment: Commenters suggested a number of additional factors that they thought CMS should adjust for in calculating the coding pattern difference adjustment factor. The additional factors suggested are: age, gender, originally disabled, Medicaid eligibility, institutional status, hospice status, beneficiaries with multiple chronic conditions, duration in managed care, health status, type of plan, plan size, socio-economic status, racial/ethnic differences, and enrollment in the Veterans Affairs or Department of Defense health programs. A number of commenters requested that CMS adjust for regional differences in FFS coding differences. One commenter felt that plans with a high proportion of recent FFS members or in regions where MA coding changes are not greater than FFS are disadvantaged. One commenter suggested that possible anti-selective effects in MA were resulting in an overestimate of MA's rising risk scores. One commenter asked how CMS knew that measured differences in coding changes between MA and FFS were really coding pattern changes and not changes in health status.

Response: CMS did take into account factors that we believed would have an important influence on the rate of change in disease score growth between MA and FFS. For example, we adjusted the difference factor (the annual average difference in disease score growth between MA and FFS) for age and survivor status variations between MA and FFS. Because a greater proportion of disabled beneficiaries are enrolled in FFS than in MA, and because disabled beneficiaries risk scores tend to grow more slowly than aged beneficiaries' risk scores, adjusting for age reduced the differences in disease score growth between the two sectors. In addition, the enrollment duration factor (EDF) takes into account the average duration of enrollment in the MA sector of those who are present in the year prior to the payment year. We believe that age and survivor status are correlated to the differential change in disease scores between MA and FFS, and that duration of enrollment in the MA sector directly affects how long a beneficiary's disease score has been exposed to this differential. It is not clear that other factors would affect differential changes in disease score.

Comment: One commenter inquired about which version of the CMS-HCC model we used to calculate the coding pattern differences.

Response: CMS used the version of the CMS-HCC model that was used in payment from 2004 through 2006 to calculate the difference factor. We ran all cohorts through the same version of the model, so that measurements of differences would not be affected by model changes.

Comment: One commenter wanted CMS to establish an appeals mechanism that would allow plans to demonstrate that their coding patterns are correct.

Response: As discussed above, the MA coding pattern difference adjustment is not adjusting for coding that is incorrect, but for coding that differs from FFS and is therefore inaccurate for payment. Further, the industry-wide adjustment factor will not be modified for individual plans.

Comment: In the 2010 Advance Notice, CMS invited comments on the decision to adjust for differences in disease growth for the three-year period prior to 2010, as well as on alternative approaches involving a greater or smaller number of years. A number of commenters wanted CMS to adjust for one year instead of three. One commenter states that using the annual rate going back to 2004 would the most reasonable approach. One commenter stated that CMS should make an adjustment on a prospective basis only, which they took to mean a single year adjustment. Several commenters argued that the DRA requires CMS to adjust for all differences in coding patterns, and suggested that CMS should adjust for all measured and projected differences, including those attributable to the excluded period for 2004-2007. Another commenter noted that, while one alternative was to make an adjustment for all years during which comprehensive risk adjustment has been in place – that is, 2004 to 2010 -- on balance they were inclined to think that the methodology described in the Advance Notice was appropriate.

Response: The difference factor, which takes into account coding pattern differences from 2004 to 2007, is an average annual difference in the growth of disease scores between MA and FFS. Based on the data that we have, it is clear that coding pattern differences have continuously grown since 2004 and that 2010 risk scores will incorporate repeated years of coding pattern differences. We have decided to maintain for 2010 the use of three cohorts as proposed in the Advance Notice.

Comment: One commenter expressed concern that the MA coding difference adjustment would reduce the disease score, causing a greater portion of the risk score to be based on demographic factors, which would introduce limitations and problems of the old AAPCC approach.

Response: CMS is calculating the MA coding pattern differences adjustment factor based on disease scores because that is the portion of the risk score that plans have control over. However, the adjustment is being applied simply as an overall proportional reduction to the risk scores, leaving the proportion of the risk score that is determined by diseases intact.

Comment: One commenter suggested that FFS normalization and MA coding pattern difference adjustment should be subtractive, not additive, or plans will be penalized twice for coding practices observed in the FFS program.

Response: The two adjustments address two different measures of coding changes: the FFS normalization factor adjusts risk scores for underlying changes in FFS coding and the MA coding pattern difference adjustment factor adjusts for coding patterns above and beyond the FFS changes.

Comment: One commenter asked if the three-year adjustment discussed in the Advance Notice would lead to a restatement of the historical budget neutrality adjustments for those years.

Response: As discussed above, the 2010 MA coding pattern differences adjustment is not a retroactive adjustment, but an estimate of the cumulative difference between MA and FFS stayers' disease score in 2010. CMS will take the projected reduction in 2010 risk scores into account when calculating the 2010 budget neutrality factor.

Comment: One commenter expressed concern that the extent of the adjustment may cause health plans to consider withdrawing from the market given the short time to prepare the 2010 bids. A couple commenters expressed concern that the proposed across-the-board 3.74% reduction would have a major negative effect and is a departure from last year's proposal to gather plan-specific coding changes through targeted audits.

Response: While we appreciate that the application of the MA coding pattern difference adjustment will need to be taken into account in MA plan bids, we believe that the final 3.41 percent adjustment is an appropriate correction that will result in more accurate payments. In addition, the adjustment is consistent with the statutory requirement that we study whether there are different diagnoses coding patterns between MA and FFS and, if we find differences, that we adjust MA risk scores accordingly.

Comment: A number of commenters did not support an industry-wide coding pattern difference adjustment and either wanted CMS to implement a more targeted adjustment or delay or phase in the adjustment. Some commenters wanted CMS to apply the coding pattern difference adjustment to a defined subset of plans that fail the risk validation audit or plans with larger differences in risk score growth. Commenters felt that an industry-wide adjustment would be unfair to plans that have under-coded and create an incentive of promoting coding intensity by those plan that have previously under-coded. Commenters suggested that CMS use a plan-specific EDF, or apply an adjustment in tiers to take into account different levels of turnover. A few commenters felt that SNPs would be at a disadvantage because there was an increased

volume of encounters for their members and because the percent of stayers was likely to be less than the average MA plan rate. A number of commenters supported an industry-wide adjustment; one commenter cited the following advantages: (1) industry-wide adjustments were the practice in other sectors of Medicare, (2) all MA plans should be paying close attention to coding and documentation and it was reasonable to expect coding changes to be widespread, (3) coding behavior of a particular provider does not necessarily affect just one plan, (4) beneficiaries move from one plan to another and retain the diagnosis codes assigned; and (5) when using MA data, a system-wide adjustment will ensure that baseline information is accurate.

Response: In addition to the reasons given by commenters, CMS was also persuaded by comments on the 2009 proposal – which proposed an adjustment on a subset of contracts – that an industry-wide adjustment provides an even playing field when plans compete: newer plans may be able to code just as intensely as older plans, but would not have been in existence long enough for CMS to calculate an adjustment factor for them. Further, applying an adjustment factor to a subset, or tiered adjustment factors across contracts, results in cut offs that can potentially appear unfair, especially if one contract falls just above and another just below a cutoff. To avoid these problems, as well as for the reasons cited by the more recent comments, we have decided that an industry-wide adjustment is the most efficient and effective approach to making an adjustment for MA coding pattern differences.

Comment: One commenter suggested that CMS should review and compare samples of MA plan member medical records with a FFS control group and that the difference in risk scores derived from the medical records could support an across-the-board coding pattern adjustment in a subsequent year.

Response: While a comparison of diagnostic coding captured on medical records in MA and FFS would indicate differences in documentation of diagnoses coding in the medical record, there are two key shortcomings of this approach in calculating an MA coding pattern difference adjustment factor. The key comparison in studying the impact on payment of differences in coding patterns between MA and FFS is the codes that are submitted and codes that are reflected in the model. In addition, CMS is taking into account changes in disease scores over time and taking a sample of medical records will not provide that information.

Comment: One commenter did not agree that CMS should calculate coding pattern differences for each individual and, instead, recommended that the difference be calculated by dividing the MA growth in risk scores by the FFS growth in risk scores for each age and survivor status grouping in each cohort.

Response: CMS did not calculate individual differences in disease score growth; we calculated the difference between the average growth in disease scores among MA stayers and the average growth in disease scores among FFS stayers for each cohort. This difference calculation was adjusted for each age and survivor grouping in each cohort. It is not clear how CMS would use the ratio of MA growth to FFS growth in applying an adjustment.

Comment: A number of commenters requested that CMS release all relevant information and calculations concerning the MA coding pattern difference adjustment factor in order to make sure that the adjustment is fully explained and transparent to the public to the same extent that

they are for the FFS program through regulation. A couple commenters believed that CMS has not provided enough transparency in the methodology used to calculate the coding pattern differences for the public to properly evaluate the calculation CMS has completed.

Response: We would be happy to provide addition information about the steps and results of our MA coding pattern differences analysis to interested stakeholders.

Section F. Encounter Data Reporting

Comment: One commenter encouraged CMS to continue its efforts to collect additional data from MA plans, including data relating to all medical encounters between beneficiaries and providers, to improve the accuracy of the risk adjustment system, and to measure the effectiveness and integrity of MA plan benefits.

Response: CMS will release guidance in 2009 regarding the collection and use of MA encounter data. As we discussed in the final IPPS rule in August 2008, CMS will provide opportunity for stakeholders to provide feedback on our plans for implementation.

Comment: One commenter expressed concern about the burden of collecting and reporting encounter data and asked that plans be given a long lead time to implement this new requirement; the commenter suggested that CMS phase in the changes.

Response: CMS is sympathetic to plans' desire for adequate lead time to implement encounter data requirements. We will explore options for the start up of reporting and will provide opportunity for feedback on our approach.

Section G. IME Phase Out

Comment: Related to CMS 4138-IFC −42 CFR 422.306(c) and the phase-out in MIPPA of the IME portion of the MA capitation rate, one commenter asked how a plan calculates the phase-out of the IME in a county and the role of 0.6% in determining the phase-out.

Response: To help plans identify the impact, CMS has separately identified the amount of IME for each county rate in the 2010 rate book. We intend to publish the rates with and without the IME reduction in future years as well. The role of 0.6% is that it is the maximum reduction possible to the FFS per capita costs in a county in 2010.

Section H. Location of Network Areas for PFFS Plans in Plan Year 2011

Comment: A commenter questioned CMS's interpretation of the statutory definition of "having" a network-based plan to mean offering a plan "that is generally open to enrollment," and asked CMS to clarify whether such plans are "open to enrollment" as of January 2009.

Response: First, CMS believes Congress intended to eliminate non-network PFFS plans only in those areas where at least two coordinated care plan options are available. Limited enrollment

plans are not generally available to current PFFS plan enrollees, and we believe should not be counted under the two plan test. We therefore excluded plans that are not generally open to enrollment from our analysis, such as employer group health plans and special needs plans. As required by MIPPA, for purposes of identifying the location of the network areas for plan year 2011, we determined whether at least two generally available network-based plans with enrollment as of January 1, 2009 exist in each county (or partial county in some cases). Therefore, for a network-based plan to be counted in our analysis, the plan was required to have at least 1 beneficiary enrolled in the plan as of January 1, 2009.

Comment: Three commenters recommended that CMS interpret the definition of "network area" to mean an area with at least two network-based plans that are offered by different MAOs in order to ensure meaningful choice for Medicare beneficiaries. Two of the commenters were concerned about the creation of regional monopolies if CMS interprets the definition of network area as an area with at least two network-based plans, where the plans can be offered by the same MAO.

Response: MIPPA defines "network area," for a given plan year, as the area that the Secretary identifies (in the announcement of the risk and other factors to be used in adjusting MA capitation rates for each MA payment area for the previous plan year) as "having at least 2 network-based plans with enrollment as of the first day of the year in which the announcement is made." "Network-based plan" is defined in MIPPA as (1) an MA plan that is a coordinated care plan as described in section 1851(a)(2)(A)(i) of the Act, excluding non-network regional PPOs; (2) a network-based MSA plan; or (3) a section 1876 cost plan. We interpret "having at least 2 network-based plans" to mean that there are at least 2 plans, which meet the definition of a network-based plan, that are offered by the same MAO as well as plans offered by different MAOs. We believe this interpretation is consistent with the statutory requirements for identifying network areas.

Comment: A commenter understood that the network-based plans with enrollment as of January 1, 2009 are used to determine the location of network areas for PFFS plans in CY 2011 as required by MIPPA, but wanted CMS to address what would happen if plans in this data group leave the market. The commenter asks whether this would result in a new list being issued?

Response: The methodology for identifying the location of network areas is specified in the statutory definition of a "network area." MIPPA defines "network area," for a given plan year, as the area that the Secretary identifies (in the announcement of the risk and other factors to be used in adjusting MA capitation rates for each MA payment area for the previous plan year) as "having at least 2 network-based plans with enrollment as of the first day of the year in which the announcement is made." We accordingly have used enrollment data as of January 1, 2009 to identify the network areas for plan year 2011. The methodology we used to identify the list of network areas for plan year 2011 in this notice is consistent with statutory requirements. However, should the circumstances reflected in this year's payment notice change such that an area no longer meets the standard of "having at least 2 network-based plans" in the area, CMS will determine at that time how this would affect PFFS plans in that area if bids have not yet been submitted for the subsequent year (e.g., if there are fewer than 2 network plans in the area on January 1, 2010).

Comment: Two commenters recommended that CMS evaluate the provider contracting data for regional PPOs in areas where a regional PPO's network structure is the deciding factor in determining whether the area is a network area. One of the commenters noted that CMS is relying on data from regional PPOs on how they meet access requirements in their service areas, without any validation of the regional PPOs' responses. The commenter is concerned that regional PPOs will face no negative consequences for over-reporting their network breadth and get a competitive advantage by excluding competing PFFS plans.

Response: Regional PPOs meet the definition of a network-based plan only in those areas where the plan is meeting access requirements through written contracts with providers. MIPPA requires us to identify the location of network areas for plan year 2011 in the *Announcement of Calendar Year (CY) 2010 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies.* Due to the limited amount of time we had available prior to the release of the list of network areas for plan year 2011, we used data in our analysis that was obtained directly from the regional PPOs on how these plans are meeting CMS' network adequacy requirements in each of the counties in their service area. The data reported to us by the regional PPOs is the best available data we have for identifying the location of the network areas for plan year 2011. We believe that using this data is appropriate for identifying the location of plan year 2011 network areas. CMS will conduct network adequacy reviews of the regional PPO access data on an annual basis in future years.

Comment: A commenter stated that network-based plans with enrollments of 10 or fewer members should not meet the requirement of a network-based plan as these plans do not appear to offer a compelling choice for seniors.

Response: MIPPA defines "network area," for a given plan year, as the area that the Secretary identifies (in the announcement of the risk and other factors to be used in adjusting MA capitation rates for each MA payment area for the previous plan year) as "having at least 2 network-based plans with enrollment as of the first day of the year in which the announcement is made." We interpret the phrase "with enrollment" to mean that a network-based plan is required to have at least 1 beneficiary enrolled in the plan in order to be counted for purposes of identifying the location of the network areas. We believe that interpreting "with enrollment" any differently would result in an artificial threshold and would not be consistent with the statute.

Section I. Adjustment to FFS Per Capita Costs for VA-DOD Costs

Comment: One commenter noted that 54 counties have a rate increase of greater than $12.50 per person per month. The commenter believes that $12.50 is not a negligible amount. The commenter would like CMS to provide more information as to why the 54 counties should not receive a rate adjustment. Specifically, the commenter wanted details on whether in these 54 counties, differences observed between the two populations appear to be normal, random variations and not indicative of true underlying differences of the FFS costs between the total and non-vets.

Response: We agree that a $12.50 adjustment is not a negligible amount. As discussed in the Notice, however, the observed variations are not attributable to a true underlying difference

between the veteran and non-veteran populations, but due to normal, random fluctuations. For example, the 54 counties identified with large differences have less than one-sixth of the average level of enrollment. Not surprisingly, the effect of a random fluctuation is more significant when smaller sample sizes are considered.

Comment: One commenter argued that the DOD data should help determine whether the effects are random rather than systematic. The commenter believes that if counties have substantial, nonrandom difference when the VA and DoD data are analyzed, adjustments should be made to county rates.

Response: We agree that the effects of DoD eligible enrollees need to be evaluated. We continue to work with the Department of Defense to obtain the necessary data to support this analysis. Recently the DoD published a Privacy Act notice which will allow us access to their data. Please refer to paragraph 8(d), "Notice to alter a system of records." 74 FR 400-4006 (January 22, 2009).

Comment: One commenter requested that CMS include the cost of care received at VA/DoD healthcare facilities in the calculation of MA benchmarks as required by law. By excluding the cost of care received at VA and DoD facilities, the commenter believes CMS is underestimating FFS spending which inappropriately reduces MA benchmarks. The commenter argued that geographic areas with higher numbers and concentrations of VA/DoD facilities will be impacted the hardest by excluding these costs. Congress required CMS to incorporate these costs for years beginning in 2004 and CMS has yet to implement this factor. In the Advance Notice to CY 2009 rates, the commenter states, CMS proposed an option to include VA/DoD costs in the calculation of MA benchmarks. Although the proposed methodology presented some problems, the commenter encourages CMS to continue to explore alternative ways to collect the necessary data to incorporate this required adjustment.

Response: As outlined in the CY 2010 Advance Notice, we evaluated VA data using the methodology included in the CY 2009 Advance Notice and concluded that there is insufficient evidence to incorporate a VA adjustment into the rate making process for 2010. This conclusion was based on the view that the differences observed between the veteran and non-veteran populations appear to be normal, random variations and not indicative of true underlying differences of the FFS costs between the two populations. CMS will continue to study this issue. We are working to obtain data from the DoD that will support a study similar to the VA analysis.

Section J. Calculation and Source Data of MSP Factor

Comment: Commenters requested that plans have a mechanism to request correction to the CMS data where inaccurate or inconsistent information is identified in the COB file.

Response: Plans will have access to the Electronic Correspondence Referral System (ECRS). When a discrepancy is noted, there will be a mechanism to initiate corrections to the CMS data. ECRS is an electronic interface between plans and the COB Contractor. ECRS will allow MSP representatives at plans, FFS contractors, and authorized CMS RO to complete various online forms and electronically transmit requests for changes to existing CWF MSP information, inquire concerning possible MSP coverage, and document transactions to the COB contractor.

ECRS will allow plans to submit post enrollment transactions that change or add to information posted by those plans.

Comment: Commenters requested details on how payments will be adjusted as a result of plan submitted corrections.

Response: Starting January 2010 we will adjust payments to account for beneficiaries with working aged and disabled Medicare Secondary Payer (WA/WD MSP) status.

Comment: Several commenters felt that COB data was not accurate because a lot of new data are being entered due to the implementation of Section 111 of MMSEA this year and plans will not have a chance to populate the database in time for a 2010 payment calculation and that the data are not sufficiently reliable. Commenters asked that CMS study the accuracy of the COB data before going forward with this policy.

Response: CMS believes the COB data submitted by other insurers and payers is the most accurate source of other coverage information and CMS is working with the COB contractor to establish additional procedures to validate and update COB data. We also expect plans to initiate changes to MSP status in the event they become aware of them. Please see the 2010 Call Letter for ongoing Part D plan sponsor beneficiary notification and data correction requirements. We will send the COB file to plans on a daily basis whenever changes to data are processed by CMS systems. We also plan edits to the MARx system and will undertake additional operational initiatives to further eliminate problems with the reliability of the data.

Comment: One commenter asked that CMS estimate the impacts of changing the MSP approach before moving forward with the elimination of the current method for collecting MSP data.

Response: CMS will post to HPMS estimated MSP impacts for each plan as part of the risk score information for the 2010 bidding cycle.

Comment: Several commenters stated it was too late in the process to stop the MSP survey for 2009 reporting.

Response: The COB contractor will maintain the COB data for MSP beneficiaries. Plans will no longer be responsible for the MSP survey for MA beneficiaries for Part C beginning in 2009 for payment year 2010. (Please see the 2010 Call Letter for ongoing Part D plan sponsor requirements for beneficiary notification and data corrections related to COB data in CMS systems.) Each year in the middle of February CMS announces changes to payment policy in the Advance Notice. Plans make their own business decisions as to when to begin administering the MSP survey and when to initiate implementation of other aspects of the MA program. Plans should keep in mind that although the survey is not required in 2009 for 2010 payment, data derived from completed surveys may be helpful to plans in initiating updates of MSP information in ECRS.

Comment: One commenter felt that CMS should revert to the MSP process in place prior to the Spring 2009 software release for submission of MSP data in 2009, as it is not necessary for plans to expend significant resources to update their IT coding systems in 2009 if they will be obsolete in under a year.

Response: The requirements laid out in the Spring 2009 software release regarding MSP will no longer be necessary, as MA plans will no longer be required to submit the survey for Part C in the summer/fall of 2009.

Comment: A few commenters requested details about the process used to separate WA/WD beneficiaries for MA payment from other COB data.

Response: We will adjust MA payments for Working Aged/Working Disabled MSP status. These beneficiaries have a special flag in the COB data that we will use to adjust payments. Plans should report all MSP statuses, such as workers' compensation and auto-liability, to ECRS so that other plans and original Medicare know of primary payers.

Comment: One commenter requested that CMS increase the USPCC for MA plans as if Medicare paid primary with respect to the working aged/disabled since MA plans have benefit payments reduced when they have working aged members.

Response: The coefficients in the CMS risk models do not account for the impact of individuals with MSP. The standard rate is raised by the risk model as if Medicare was paying primary for all MA beneficiaries. The MSP adjustment is then used to reduce the rate when an individual is WA/WD. In this way the adjustment is applied to the appropriate individuals and plans rather than to all individuals and plans.

Comment: One commenter asserted that many SNPs have a small number of working aged or working disabled beneficiaries or none at all. The commenter was concerned that an industry-level MSP factor based on averages from a common file would not inaccurately reflect the proportion of working aged and working disabled in SNP plans and would inaccurately reduce payments.

Response: We agree with the commenter that an industry level factor would not result in the most accurate MA payments since some plans may have more WA/WD beneficiaries than others. As stated in the Advance Notice, we plan to do an MSP adjustment that reflects the MSP status of the beneficiaries in each plan. We believe this will result in the most accurate MSP adjustment for all plans and enrollees.

Section K. Medicare Part D Benefit Parameters: Annual Adjustments for Defined Standard Benefit in 2010

Comment: We received a comment requesting clarification regarding whether the deductible for Part D non-full benefit dual eligible beneficiaries receiving the full subsidy with resources between $6,600 and $11,010 (individuals) or between $9,910 and $22,010 (couples) is $62.00 or $60.00.

Response: The deductible for Part D non-full benefit dual eligible beneficiaries receiving the full subsidy with resources between $6,600 and $11,010 (individuals) or between $9,910 and $22,010 (couples) is $63.00. We thank the commenter for identifying this error in Table III-1, Updated Part D Benefit Parameters for Defined Standard Benefit, Low-Income Subsidy, and Retiree Drug Subsidy. Please see Attachment IV for the revised Part D benefit parameters.

Comment: Two commenters requested that CMS describe and explain the methodology for calculating the 1.70% correction to the 2009 annual percentage increase in the Consumer Price Index (CPI) for prior year revisions. One commenter indicated that based on the calculation methodology described in the 2009 Advance Notice (1.0494/1.026 – 1), it appears that the correction to the 2009 annual percentage increase in the CPI should be 2.28% instead of 1.70%. The commenter asked that CMS provide an explanation if the methodology is different from the methodology provided in the 2009 Advance Notice.

Response: The methodology for calculating the revisions to the estimates of prior years' annual percentage increases in average expenditures for Part D drugs per eligible beneficiary and CPI are unchanged from 2009. An error was identified in a component of the calculation of the revisions. The updated prior year revisions percentage and annual percentage increase for 2009 are −1.07% and 4.66%, respectively, for the average expenditures for Part D drugs per eligible beneficiary. The updated prior year revisions percentage and annual percentage increase for 2009 are 2.28% and 2.65%, respectively, for CPI. Please see Attachment IV for the revised table.

Comment: Commenters requested clarification regarding whether the annual percentage trend for September 2009 in Table IV-2, Cumulative Annual Percentage Increase in CPI, should be expressed as a factor rather than a percentage.

Response: The value for the annual percent trend for September 2009 in this table should be 0.36%. We thank the commenters for identifying this error in Table IV-2 in the 2010 Advance Notice. Please see Attachment IV for the revised table.

Section L. Reporting Drug Costs When Contracting with a Pharmacy Benefit Manager (PBM)

Comment: One commenter indicated that requiring Part D sponsors to use the amount paid to the pharmacy or other provider to report drug costs and determine beneficiary cost sharing lowers Part D program costs by increasing beneficiary premiums. The commenter requested clarification regarding the expected impact of these increases in beneficiary premiums on the regional LIS benchmarks.

Response: Under this regulatory change, Part D sponsors must exclude the PBM spread and any other administration costs from the negotiated prices used to determine the Part D drug costs reported to CMS. As a result, CMS expects the drug costs reported by Part D sponsors to decrease, reducing the reinsurance and low-income cost sharing subsidy payments made by the federal government. These lower negotiated prices are also expected to decrease beneficiary cost sharing such that the total amount paid by beneficiaries for their prescription drug coverage (premiums plus cost sharing) would be lower. However, the expected reductions in beneficiary cost sharing and federal reinsurance and low-income cost sharing subsidy payments may increase plan liability. This increase in plan liability may result in higher Part D bids and higher beneficiary premiums for plans that utilize the lock-in pricing approach. Similarly, the regional LIS benchmarks may increase if beneficiary premiums increase for Part D plans which previously utilized the lock-in pricing approach. Thus, while this policy is expected to reduce federal reinsurance and low-income cost sharing payments to Part D sponsors, it is expected to

increase federal Part D payments overall due to increased federal direct subsidy payments resulting from higher Part D bids.

In addition to lowering the drug costs reported to CMS, this policy is expected to provide Part D sponsors with increased transparency regarding their drug costs and administration fees. This increase in transparency may allow Part D sponsors to negotiate their drug prices and administrative fees paid to PBMs more effectively, which could have a downward impact on Part D bids and beneficiary premiums. Thus, the reduction in beneficiary cost sharing and federal reinsurance and low-income cost sharing subsidies may increase Part D bids while the increase in transparency may decrease Part D bids. As a result, it is unclear whether this regulatory change will have the net impact of increasing Part D bids and beneficiary premiums.

Comment: One commenter requested clarification regarding the expected impact of beneficiary premium increases on supplemental benefits as Part D sponsors use A/B rebates to buy down the Part D premium. In addition, the commenter asked for clarification regarding whether special needs plans (SNPs) were more likely than other plans to use the lock-in pricing approach in 2009.

Response: Higher Part D beneficiary premiums may require some MA-PD plans to utilize a larger share of their A/B rebates to reduce their Part D premiums to $0, such that they have fewer A/B rebates available for providing supplemental benefits. However, as we stated previously, it is unclear whether Part D premiums will increase as a result of this regulatory change.

Based on the information provided by Part D sponsors regarding their pricing approach in 2008 and 2009, the percentage of SNPs utilizing the lock-in pricing approach is about the same as the percentage of Part D plans utilizing the lock-in pricing approach (approximately 20% in 2008 and 16% in 2009).

Attachment IV 2010 Part D Benefit Parameters

Updated Part D Benefit Parameters for Defined Standard Benefit, Low-Income Subsidy, and Retiree Drug Subsidy

Annual Percentage Increases

	Annual percentage trend for 2009	Prior year revisions	Annual percentage increase for 2009
Applied to all parameters but (1)	5.79%	−1.07%	4.66%
CPI (all items, U.S. city average): Applied to (1)	0.36%	2.28%	2.65%

Part D Benefit Parameters

	2009	2010
Standard Benefit Design Parameters		
Deductible	$295	$310
Initial Coverage Limit	$2,700	$2,830
Out-of-Pocket Threshold	$4,350	$4,550
Total Covered Part D Drug Spend at OOP Threshold (2)	$6,153.75	$6,440.00
Minimum Cost-sharing in Catastrophic Coverage Portion of Benefit		
Generic/Preferred Multi-Source Drug	$2.40	$2.50
Other	$6.00	$6.30
Part D Full Benefit Dual Eligible Parameters		
Copayments for Institutionalized Beneficiaries	$0.00	$0.00
Maximum Copayments for Non-Institutionalized Beneficiaries		
Up to or at 100% FPL		
Up to Out-of-Pocket Threshold (1)		
Generic/Preferred Multi-Source Drug (3)	$1.10	$1.10
Other (3)	$3.20	$3.30
Above Out-of-Pocket Threshold	$0.00	$0.00
Over 100% FPL		
Up to Out-of-Pocket Threshold		
Generic/Preferred Multi-Source Drug	$2.40	$2.50
Other	$6.00	$6.30
Above Out-of Pocket Threshold	$0.00	$0.00
Part D Non-Full Benefit Dual Eligible Full Subsidy Parameters		
Resources ≤ $6,600 (individuals) or ≤ $9,910 (couples) (4)		
Maximum Copayments up to Out-of-Pocket Threshold		
Generic/Preferred Multi-Source Drug	$2.40	$2.50
Other	$6.00	$6.30
Maximum Copayments above Out-of-Pocket Threshold	$0.00	$0.00
Resources bet $6,600-$11,010 (ind) or $9,910-$22,010 (couples) (4)		
Deductible (3)	$60.00	$63.00
Coinsurance up to Out-of-Pocket Threshold	15%	15%
Maximum Copayments above Out-of-Pocket Threshold		
Generic/Preferred Multi-Source Drug	$2.40	$2.50
Other	$6.00	$6.30
Part D Non-Full Benefit Dual Eligible Partial Subsidy Parameters		
Deductible (3)	$60.00	$63.00
Coinsurance up to Out-of-Pocket Threshold	15%	15%
Maximum Copayments above Out-of-Pocket Threshold		
Generic/Preferred Multi-Source Drug	$2.40	$2.50
Other	$6.00	$6.30
Retiree Drug Subsidy Amounts		
Cost Threshold	$295	$310
Cost Limit	$6,000	$6,300

(1) CPI adjustment applies to copayments for non-institutionalized beneficiaries up to or at 100% FPL.
(2) Amount of total drug spending required to attain out-of-pocket threshold in the defined standard benefit if beneficiary does not have prescription drug coverage through a group health plan, insurance, government-funded health program or similar third party arrangement.
(3) The increases to the LIS deductible, generic/preferred multi-source drugs and other drugs copayments are applied to the unrounded 2009 values of $60.13, $1.08, and $3.23 respectively.
(4) The actual amount of resources allowable will be updated for contract year 2010.

Medicare Part D Benefit Parameters for the Defined Standard Benefit: Annual Adjustments for 2010

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) directs CMS to update the statutory parameters for the defined standard Part D drug benefit each year. These parameters include the standard deductible, initial coverage limit, and catastrophic coverage threshold, and minimum copayments for costs above the annual out-of-pocket threshold. In addition, CMS is statutorily required to update the parameters for the low income subsidy benefit and the cost threshold and cost limit for qualified retiree prescription drug plans eligible for the Retiree Drug Subsidy. Included in this notice are (i) the methodologies for updating these parameters, (ii) the updated parameter amounts for the Part D defined standard benefit and low-income subsidy benefit for 2010, and (iii) the updated cost threshold and cost limit for qualified retiree prescription drug plans.

As required by statute, the parameters for the defined standard benefit formula are indexed to the percentage increase in average per capita total Part D drug expenses for Medicare beneficiaries. Accordingly, the actuarial value of the drug benefit increases along with any increase in drug expenses, and the defined standard Part D benefit continues to cover a constant share of drug expenses from year to year.

All of the Part D benefit parameters are updated using one of two indexing methods specified by statute: (i) the annual percentage increase in average expenditures for Part D drugs per eligible beneficiary, and (ii) the annual percentage increase in the Consumer Price Index (CPI) (all items, U.S. city average).

I. Annual Percentage Increase in Average Expenditures for Part D Drugs Per Eligible Beneficiary

Section 1860D-2(b)(6) of the Social Security Act defines the "annual percentage increase" as "the annual percentage increase in average per capita aggregate expenditures for covered Part D drugs in the United States for Part D eligible individuals, as determined by the Secretary for the 12-month period ending in July of the previous year using such methods as the Secretary shall specify." The following parameters are updated using the "annual percentage increase":

Deductible: From $295 in 2009 and rounded to the nearest multiple of $5.

Initial Coverage Limit: From $2,700 in 2009 and rounded to the nearest multiple of $10.

Out-of-Pocket Threshold: From $4,350 in 2009 and rounded to the nearest multiple of $50.

Minimum Cost-Sharing in the Catastrophic Coverage Portion of the Benefit: From $2.40 per generic or preferred drug that is a multi-source drug, and $6.00 for all other drugs in 2009, and rounded to the nearest multiple of $0.05.

Maximum Copayments below the Out-of-Pocket Threshold for certain Low Income Full Subsidy Eligible Enrollees: From $2.40 per generic or preferred drug that is a multi-source drug, and $6.00 for all other drugs in 2009, and rounded to the nearest multiple of $0.05.

Deductible for Low Income (Partial) Subsidy Eligible Enrollees: From $60[1] in 2009 and rounded to the nearest $1.

Maximum Copayments above the Out-of-Pocket Threshold for Low Income (Partial) Subsidy Eligible Enrollees: From $2.40 per generic or preferred drug that is a multi-source drug, and $6.00 for all other drugs in 2009, and rounded to the nearest multiple of $0.05.

II. Annual Percentage Increase in Consumer Price Index, All Urban Consumers (all items, U.S. city average)

Section 1860D-14(a)(4) of the Social Security Act specifies that the annual percentage increase in the CPI, All Urban Consumers (all items, U.S. city average) as of September of the previous year is used to update the maximum copayments below the out-of-pocket threshold for full benefit dual eligible enrollees with incomes that do not exceed 100% of the Federal poverty line. These copayments are increased from $1.10 per generic or preferred drug that is a multi-source drug, and $3.20 for all other drugs in 2009[2], and rounded to the nearest multiple of $0.05 and $0.10, respectively.

III. Calculation Methodology

Annual Percentage Increase

For the 2007 and 2008 contract years, the annual percentage increases, as defined in section 1860D-2(b)(6) of the Social Security Act, were based on the National Health Expenditure (NHE) prescription drug per capita estimates because sufficient Part D program data was not available. Beginning with the 2009 contract year, the annual percentage increases are based on Part D program data. For the 2010 contract year benefit parameters, Part D program data is used to calculate the annual percentage trend as follows:

$$\frac{\text{August 2008 – July 2009}}{\text{August 2007 – July 2008}} = \frac{\$2{,}829.52}{\$2{,}674.62} = 1.0579$$

In the formula, the average per capita cost for August 2007 – July 2008 ($2,674.62) is calculated from actual Part D prescription drug event (PDE) data and the average per capita cost for August 2008 – July 2009 ($2,829.52) is calculated based on actual Part D PDE data incurred from August – December, 2008 and projected through July, 2009.

The 2010 benefit parameters reflect the 2009 annual percentage trend as well as a revision to the prior estimates for prior years' annual percentage increases. Based on updated NHE prescription drug per capita costs and PDE data, the 2007, 2008 and 2009 increases are now estimated to be 6.42%, 5.33% and 6.12%. Accordingly, the 2010 benefit parameters reflect a multiplicative update of −1.07% for prior year revisions. In summary, the 2009 parameters outlined in section I are updated by 4.66% for 2010 as summarized by Table III-1.

[1] Consistent with the statutory requirements of 1860D-14(a)(4)(B) of the Social Security Act, the update for the deductible for low income (partial) subsidy eligible enrollees is applied to the unrounded 2009 value of $60.13.
[2] Consistent with the statutory requirements of 1860D-14(a)(4)(A) of the Social Security Act, the copayments are increased from the unrounded 2009 values of $1.08 per generic or preferred drug that is a multi-source drug, and $3.23 for all other drugs.

Table III-1. Annual Percentage Increase

Annual percentage trend for July 2009	5.79%
Prior year revisions	(1.07%)
Annual percentage increase for 2009	4.66%

Note: Percentages are multiplicative, not additive. Values are carried to additional decimal places and may not agree to the rounded values presented above.

Annual Percentage Increase in Consumer Price Index, All Urban Consumers (all items, U.S. city average)

The annual percentage increase in the CPI as of September of the previous year referenced in section 1860D-14(a)(4)(A)(ii) is interpreted to mean that, for contract year 2010, the September 2009 CPI should be used in the calculation of the index. To ensure that plan sponsors and CMS have sufficient time to incorporate the cost-sharing requirements into benefit, marketing material and systems development, the methodology to calculate this update includes an estimate of the September 2009 CPI based on the projected amount included in the President's FY2010 Budget. The September 2008 value is from the Bureau of Labor Statistics. The annual percentage trend in CPI for contract year 2010 is calculated as follows:

$$\frac{\text{Projected September 2009 CPI}}{\text{Actual September 2008 CPI}} \text{ or } \frac{219.6}{218.8} = 1.004$$

(Source: President's FY2010 Budget and Bureau of Labor Statistics, Department of Labor)

The 2010 benefit parameters reflect the 2009 annual percentage trend in the CPI, as well as a revision to the prior estimate for the 2008 annual percentage increase. The 2009 parameter update reflected an annual percentage trend in CPI of 2.60%. Based on the actual reported CPI for September 2008, the September 2008 CPI increase is now estimated to be 4.94%. Thus, the 2010 update reflects a multiplicative 2.28% correction for prior year revisions. In summary, the cost sharing items outlined in section II are updated by 2.65% for 2010 as summarized by Table III-2.

Table III-2. Cumulative Annual Percentage Increase in CPI

Annual percentage trend for September 2009	0.36%
Prior year revisions	2.28%
Annual percentage increase for 2009	2.65%

Note: Percentages are multiplicative, not additive. Values are carried to additional decimal places and may not agree to the rounded values presented above.

IV. Part D Reinsurance Payment Demonstration Adjustment

The fixed capitated option of the Part D Reinsurance Payment Demonstration includes a catastrophic benefit that begins at the total drug expense corresponding to the out-of-pocket threshold in the Defined Standard Benefit. For 2010, this amount is increased from $6,153.75 in 2009 to $6,440. Specifically, this is the minimum amount of total covered Part D drug expenditures that will have occurred when the beneficiary reaches the out-of-pocket threshold of $4,550 in 2010 in the defined standard benefit. This expense level is determined arithmetically as a function of the 2010 out-of-pocket threshold (as opposed to being indexed directly).

V. Retiree Drug Subsidy Amounts

As outlined in §423.886(b)(3) of the regulations implementing the Part D benefit, the cost threshold and cost limit for qualified retiree prescription drug plans that end in years after 2006 are adjusted in the same manner as the annual Part D deductible and out-of-pocket threshold are adjusted under §423.104(d)(1)(ii) and (d)(5)(iii)(B), respectively. Specifically, they are adjusted by the "annual percentage increase" as defined previously in this document and the cost threshold is rounded the nearest multiple of $5 and the cost limit is rounded to the nearest multiple of $50. The cost threshold and cost limit are defined as $275 and $5,600, respectively, for plans that end in 2008, and, as $295 and $6,000, respectively, for plans that end in 2009. For 2010, the cost threshold is increased to $310, and the cost limit is increased to $6,300.

NOTE TO: Medicare Advantage Organizations, Prescription Drug Plan Sponsors, and Other Interested Parties

SUBJECT: Advance Notice of Methodological Changes for Calendar Year (CY) 2006 Medicare Advantage (MA) Payment Rates

In accordance with Section 1853(b)(2) of the Social Security Act (the Act), we are notifying you of proposed changes in the MA capitation rate methodology and risk adjustment methodology applied under Part C of the Act for CY 2006. Preliminary estimates of the national per capita MA growth percentage and other payment methodology changes for CY 2006 are also discussed. For 2006, CMS will announce the MA capitation rates on the first Monday in April, 2005, in accordance with the new timetable established in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). This Advance Notice is published 45 days before that date.

In accordance with Section 1860D-15(c)(1)(D) of the Act, we are notifying you of the proposed health status risk adjustment methodology for Part D. We are also notifying you of the proposed payment methodologies for the direct, low-income, and reinsurance subsidies, in addition to risk sharing.

Attachment I shows the preliminary estimates of the national per capita MA growth percentage for the minimum percentage increase applied to the MA capitation rates. All counties will receive the minimum update percentage for 2006. The CMS has decided not to rebase the county fee-for-service rates for 2006.

Attachment II sets forth in detail the changes in payment methodology for 2006 for MA organizations.

Attachment III provides an overview of payment for Medicare Advantage – Prescription Drug (MA-PD) plans and Prescription Drug Plans (PDP).

Attachment comments or questions may be addressed to:

Deondra Moseley (for Attachments I and II)
Mark Newsom (for Attachment III)
Centers for Medicare & Medicaid Services
7500 Security Boulevard
S1-05-06
Baltimore, Maryland 21244

Comments also may be submitted electronically to the following address: AdvanceNotice2006@cms.hhs.gov. In order to receive consideration prior to the April 4, 2005 announcement of MA and PDP capitation rates, comments must be received by 5:00 PM EST on March 4, 2005.

/ s /
Leslie Norwalk
Acting Director
Center for Beneficiary Choices

/ s /
Solomon Mussey, A.S.A.
Director
Medicare and Medicaid Cost Estimates Group
Office of the Actuary

Attachments

Attachment I

Preliminary Estimate of the National Per Capita Growth Percentage for Calendar Year (CY) 2006

The MMA provides that the minimum percentage increase is the higher of two percent or the national per capita MA growth percentage, with no adjustment to this percentage for over- or under-estimates for years before 2004. The CMS has decided not to rebase the county fee-for-service (FFS) rates for 2006.

The current estimate of the change in the national per capita MA growth percentage for aged enrollees in CY 2006 is 4.0 percent. This estimate reflects an underlying trend change for CY 2006 in per capita costs of 4.5 percent and an adjustment for the fact that the current estimates of CY 2005 and CY 2004 aged MA growth percentages are .2 percent and .3 percent, respectively, lower than the estimates actually used in calculating the CY 2005 capitation rate book that was published May 10, 2004 (as required by Section 1853(c)(6)(C) of the Act).

The following table summarizes the estimates for the change in the national per capita MA growth percentage, which will be used for the minimum percentage increase.

Table I-1. National Per Capita Growth Percentage

	Aged	Disabled	ESRD	Aged+Disabled
2006 Trend Change	4.5%	4.7%	3.9%	4.5%
Revision to CY 2005 Estimate	-0.2%	-0.5%	-0.5%	-0.3%
Revision to CY 2004 Estimate	-0.3%	-0.3%	1.0%	-0.2%
Total Change	4.0%	3.9%	4.4%	4.0%

Note: The above percentages are multiplicative not additive.

These estimates are preliminary and could change before the final rates are announced on April 4, 2005. Further details on the derivation of the national per capita MA growth percentage will also be presented in the April 4 announcement.

Attachment II

Changes in the Payment Methodology for Original Medicare Benefits for CY 2006

The MMA revised the pricing and payment methodologies for MA organizations beginning in 2006. We provide an overview of the new bidding methodology in Section A, followed by a discussion in Section B of changes in payment that follow from the bidding methodology introduced by the MMA. In Section C, we discuss how payments for End-Stage Renal Disease (ESRD) enrollees and enrollees who have elected hospice will be made in 2006, the payment methodology for MSA plans, and several other payment policies. Section D addresses a payment provision unique to regional organizations – risk sharing (applicable to payments in 2006 and 2007; regional organization entry and retention bonus payments can be applicable in 2007 and thereafter but are not discussed in this notice). In Section E, we discuss the submission of bids by demonstration plans. In Section F, we discuss changes in risk adjustment for 2006, including the recalibration of the CMS-HCC models for aged/disabled and ESRD enrollees. Finally, Section G discusses developments in the budget neutral risk adjustment policy.

The terminology used in this Advance Notice differs from that in statute and regulation. Section 1854(b)(3)(C) of the Act refers to the "risk-adjusted benchmark" and "risk-adjusted bid" when describing the determination of savings. For the savings calculation, adjustment for risk is done at the plan level, based on the plan projected average risk score. However, based on how bids are actually constructed, the use of the terms "risk adjusted bid" and "unadjusted bid" has caused confusion.

The starting point for the bid is the plan's own estimate of its revenue requirements based on its projected enrollment. These revenue requirements are then reduced to reflect Medicare cost-sharing in order to produce the plan bid for A/B services (as explained below). Because this amount reflects the characteristics of the plan's projected enrollment, it is by definition "risk adjusted." However, referring to this amount as the "risk adjusted" bid has been construed to imply that this A/B bid amount results from applying risk adjustment factors to a standardized amount, when in fact the reverse is true. (This confusion is due to the fact that historically CMS has used the term "risk adjustment" to describe a payment adjustment using factors from CMS risk adjustment models.) That is, the standardized A/B bid amount is derived from normalizing what the statute refers to as the "risk adjusted" bid. So in this document we will be referring to the "risk adjusted" bid as simply the "plan A/B bid." The statutory term "unadjusted bid" will be referred to in this notice as the "standardized A/B bid." For consistency purposes we are making parallel changes to the terminology for benchmarks. In summary:

- The statutory term "risk adjusted bid" will be referred to in this notice as the "plan A/B bid" (which excludes Medicare cost sharing).

- The "risk adjusted benchmark" will be referred to in this notice as the "plan A/B benchmark" (the amount compared to the "plan A/B bid" to determine whether there are savings).

- The "unadjusted bid" will be referred to in this notice as the "standardized A/B bid."

- The "unadjusted benchmark" will be referred to in this notice as the "standardized A/B benchmark." (For plans with plan A/B bids above the plan A/B benchmark, the basic premium members will pay is the difference between the standardized A/B bid and the standardized A/B benchmark. That is, the premium is determined for a 1.0 beneficiary.)

Section A. Overview of Bidding Methodology for Non-drug Benefits

One purpose of bidding by MA organizations is to base payment for Medicare Part A and B benefits on an organization's monthly expected revenue needs for covering those benefits, rather than solely on an administratively set amount. The bidding process also determines how much (if anything) a Medicare enrollee would have to pay for Part A and B benefits, and how much an enrollee would receive in rebates or benefits in addition to A and B benefits. On the first Monday of June in each year beginning in 2005, MA organizations will submit a bid for the upcoming year based on their determinations of their monthly expected revenue needs, i.e. their medical and administrative costs, including profit. The Instructions for the Bid Pricing Tool (draft available at www.cms.hhs.gov/healthplans/) and the 2006 Call Letter (available this spring at www.cms.hhs.gov/healthplans/letters/), will describe the bidding method and policies in detail. We provide an overview of bidding below, as background to the discussion of payment methodology.

1. Bids. An MA organization's combined bid for its service area, for both local and regional organizations (or service area segment, in the case of a local organization), will have three parts:

- An amount for the provision of Medicare Parts A and B medical benefits – (This is the standardized A/B bid. It is exclusive of an amount actuarially equivalent to Medicare cost sharing.);

- An amount for basic coverage of Medicare prescription drug benefits (if any); and

- An amount for the provision of supplemental medical and prescription drug benefits (if any).

Note that for bidding purposes only, supplemental benefits will be divided into those related to prescription drug coverage and all other supplemental benefits. This treatment for bidding purposes does not affect how the benefits are offered to enrollees or the premium charged. That is, supplemental benefits include both medical and prescription drug benefits (if offered) and are offered for a single supplemental benefits premium.

2. Actuarially equivalent cost sharing. The plan A/B bid must reflect cost sharing as required under original Medicare, or an actuarially equivalent amount. As discussed in the preamble for Subpart F of the Final Rule implementing the Medicare Advantage program (Final Rule), which was published in the *Federal Register*, January 28, 2005 (70 FR 4588), plan-specific actuarially equivalent cost sharing will be determined based on cost sharing proportions in original Medicare that are applied to projected plan allowed costs for Medicare benefits. The actuarially equivalent amount will be determined using five service-specific proportions (proportions for inpatient facility, SNF facility, home health services, outpatient facility, and all other Part B services) that may vary by geographic area, and/or service type.

The proportions will be developed using 100 percent of Medicare FFS claim data for non-ESRD beneficiaries, as captured in our CY 2002 and/or CY 2003 National Claims History data files and projected to calendar year 2006. The development of the factors will take into consideration the validity and credibility of the data at the service-specific and county-specific level. For example, the Part B-other factor may reflect local (either county-level or metropolitan statistical area-level) variations in cost sharing proportions, or the same factor may be used in all counties (that is, a nationwide factor). Similarly, the local factor may be used for all non-home health Part B services, or separate factors may be provided for outpatient hospital and other Part B services. The CMS will publish the proportions each year for each county or other geographic area.

A single enrollment-weighted proportion across all counties in the organization's service area (or service area segment) for each of these five service categories will be used. Each service category proportion is multiplied by the appropriate allowed costs for that category, and then these amounts are summed to generate the cost sharing amount that is considered to be actuarially equivalent to average FFS cost sharing. The total actuarially equivalent cost sharing amount is then subtracted from the allowable costs to determine the plan A/B bid.

The factors to be used in the 2006 bids will be published by CMS on April 4, 2005.

3. Benchmarks. For both local and regional MA plans, the plan A/B benchmark, when compared against a plan A/B bid, determines whether a plan will have savings and offer rebates or additional benefits, or whether the MA organization will have to charge a basic premium for the plan's coverage of Part A and B benefits.

For local plans, the plan A/B benchmark is determined according to formulas established in the MMA. For a single-county plan (or segment), the plan A/B benchmark is the capitation rate for that county, adjusted to reflect the plan's projected risk profile to allow

comparison to the plan A/B bid. For local plans serving more than one county, the plan A/B benchmark is the enrollment-weighted average of all the county capitation rates in the plan's service area (or segment), adjusted by the projected risk profile of the plan. (In determining the enrollment-weighted average, the weights are based on the plan's projected enrollment in each county of its service area.)

Local plan A/B benchmarks are plan-specific, because the MA organization selects which counties to include in a plan's service area, and each plan's benchmark is weighted by the plan's projected enrollment. Regional plan A/B benchmarks are based on a different statutory formula that results in a single (standardized) benchmark amount for each region applicable to all regional plans in that region. The CMS will determine a standardized A/B benchmark annually for each of the 26 MA regions, and an MA regional plan will adjust the standardized benchmark to reflect the plan's projected risk profile.

The standardized benchmark for each MA region is a blend of two components: a statutory component consisting of the weighted average of the county capitation rates across the region; and a competitive component consisting of the weighted average of all of the standardized A/B bids for regional plans in the region. The weighting for the statutory component is based on MA eligible individuals in the region. "MA eligibles" refers to all Medicare beneficiaries in the FFS and MA programs. The MA eligibles will not include Part B-only enrollees. For 2006 only, ESRD beneficiaries are not included in the count of MA eligibles for the purpose of calculating the statutory component of the regional benchmark, because ESRD enrollee costs are not included in the bid for 2006. The weighting for the competitive component (which includes each regional plan's bid) is based on the projected enrollment of the regional plans competing in the region. The blend of the two components will reflect the market share of traditional Medicare (for the statutory component) and the market share of all MA organizations (for the competitive component) in the Medicare population nationally.

The statutory components of the 26 regional standardized A/B benchmarks will be published each year as part of the Announcement of CY 2006 Medicare Advantage Payment Rates. For the annual June bid submission, an MA organization will estimate the regional plan benchmark by weighting together the appropriate statutory component published by CMS with the regional plan's standardized A/B bid as a proxy for the competitive component of the benchmark. In early August each year, CMS will publish the final MA regional standardized A/B benchmarks which will reflect the average bid component and the statutory component. Regional plans will adjust the standardized regional benchmark by their plan projected risk profile to arrive at the regional plan A/B benchmark, which is used for the savings calculation. (Note on the weighting used for the competitive component of regional benchmarks: If an MA region has approved bids for regional plans only open to a specific subgroup of Medicare beneficiaries (e.g., special needs plans for institutionalized beneficiaries), the Office of the Actuary (OACT) will consider assigning one weight to standard plans and a different weight to plans enrolling a specific subgroup of beneficiaries.)

4. Computation of benchmarks based on transition payment blends. The schedule for the transition from demographic to fully risk adjusted payments requires that, for 2006, 75 percent of payments for A/B benefits will be based on the CMS-HCC risk adjustment model, and 25 percent of payments will be based on the demographic-only model. This means that, under the bidding methodology, the savings calculation must be done using a blended benchmark. This type of blending should be distinguished from the statutory requirement for calculation of regional MA benchmarks, which combines competitive and statutory components, as described above under item (3). For 2006, the Bid Pricing Tool will calculate a blended benchmark that combines aged and disabled demographic benchmarks with risk benchmarks. As a result, the savings and rebate amounts (if any) will be determined by subtracting a blended plan A/B bid from a blended A/B benchmark. The beneficiary premium amount (if any) will also be determined by using a blended benchmark (in this case the standardized A/B benchmark). However, the demographic and risk adjusted payment amounts are determined separately, as discussed in the next section.

5. Treatment of ESRD enrollee costs. For 2006, ESRD enrollees will not be included in the plan A/B bid. MA organizations will have the option to adjust a plan's supplemental benefit premium by an ESRD factor, based on an organization's estimate of higher supplemental benefit costs for ESRD enrollees in the plan.

6. Computation of savings, rebate, and premium. In order to calculate plan savings or beneficiary premiums, CMS will compare the plan A/B bid with the plan A/B benchmark. The plan A/B bid for Medicare-covered costs is the sum of the medical expenses for A/B services (reduced by Medicare cost sharing), non-medical expenses, and the gain/loss margin. For 2006, the plan transitional-blend A/B bid will be compared to the transitional-blend A/B benchmark described above in item 4 to determine whether an organization will have savings (for organizations with bids below benchmarks) and, therefore, offer rebates or additional benefits (equal to 75 percent of the savings), or whether an organization will have to charge a beneficiary basic premium (for organizations with bids above benchmarks). The basic premium is equal to the difference between the standardized A/B bid and standardized A/B benchmark. For local organizations 25% of savings is retained by the government in the Medicare Trust Funds. For regional organizations one-half of the 25% savings is retained in the Medicare Trust Funds and the other half is placed in the stabilization fund.

Note that after 2005, if an organization chooses to use savings to offer a full or partial reduction of the Part B premium, such reductions will be funded on the same basis as other uses of rebate dollars (e.g., provision of additional benefits); that is through the use of rebate dollars which equal 75% of plan savings. For example, if an organization chooses to apply $10 of a plan's rebate to buy-down the Part B premium, enrollees' Part B premiums will be reduced by $10. The BIPA Section 606 provision on Part B premium reductions, enacted at Section 1854(f)(1)(E) of the Act, applies only to years before 2006.

The MMA permitted CMS to choose among various alternatives, including using a statewide average risk factor for all plans, in order to determine savings at the plan level. As indicated in the Final Rule, we will be using the plan-specific risk adjustment approach – that is, an organization will determine a plan A/B bid based on projected costs for the expected enrollee mix in the plan. In this sense, risk is defined at the plan-level. For the purpose of plan payments, however, risk adjustment is applied at the level of the individual beneficiary, based on the CMS-HCC risk adjustment model.

Section B. Changes in Payment for Non-Drug Benefits

This section discusses several elements of the new payment formula:

- Basic payment rules, based on the bid-benchmark relationship;
- The geographic Intra-Service Area Rate (ISAR) adjustment (discussed in item 2 below);
- Risk adjustment (discussed in item 3 below and Section F);
- The rebate (discussed in Section A); and
- The government premium adjustment (discussed in item 4 below).

1. Statutory formulas for non-drug benefits. The MMA describes three formulas for payments to MA organizations beginning in 2006.

(a) If the plan A/B bid is less than the plan A/B benchmark, monthly payment from CMS for an individual is:

> [(Standardized A/B bid, adjusted by the plan's ISAR factor for the enrollee's county of residence) adjusted by the enrollee risk factor] + rebate minus amount for Part B premium reduction (if any).

(b) If the plan A/B bid is equal to the plan A/B benchmark, monthly payment from CMS for an individual is:

> (Standardized A/B benchmark, adjusted by plan's ISAR factor for the enrollee's county of residence) adjusted by the enrollee risk factor.
>
> There is no rebate and no basic beneficiary premium.

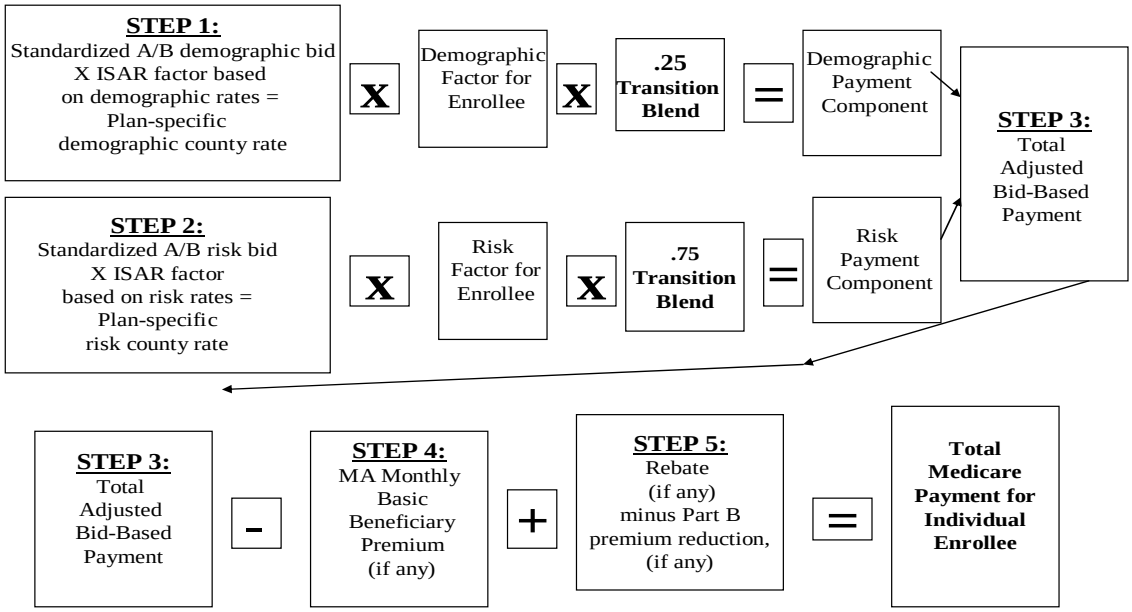
(c) If the plan A/B bid is greater than the plan A/B benchmark, monthly payment from CMS for an individual is:

[(Standardized A/B benchmark, adjusted by plan's ISAR factor for the enrollee's county of residence) adjusted by the enrollee risk factor] + government premium adjustment.

There is no rebate and the enrollee pays a basic premium. The combined payment from CMS and the enrollee will on average equal the organization's bid (based on enrollment assumed in the bid submission).

See Figure II-1 below for a diagram depicting the payment formula for 2006, which includes the impact of the 25%/75% transition blend on payment calculations. It is important to keep in mind that Figure II-1 describes the three statutory formulas listed above as a single formula, representing how payment calculations will be determined in the MMCS payment system. See Table II-1 for descriptions of 2006 payment formulas for non-ESRD enrollees and ESRD enrollees, and the MSA plan formula for 2006 and subsequent years.

Figure II-1. 2006 Payment for Non-ESRD Enrollees in Coordinated Care Plans or PFFS Plans (Payment System Formula Combining 3 Statutory Formulas)



2. Geographic Intra-Service Area Rate (ISAR) Adjustment: MA Rate as Basis of Adjustment. Under Section 1853(a)(1)(F) of the Social Security Act, payments to organizations must be adjusted "to take into account variations in MA local payment rates under this part among the different MA local areas" that are included in the service area, or segment, of the MA plan. As explained in the MA Final Rule, we are implementing this provision by providing for an adjustment of organization payments based on the variation among MA capitation rates in the counties of a MA plan's service area. According to the statutory formulas, this adjustment applies to the standardized A/B bid, in the case where the plan A/B bid is below the plan A/B benchmark, or to the standardized A/B benchmark, in the case where the plan A/B bid is at or above the plan A/B benchmark.

Plans with bids below benchmark. For both local and regional plans with plan A/B bids below the plan A/B benchmark, each plan-specific county rate equals the standardized A/B bid adjusted by the relationship between that county's MA capitation rate and the weighted average of all MA capitation rates for counties in the plan's service area, with each county MA rate weighted by the plan's projected enrollment in that county.

Plans with bids at or above benchmark. For local and regional plans with bids at or over the benchmark, the ISAR adjustment also results in a county-level payment rate for each county in the plan's service area. For a local plan serving a single county, the payment rate would be the county benchmark (i.e., the county MA capitation rate published by CMS, because no geographic adjustment is necessary). For multi-county local plans and for regional plans, each plan-specific county rate equals the standardized A/B benchmark adjusted by the relationship between that county's MA capitation rate and the weighted average of all MA capitation rates for counties in the plan's service area, with each county MA rate weighted by the plan's projected enrollment in that county.

Both bid-based and benchmark-based payments are further adjusted for the demographic and risk characteristics of the individual enrollee.

ISAR adjustment factors. The relationship (or ratio) of a county rate to the weighted average rate for the service area is expressed as an ISAR factor, such as .98 for county X, 1.12 for county Y, and .9 for county Z. The weighted average of all the county ISAR factors for a plan's service area must equal 1.0.

As discussed above in item (1), the MMA lays out three statutory formulas for plans with: (1) bids below benchmark; (2) bids equal to benchmark; and (3) bids above benchmark. See the diagram in Figure II-1, which rolls the three statutory formulas into a single formula, representing how the CMS payment system will actually process MA payments. The diagram is a bid-based depiction of payment.

For plans with bids above the benchmark, the statutory and payment system formulas are distinct but mathematically equivalent. This is because for bid-above-benchmark plans, the bid consists of two distinct payment streams: from CMS to the plan (monthly capitated payment based on the benchmark) and from the beneficiary to the plan (monthly basic premium payment).

Statutory formula for bid-over-benchmark plans:

> Standardized A/B benchmark, adjusted for enrollee risk plus a government premium adjustment amount.

Figure II-1 diagram (payment system) formula:

> Standardized A/B bid, adjusted for enrollee risk minus the standardized beneficiary premium

There are three basic steps to determine the ISAR-adjusted county rates for a plan, where the ISAR factors are based on the MA rates. (See below for a discussion of the alternative ISAR adjustment option for regional plans.) Because in 2006, payment will be based on a demographic rate book (25 %) and a risk rate book (75%), the steps outlined below would have to be done for each rate book to determine the risk adjusted and demographic components of payment. (The acronym SA, used below, is the plan service area.)

Step (a): Calculate the SA-level combined aged and disabled enrollment-weighted demographic rate using the published local MA rates. Calculate SA-level enrollment-weighted risk rate. The weights are the plan's projected enrollment in each county.

Step (b): Calculate county-level aged ISAR factor, county-level disabled ISAR factor, and county-level risk ISAR factor.

Step (c): From the perspective of the payment system formula (Figure II-1), calculate county-level aged ISAR-adjusted payment rate by multiplying the standardized A/B bid by the plan ISAR factor for the enrollee's county of residence. The same calculation of ISAR-adjusted county rates is done using disabled and risk ISAR factors.

Thus, for each county in the plan's service area, there will be a plan-specific county rate derived from the bid and the ISAR factor. For enrollees who are out of the service area, the base payment will be the 1.0 bid (with individual-level risk adjustment for demographic and health status factors).

Note that the rebate amount is not geographically or otherwise adjusted. It is a fixed amount determined through comparison of the plan A/B bid to the plan A/B benchmark based on the plan's projected enrollment.

Alternative ISAR Option for Regional Plans: Plan-Determined Adjustment Factors. A plan bid represents a statement of the average per member revenue that it needs to provide the Medicare A/B benefit. Particularly for regional plans covering a wide geographic area, underlying the single bid there could be significant variation in costs

across the geographic area that the organization is required to serve. If a plan's actual enrollment matches its enrollment projections—in terms of the proportion of beneficiaries coming from different counties—the ISAR adjustment has no effect on the average payment a plan will receive for its enrolled population (the total revenue received by the plan will match its bid). The purpose of the ISAR adjustment is to permit an adjustment to payments to compensate for any variation between the expected enrollment mix (by county) that formed the basis of a plan's bid, and the actual enrollment mix by county. By using the MA capitation rates as a basis for this adjustment, the presumption is that the variation in MA local rates among counties constitutes an accurate measure of the variation in plan revenue needs across different counties. That is, if, for example, one county has an MA rate that is twice that of another county, it is assumed that plan revenue needs for the former county are twice the plan's revenue needs for the latter county. The ISAR adjustment would pay an amount higher than the bid (which represents a multi-county average) in the former county, and a lower amount in the latter county.

In order to encourage the submission of regional MA plan bids, CMS will make available to MA organizations offering regional plans an alternative methodology for calculating the geographic ISAR adjustment. In the event that an MA organization believes that the variation in MA rates among the counties in the region covered by its regional plan is not an accurate reflection of the variation in its projected revenue needs in the region, the organization can request to have payments geographically adjusted at the county level using an organization-determined statement of the relative revenue needs for the provision of Medicare-covered services in the service area. We would review the organization-provided ISAR factors for reasonableness and actuarial soundness, as well as reviewing the enrollment projections (which are reviewed for all organizations, both those using the plan-specific ISAR factors and those using the MA rate-based factors for the geographic ISAR adjustment).

The MA organizations will be required to provide support for their plan-specific ISAR factors (such as the projected utilization and cost by service category for each county), with the understanding that we could ask for additional detail (for example, fee schedules) during bid negotiation or during an audit. The CMS reserves the right to ask for additional documentation of these plan-determined factors in order to assess their actuarial soundness. Approval of plan-determined factors will be contingent on the comprehensiveness, actuarial soundness, and reasonableness of the MA organization's cost, utilization and enrollment assumptions, and associated documentation. (We would note that this ISAR factor, like the MA rate-based ISAR factor, will result in a different average payment to the plan *only if* the actual enrollment mix differs from the projected mix that formed the basis of the plan bid.)

3. Risk adjustment of A/B payments. The county rates for the counties included in a local MA plan's service area will be adjusted for beneficiary health status using each individual enrollee's risk score to ensure that the MA organizations are paid appropriately based on the health status of their enrollees. For 2006, the CMS-HCC model will be applied at 75 percent risk adjusted payment, while the remaining 25 percent will be

calculated using a demographic payment. For more information on demographic and risk adjusted payments, please see the Advance Notice of Methodological Changes for Calendar Year (CY) 2004 Medicare+Choice Payment rates at http://www.cms.hhs.gov/healthplans/rates/. Also see Figure II-1 for a diagram showing how the individual enrollee's demographic and risk scores are applied in the payment formula. For more information on risk adjustment, please see Section F.

4. Government premium adjustment. Organizations with plan A/B bids above the plan A/B benchmark must charge a uniform basic beneficiary premium. Because beneficiary premiums are not adjusted for individual health status, organizations with bids above the benchmark will be subject to an additional adjustment to their payments pursuant to Section 1854(a)(6)(B). This adjustment, which we are calling the government premium adjustment, will adjust an organization's payment upward or downward to ensure that the organization's revenue needs are met, with regard to that portion of their payment coming from the basic premium, regardless of whether the plan enrolls more or less healthy beneficiaries. Organizations with bids at or below the benchmark do not charge a basic premium, and therefore are not subject to this adjustment.

Conceptually, this adjustment is the difference between the risk adjusted beneficiary basic premium and the beneficiary basic premium actually paid by enrollees, which is based on a 1.0 beneficiary. This incremental payment is ISAR-adjusted to reflect differences between projected and actual enrollment. Note that the government premium adjustment is called the "adjustment relating to risk adjustment" in Section 1853(a)(1)(G) of the Act.

Section C. ESRD and hospice enrollees, MSA plan payments, and other policies.

1. A/B payments for ESRD enrollees. In 2006, we will pay for ESRD enrollees using the same methodology as in 2005 because ESRD enrollee costs are not included in the plan A/B bid. For enrollees on dialysis and in transplant status, we pay the State capitation rate, adjusted by the enrollee risk score. For functioning graft enrollees, we pay the county rate, adjusted by the enrollee risk score. To the extent that the plan provides for a reduction in the Part B premium, the amount of the reduction would be netted from the adjusted rate.

2. Payments for enrollees electing hospice. Prior to the MMA, no payment was made to an MA organization on behalf of a Medicare enrollee who had elected hospice care except for the portion of the payment applicable to additional benefits. Effective 2006, the MA organization will be paid the portion of the payment attributable to the beneficiary rebate for the MA organization (minus the Part B premium reduction amount, if any) plus the amount of the subsidies related to basic prescription drug coverage for organizations that offer prescription drug coverage.

When a beneficiary enrolled in an MA organization elects hospice, that beneficiary is still an enrollee in the plan, and is still liable for any plan premiums and cost sharing for

benefits not covered under the hospice benefit. It is possible that an enrollee who has elected hospice will need prescription drugs for conditions not related to hospice care, which will be the organization's responsibility (to the extent that they are covered under Part D or under the plan). We believe that it is appropriate for Medicare Advantage Prescription Drug (MA-PD) organizations to manage the prescription drug coverage of enrollees who have elected hospice, and therefore CMS will pay MA-PD organizations the Part D premium for all enrollees.

For Program of All-inclusive Care for the Elderly (PACE) organizations, PACE enrollees must elect either their PACE organization or the hospice benefit as their provider of Medicare services. An enrollee who elects to enroll in hospice is thereby disenrolled from the PACE benefit. However, PACE organizations provide a service similar to hospice known as "end-of-life-care."

3. Payment Method for MSA plans. A Medicare MSA plan combines a high-deductible insurance policy with a MSA for health care expenses. The maximum annual MSA plan deductible is set by law. The Medicare program pays premiums for the high deductible insurance policies and makes a contribution to the beneficiaries' MSAs. The beneficiaries use the money in their MSAs to pay for their health care before the high deductible is reached. Once the deductible is met, the MA organization offering the MSA plan is responsible for payment of 100 percent of the expenses related to covered services. In both cases, whether it is the enrollee or the MSA that assumes responsibility for payment, providers and other entities are required to accept the amount that the Medicare FFS would have paid as payment in full.

The MMA did not amend Section 1853(e)(1), which governs the calculation of the CMS deposit into an enrollee's MSA. However, we have interpreted the existing language referencing capitation rates "applied under this section for the area" as incorporating the new MMA bidding and payment methodology that now applies to MA plans under section 1853. An MSA organization offering an MSA plan will submit the "MSA premium" for benefits under original Medicare, called the MSA plan A/B bid in this Advance Notice. The MSA plan may include optional supplemental benefits, and the MA organization would submit a bid amount for these supplemental benefits. The MSA premium (MSA plan A/B bid) reflects the expected risk profile of plan enrollees, so in this sense is risk adjusted at the plan level. (The requirement at Section 1854(a)(6)(A) that MA organizations submit a standardized A/B bid does not apply to MSA plans.)

The MA organization offering an MSA plan also will submit an expected plan average risk score. The plan A/B benchmark is then calculated using the same formula as for other local MA organizations: the plan-level risk score is multiplied by the standardized A/B benchmark. For 2006, the transition blend would also apply to MSA plan benchmarks. A blended standardized A/B benchmark reflecting the 25% demographic rates/75% risk rates transition blend will be calculated in same manner as the blended standardized A/B benchmark is calculated in the bid pricing tool for CCP and PFFS plans (see Section A, item 4).

MSA enrollee deposit and payment to plan. The deposit into each MSA enrollee's account is calculated at the service area or service area segment level as the plan A/B benchmark minus the plan A/B bid. The deposit is uniform for each enrollee in the service area or service area segment. The payment to an MSA plan for an MSA plan enrollee is determined according to the following formula: the standardized A/B benchmark, adjusted by the enrollee's risk factor, minus the MSA deposit. Thus, while the MSA deposit is uniform, the monthly payments that CMS will make to the MSA plans will vary based on the risk characteristics of the enrollee. The ISAR adjustment does not apply to MSA plans. The transition payment blend discussed below in Section F- Changes to the Risk Adjustment Method for MA Organizations also applies to MSAs.

4. Payment Method for Religious Fraternal Benefit Society (RFB) Plans. The RFB plans will be paid as provided for in the MMA. An RFB society may offer any type of MA plan (CCP, PFFS, or MSA plan), and the appropriate payment rules for that type of plan will apply.

Under Section 1859(e)(4), CMS is required to adjust MA payment rates to RFB plans to appropriate levels, taking into account "the actuarial characteristics and experience" of RFB enrollees. This provision pre-dates implementation of risk adjustment by CMS. In 2006, we will be using the third generation risk adjustment model and we intend to adjust payments to RFBs to account for the actuarial characteristics of their enrollees using this model (known as the CMS-HCC risk adjustment model). We believe that our risk adjustment model will appropriately adjust payments to RFB societies for the characteristics of their RFB plan enrollees. The CMS-HCC model was outlined in the Advance Notice of Methodological Changes for Calendar Year (CY) 2004 Medicare+Choice (M+C) Payment Rates (http://www.cms.hhs.gov/healthplans/rates/2004/45day.pdf) and updates to the model are discussed in Section F of this notice.

Table II-1 below summarizes payment formulas for coordinated care plans, private fee-for-service plans, and medical savings account plans.

Table II-1. Payment Formulas for MA Plans

Payments for Non-ESRD Enrollees of Coordinated Care Plans and Private Fee-for-Service Plans

Step 1: Determine demographic payment component.
[("1.0" demographic bid multiplied by the plan's ISAR factor for enrollee county of residence based on demographic MA rates) multiplied by the enrollee demographic factor] multiplied by the transition blend of .25

Step 2. Determine risk payment component.
[("1.0" risk bid multiplied by the plan ISAR factor for enrollee county of residence based on risk MA rates) multiplied by the enrollee risk factor] multiplied by the transition blend of .75

Step 3. Sum demographic and risk payment components to get total adjusted plan A/B bid-based payment.

Step 4. Subtract monthly basic beneficiary A/B premium (if any).

Step 5. Add rebate, net of Part B premium reduction amount (if any)

Note: The rebate amount results from the savings calculation and thus reflects plan average projected risk. It is a uniform amount for all enrollees and is not adjusted for individual risk. The rebate is not ISAR-adjusted.

Payments for ESRD Enrollees of Coordinated Care Plans and Private Fee-for-Service Plans

Dialysis and Transplant Status: (State capitation rate multiplied by the enrollee risk score from ESRD CMS-HCC model) less Part B premium reduction amount (if any)

Functioning Graft Status: (county capitation rate multiplied by the enrollee risk score from ESRD CMS-HCC model) less Part B premium reduction amount (if any)

Payment for All Enrollees of Medical Savings Account Plans

Step 1 Determine lump sum annual deposit (CMS payment to enrollee MSA).
[(Blended standardized A/B benchmark multiplied by the plan projected average risk score) less MSA plan A/B bid for plan's projected enrollee mix] multiplied by 12 (to annualize)

Step 2. Determine CMS monthly payment
(a) Calculate demographic payment amount: [1.0 A/B demographic benchmark * enrollee demographic factor * .25]

(b) Calculate risk payment amount: [1.0 A/B risk benchmark * enrollee risk factor * .75]

(c) Sum demographic and risk payment amounts, and subtract monthly deposit.

Note: the geographic ISAR adjustment does not apply to MSA plan payments.

5. Changes to Payment Adjustment for the Effect of National Coverage Determinations. Section 1853(c)(7) of the Act requires us to "adjust" MA payments when a national coverage determination (NCD) or legislative change in benefits will result in a significant increase in costs to MA organizations sponsoring MA organizations. We historically interpreted what constituted "significant" costs at 42 CFR Section 422.109, where the costs of a coverage change are considered "significant" if either the average cost of providing the service exceeds a specified threshold, or the total cost for providing the service exceeds an aggregate cost threshold.

In CMS-4041-F, published August 22, 2003, we amended Section 422.109 to refine the definition of "significant" cost to include a new test. By adding a new paragraph at the end of Section 422.109(a)(2), we provided that, for purposes of determining whether to make an additional payment adjustment under Section 422.256, the tests for reaching the "significant" cost threshold were to include the aggregate costs of all NCDs and legislative changes in benefits made in the prior calendar year.

Under that new test, the "average cost" of every NCD and legislative change in benefits for the contract year would have been added together. If the sum of these average amounts exceeded the threshold under Section 422.109(a)(l), then an adjustment to payment would have been made in the following contract year under Section 422.256 to reflect this "significant" cost. Alternatively, if the costs of the NCDs and legislative changes in benefits, in the aggregate, exceeded the level set forth in Section 422.109(a)(2), an adjustment to payment would also have been made under Section 422.256 on that basis.

Among the reasons for the above change was that even when the "significant" cost threshold had been met under the existing definition, the methodology then employed for making a payment adjustment under Section 1853(c)(7) of the Act did not result in an adjustment in the capitation rate in those counties with the "minimum" update rate (the "2 percent minimum update" counties paid under Section 1853(c)(l)(C) of the Act.) In accordance with Section 1853(c) of the Act, the CMS' OACT used the annual growth rate to update only the floor and blended rates, so the "minimum" 2 percent update rate, which was 102 percent of the prior year's rate, did not reflect the costs of new benefits effective in the middle of the previous payment year. Therefore, we decided that payments in counties in which payment was based on the "minimum" 2 percent update rate were not appropriately adjusted to reflect new coverage costs as required by Section 1853(c)(7) of the Act.

This rationale for 2003 changes to Section 422.109 no longer applies, however, in light of changes to the MA payment methodology made in the MMA. Because the new "minimum" percentage increase is now the higher of 2% or the Medicare growth percentage, the costs of mid-year NCDs will be reflected in payment rates. We therefore have revised Section 422.109 to delete the revisions made in the August 22, 2003 final rule. NCDs for 2005 and 2006 accordingly will be subject to the pre-August 22, 2003 "significant cost" test.

Section D: Regional Plan Bonus Payments and Risk Sharing Payments

1. Regional Plan Stabilization Fund. The MMA provides that expenditures from the Stabilization fund will not be available until January 1, 2007. Therefore, we will not be making payments to organizations from the stabilization funds in 2006, or discussing the process for doing so in this notice.

2. Risk Sharing and Risk Corridors for Regional MA Plans. Section 1858(c) of the Social Security Act provides for risk sharing to be in effect for regional MA plans 2006 and 2007, if plan costs are above or below specific risk corridors. The risk corridors are symmetrical in that, beyond the initial corridor, the government pays organizations if plan costs are above the target and recoups its share of the savings when plan costs are below the target. Following are the steps involved in calculating risk corridor payments for MA regional plans.

Calculate the target ratio. The following are the key elements used to determine the risk sharing target ratio for a regional MA plan. Please note that the values are expressed on a per-member, per-month (PMPM) basis:

- Projected allowed medical expense is equal to the projected medical expense in the plan A/B bid for benefits covered under original Medicare, plus the medical component of rebatable integrated benefits. Rebatable integrated benefits are non-drug supplemental benefits that are funded through beneficiary rebates and are used for (i) additional medical benefits not covered under the original Medicare program option; and (ii) benefits that require expenditures by the plan (e.g., cost sharing reductions for A/B benefits).

- Projected allowed revenue is equal to the projected allowed medical expense plus projected non-medical expense and gain/loss margin included in (i) basic plan bid, and (ii) rebatable integrated benefits.

The risk sharing target ratio is calculated as the projected allowed medical expense divided by the projected allowed revenue.

The risk sharing target amount is: actual allowed revenue multiplied by the risk sharing target ratio.

- The actual covered revenue equals the net government capitation payments (including capitation payments, rebates allocated to buy-down supplemental A/B benefits, and government premium adjustment) plus basic enrollee premium revenue.

- The basic enrollee premium revenue represents premiums billed and does not include an offset for uncollected premiums.

As an attachment to the MA bid submission, an MA organization offering a regional plan must include description of the methodology that will be used to develop actual revenue and medical expense to be included in risk sharing reconciliation. Specifically, the organization must provide a description of adjustments that will be made to the plan's medical costs reported in the general ledger to account for (i) any differences in the level of cost sharing reflected in the risk sharing target and that required of plan enrollees; and (ii) the methodology to be used to capture expenditures for non-covered services that are implicitly included in the risk sharing target.

Calculate associated risk corridor limits. The first threshold upper limit is 103 percent of the target amount and the second threshold upper limit is 108 percent of the target amount. Similarly, the first threshold lower limit is 97 percent of the target amount and the second threshold lower limit is 92 percent of the target amount.

Calculate allowed risk corridor costs. The MA organizations will report to CMS the actual allowed revenue and medical expense for the regional plan that were incurred during the contract year and processed within 12 months after the end of the contract year. For example, any medical expenses incurred during 2006 and paid by December 31, 2007 will be reported as an actual incurred claim. Allowed medical expense will reflect reimbursements received, or expected to be received, by the plan under coordination of benefits, subrogation, reinsurance, Part B Rx rebates, or other sources. Further, excluded from medical expenses will be expenditures for case management and disease management services that are not considered to be an enrollee "encounter."

The calculation of the actual plan revenue and medical expense will be verified by an independent auditor, paid for by the plan.

Determine where actual allowed medical expenses are relative to thresholds; calculate payment adjustment. If actual allowed medical expenses fall within 3 percent of the target amount (above or below it), there is no risk sharing of additional cost or "savings." If actual allowed medical expenses are more than 3 percent outside the risk sharing target (above or below it), costs or savings will be shared in accordance with the following provisions:

- Actual allowed medical expense greater than 103 percent of target amount and less than or equal to 108 percent of target amount: CMS pays the MA organization 50 percent of the difference between actual allowed medical expense and 103 percent of target amount.

- Actual allowed medical expense greater than 108 percent of target amount: CMS pays the MA organization 2.5 percent of target amount plus 80 percent of the difference between actual allowed medical expense and 108 percent of target amount.

- Actual allowed medical expenses less than 97 percent of the target amount and greater than or equal to 92 percent of the target amount: CMS applies a negative

adjustment to the plan payment of 50 percent of the difference between 97 percent of target amount and actual allowed medical expense.

- Actual allowed medical expenses less than 92 percent of target amount: CMS applies a negative adjustment to the plan payment of 2.5 percent of target amount plus 80 percent of difference between 92 percent of target amount and actual allowed medical expense.

Section E. Submission of Bids by Demonstration Plans

In 2006, the Social/HMO (S/HMO) demonstration plans will submit bids for original Medicare A/B benefits, mandatory supplemental, prescription drug, and other benefits. The Wisconsin Partnership (WPP), Minnesota Senior Health Options and Minnesota Disability Health Options (MSHO/MnDHO) and Massachusetts Senior Care Options (SCO) demonstrations will submit bids only for Medicare-covered benefits. Medicaid covered benefits, including payment of Medicare cost-sharing, are not to be included in their bids.

Section F. Changes to the Risk Adjustment Method for MA Organizations

1. Update of the CMS-HCC risk adjustment model. The year 2006 will occasion the first major update and recalibration of the CMS-HCC model. (HCC refers to Hierarchical Condition Categories.) The model for Medicare Part C payment is being updated to reflect newer treatment and coding patterns in FFS, to use the additional codes being collected for the Part D model and to accommodate additional codes that complete an HCC or a hierarchy of disease groups. Many ICD-9-CM codes that were not recognized for payment in the first CMS-HCC model are needed for the new Medicare Part D drug risk adjustment model being implemented in 2006. As these codes will be submitted for Part D, they will also be used to enhance the model used to risk adjust the Part A and B benefits. A tentative list of additional codes to be submitted was published in May 2004. Most of the additional codes were included because they appeared to be significant in the drug model; other codes were added because they completed an almost complete HCC, or completed a hierarchy of disease groups.

The updated model will include additional disease categories to the CMS-HCC model. The same evaluation criteria that have been used in the past to determine a group's inclusion in the model will be used again, e.g., magnitude of costs predicted, relative lack of ambiguity of the ICD-9 codes, position in a hierarchy of diseases, etc. All segments of the risk adjustment system will be updated (the community, long-term institutional and ESRD segments). For this notice we are providing the new disease groupings and draft coefficients for the community model and the disease hierarchies (see Tables II-4 and II-5 at the end of Attachment II). Disease groupings will be the same across the community, long-term institutional and ESRD segments. The final coefficients for each of the segments will be provided in the Announcement of CY 2006 MA Payment Rates.

There will be some modification of the mappings of codes. For example, among the codes for neuropathy and retinopathy, the specific codes for diabetic neuropathy and diabetic retinopathy will be mapped directly or solely to the appropriate diabetes groups indicating diabetes with neurological or ophthalmologic manifestations. The other neurological and ophthalmologic codes will remain mapped to the neuropathy and retinopathy groups.

Calibration of the long-term institutionalized (LTI) segment of the model will be done with a larger sample than was used for the initial model. All persons in LTI status in the prediction year who otherwise meet the criteria for inclusion in risk adjustment modeling will be used for calibration. The effect of this work will be to refine the coefficients and better differentiate the costliness of the beneficiaries. Changes in predicted costs relative to the community population on average are not expected to result because of the larger sample.

As part of the model update, data from the years 2002 – 2003 will be used in the calibration. As the data are more current than the 1999 – 2000 data used for the initial model, the new model coefficients will reflect newer treatment and coding patterns in FFS Medicare. In association with the calibration on newer coding patterns, the FFS normalization factor, used to correct for population and coding changes between the data-year used in model calibration and data-year(s) used in implementation of the model for payment, will change. The FFS normalization factor is expected to be smaller than the 5% used in 2004 and 2005 because there will be fewer years between calibration and implementation and because the increase has been getting smaller.

We are proposing a change in how the risk adjustment methodology treats "working aged" enrollees, for whom Medicare is the secondary payer. This change would be reflected in the new model. Medicare secondary payer (MSP) status would no longer be an independent payment adjuster. Therefore all beneficiaries, regardless of MSP status will be merged in the model calibration. This will hold for all model segments including ESRD.

Due to the changes in the risk adjustment model as described above, county payment rates will be restandardized to reflect new average county risk score in the FFS sector. The Office of the Actuary intends to restandardize prior local county rates and then recalculate rates for 2004 using the payment formulas set in the MMA. OACT will then project forward to get the 2006 rates using the formula changes specified in the MMA and the latest growth trends for the intervening years.

2. Transition Payment Blends. Risk adjusted payment is being phased in for MA plan payments, including Special Needs Plans (SNPs), from 2004-2007. In 2006 the CMS-HCC model for MA plans will be applied at 75 percent risk adjusted payment, with the remaining 25 percent being a demographic payment. For the S/HMO, MSHO/MnDHO, WPP and SCO demonstrations, the CMS-HCC model with a supplemental frailty adjuster will be applied in 2006 at 50 percent risk adjusted payment, with the remaining 50

percent being based on the 2003 payment methodology for these demonstrations, respectively. For PACE organizations, the CMS-HCC model with a supplemental frailty adjuster will be applied in 2006 at 50 percent risk adjusted payment, with the remaining 50 percent being based on the 2003 PACE payment methodology.

3. Changes to Frailty Factors for PACE and Certain Demonstrations. Since January 2004, CMS has applied a Medicare payment approach known as frailty adjustment to the PACE and certain demonstrations. The frailty adjuster was developed as a further refinement to risk adjustment to ensure that capitated payments to organizations that serve frail community-based populations were accurate.

The purpose of frailty adjustment is to predict the Medicare expenditures of community populations with functional impairments that were unexplained by risk adjustment. The frailty factors were originally estimated using the Medicare Current Beneficiary Survey (MCBS) cost and use files for 1994 through 1997. Individuals were grouped according to their difficulty with Activities of Daily Living (ADLs). Their Medicare payments were predicted by the CMS-HCC model, and the difference between actual expenditures and predicted payments (i.e., "residual expenditures") was determined. The frailty factors were derived based on the residual expenditures for each ADL group (0 ADLs, 1-2 ADLs, 3-4 ADLs, and 5-6 ADLs).

As explained previously in this Notice, CMS is modifying the CMS-HCC risk adjustment model for 2006 payment. The modifications are significant enough so that the predicted payments for frail community-based populations under the revised CMS-HCC model may (on average) differ from the predicted payments under the original model. Since the frailty adjuster is applied in conjunction with risk adjustment, the frailty factors must be consistent with the revised risk adjustment model. Thus, CMS intends to recalculate the frailty factors.

We will re-estimate the frailty factors using the MCBS files for 1994 through 1997. The new frailty factors will be published in the Announcement of the 2006 Medicare Advantage Payment Rates.

4. Medicare as a Secondary Payer for Risk Adjustment in 2006. The CMS standard system for the identification of Medicare as a Secondary Payer (MSP) has been the Common Working File (CWF). Information on MSP was obtained from three primary sources, the initial Medicare enrollment process, an Internal Revenue Service Data/SSA/CMS data match and voluntary MSP data match agreements. At the present time, MSP information is complied and maintained by a Coordination of Benefits Contractor (COBC), supported by input from Fiscal Intermediaries (FIs) and carriers. The COBC submits information to the CWF.

Historically, MA organizations have questioned CMS as to the reliability of determination of Medicare as a Secondary Payer (MSP) status. In response to complaints by the MA industry about the accuracy of this MSP data, CMS changed its determination of Working Aged for MA organizations from an individual level determination based on

the CWF flag to an organization level determination based on an annual survey conducted by the MA organizations of enrollees in their organization. Working Aged status, which is a subset of MSP, refers to those Medicare enrollees over age 65 with employer group health coverage (either through their own or spousal employment). Currently each MA organization surveys all its aged members annually and reports to CMS those with coverage primary to Medicare. This survey does not include disabled members (under age 65) or enrollees with ESRD. The status of aged enrollees who do not respond to the survey (non-responders) is still determined by the CWF flag. The CMS then calculates the proportion of each MA organization's enrollment that is Working Aged and makes an organization level payment adjustment to the organization's monthly capitated payment. To date, there has been no determination as to the reliability of this survey.

A number to changes have occurred that caused CMS to review how MSP is treated under risk adjustment, particularly the inclusion of ESRD under risk adjusted payment. The ESRD model was calibrated assuming that the payment system would identify MSP at the individual level using our standard systems. However, the current survey for identification of MSP in MA organizations does not include ESRD enrollees. The use of the CWF was judged to be in conflict with our current survey approach for identification of MA enrollees for whom Medicare is a secondary payer. Given that the ESRD payment rates are very high, that the Medicare ESRD population is primarily under age 65, and that a substantial proportion of ESRD enrollees have health insurance coverage that is primary to Medicare, this is a major issue in implementing correct payments for ESRD enrollees. Having considered the data reliability issues surrounding MSP, the impact of MSP determination on ESRD payments, and the burden of MSP survey, audits and reconciliations, CMS has recalibrated the Part C risk adjustment models (CMS-HCC and ESRD) for 2006 to include the costs associated with beneficiaries for whom Medicare is a Secondary Payer (MSP). This means that on average risk scores would be appropriately adjusted for MSP and that no further adjustment would be necessary.

5. Reporting of Medicaid Status for Demographic Payment and Part C Risk Adjusted Payment. In implementing Part C payment under the demographic payment and risk adjustment methods, CMS will use a definition of Medicaid status that promotes consistency across Part C and Part D. To implement Part D, CMS will be collecting comprehensive information on Medicare/Medicaid dual enrollment. We will use this information on Medicare/Medicaid dual enrollment to define Medicaid status under Part C for demographic and risk adjustment payments.

We propose assigning Medicaid status for demographic payment and risk adjustment under Part C to low-income-subsidy (LIS) individuals who are "deemed" under Part D. In practice, the new MMA Medicare/Medicaid Dual Eligible monthly submission file, provided to CMS from the States, will be the source of the "deemed" LIS indicator for Part D. This file, which all States are required to submit under the provisions of the MMA, provides monthly identification of each actively enrolled Medicare/Medicare dual eligible beneficiary. This includes those eligible for comprehensive Medicare and Medicaid benefits (whether eligible through the state plan or a section 1115

demonstration), as well as those for whom the State pays Medicare cost sharing (Qualified Medicare Beneficiaries, Specified Low-Income Medicare Beneficiaries, and Qualifying Individuals).

The categories of dual eligibles identified on the file are listed in TableII-2. The categories of dual eligibles "deemed" eligible for the low income subsidy (LIS) under the Part D benefit include categories 1-4, 6, and 8 in Table II-2 below. These categories will be defined as Medicaid for Part C risk adjustment. The MMA Medicaid file includes a person month record for each Medicare/Medicaid dual eligible in the state Medicaid program in the reporting month, and records to report information on changes in the circumstances for individuals in a prior month.

Submission of state Medicare/Medicaid enrollment test files commences in March 2005 and production files are due to CMS each month beginning in June 2005. These files will be the source of reporting of Medicaid status for implementation of the low income subsidy provisions of Part D program. For prospective 2006 risk adjusted payments, we will use the current methodology. However, beginning in January of 2006, these files will be used as the sole source of Medicaid status for all Part C demographic payment and risk adjustment purposes, including reconciliations and payment adjustments. After January 2006, plan reported Medicaid will no longer be accepted as a source of the Medicaid indicator for payment under the demographic model or for Part C risk adjustment.

Table II-2. Categories of Dual Eligibles Identified on the Monthly Submission File

MEDICARE/MEDICAID DUAL STATUS CODE	01 = Eligible is entitled to Medicare- QMB only 02 = Eligible is entitled to Medicare- QMB AND Medicaid coverage including RX **(Medicaid drug coverage criterion only applies through December 2005)** 03 = Eligible is entitled to Medicare- SLMB only 04 = Eligible is entitled to Medicare- SLMB AND Medicaid coverage including RX (Medicaid drug coverage criterion only applies through December 2005) 05 = Eligible is entitled to Medicare- QDWI 06 = Eligible is entitled to Medicare- Qualifying individuals 08 = Eligible is entitled to Medicare- Other Full Dual Eligibles (Non QMB, SLMB,QWDI or QI)with Medicaid coverage including RX **(Medicaid drug coverage criterion only applies through December 2005)** 09 = Eligible is entitled to Medicare – Other Dual Eligibles but without Medicaid coverage, includes Pharmacy Plus and 1115 drug-only demonstration. If unknown = 99.

6. Elimination of Diagnostic Radiology Data from the Physician Specialty Type. The CMS has allowed the submission of diagnostic radiology data as a physician specialty type under the CMS-HCC payment methodology. In early 2004, CMS conducted a CMS-HCC validation pilot study to understand the extent to which payment inaccuracies could be identified when reviewing medical records from physician office settings. One key finding of the pilot study was that medical record documentation from ambulatory diagnostic radiology settings did not often provide sufficient information to confirm an ICD-9-CM code during data validation. That is, the diagnostic radiology medical record could not be used as a stand alone document (without additional follow-up information from the referring physician) to support a diagnosis. As a result of this finding, we are proposing to eliminate the radiology specialty as an acceptable risk adjustment physician provider type for payment year 2006 (dates of service: January 1 through December 31, 2005). This decision applies only to diagnostic radiology and does not impact other radiology codes (e.g. interventional radiology codes).

Section G. Budget Neutral Risk Adjustment in Payments for Local and Regional MA Organizations

There are three changes in budget neutrality for 2006, and the details on each change are discussed below:

- a change in the budget neutrality calculation to account for different payment methodologies for local MA plans versus regional MA plans;
- a phase out of budget neutrality; and
- changes in the technical adjustments we make to the budget neutrality calculation.

1. Change to account for different payment methodologies for local MA plans versus regional MA plans. Beginning in 2003, CMS has implemented risk adjusted payments in a budget neutral manner. Since that time, the budget neutrality amount has been calculated as the difference between payments to organizations at 100 percent of the demographic rate and payments at 100 percent of the risk adjusted rate. This amount was then incorporated into the rescaling factor, which redistributed payment reductions due to risk adjusted payments. This calculation used county rates, either demographic or risk, as the basis for the calculation.

Because of the difference in payment methods for local MA plans versus regional MA plans beginning in 2006, CMS will need to modify the budget neutrality calculation. Budget neutrality for 2006 will be calculated as the difference between aggregate MA payments at the local MA benchmark rate that would have been made using the demographic method for 100 percent of payments versus the aggregate payments that would be made using 100 percent of risk adjusted payments. Budget neutrality will be applied to both local and regional MA plans. For regional plans, this means that the budget neutrality factor will be applied to the statutory component of the benchmark.

2. Phase Out of Budget Neutrality. Consistent with the President's FY2006 Budget, CMS is proposing to implement a phase out of risk adjustment budget neutrality, with a transition through 2010. In order for competition to work in the long run, bidding and payment must take into account risk selection. Moreover, beginning in 2006 organizations will be paid separately for the Part D drug benefit, so organizations will be receiving direct payments for benefits (i.e., drugs) that they were previously providing as supplemental benefits

The phase out schedule is shown in Table II-3. Under the budget neutrality methodology this means that in 2006, 100% of the difference between payment under the demographic method and payment under risk adjustment will be added back to the risk payment rates via a rescaling factor. However, due to the payment blend for 2006 this will result in 75% of the budget neutrality amount being added back to the blended benchmark. In 2007, we will reduce the amount added back into the risk adjusted rates to 60% of the difference between payment under the demographic method and payment under risk adjustment and continue to reduce the percentage in accordance with the Table II-3 below until it reaches 0% in 2011.

Table II-3. Phase-Out Schedule for Budget Neutral Risk Adjustment Payments

Year	Budget Neutrality Percentage
2006	100% [1/]
2007	60%
2008	45%
2009	30%
2010	15%
2011	0%

[1/] 100% of the difference between payment under the demographic method and the payment under the risk adjusted method will be added to the risk adjusted payment rates. However, due to the payment blend for 2006 of 25% demographic and 75% risk adjustment, the net effect is a 75% budget neutrality adjustment.

The MA organizations will see payments that reflect this budget neutral approach in the beneficiary-level amounts that are shown on the Monthly Membership Reports (MMR.), beginning in January 2006. The reports for January 2006 will be available for downloading in late December 2005.

3. Technical Adjustments Applied to the Budget Neutrality Calculation. In 2005, CMS adjusted the budget neutrality calculation to consider the effects of lagged data, changes in organization enrollment during the year, and late data risk adjustment submission. Slight modifications in the methods used to make those three adjustments will be implemented for 2006 because of experience in implementing the CMS-HCC model, as well as differences in the amount of data available for making these estimates.

For 2005, we estimated budget neutrality based on non-lagged risk adjustment data (non-lagged risk adjustment data are defined as diagnoses collected for the calendar year immediately preceding the payment year). Using non-lagged risk scores for the estimation of budget neutrality was helpful because final payment for the payment year is

based on non-lagged risk adjustment factors and this procedure eliminated the need to estimate the effect of using lagged data for budget neutrality calculations. We intend to adopt the same approach for 2006. We will base the estimation of 2006 budget neutrality on a July 2004 cohort which represents the average organization enrollment for 2004. The risk scores used to calculate payment will be based on complete calendar year 2003 risk adjustment data updated through December 2004. This procedure should ensure that both the demographic information and the risk scores used in the calculation of budget neutrality are as accurate as possible.

In previous years, budget neutrality was estimated on a cohort of organization enrollees for a given month – e.g. for 2005 budget neutrality we used the January 2004 cohort. Because of changes in organization enrollment throughout the year, the average organization risk score for an organization's cohort typically occurs in the middle of the year (i.e., in July rather than in January). To account for this in 2005 we used a prediction model to estimate the effect of the change in average organization risk score through the mid point of the year. We then adjusted January risk scores on which 2005 budget neutrality was based by a factor which accounted for the decrease in average organization risk score. For 2006, we propose instead using the July 2004 cohort to estimate budget neutrality. Because July risk scores represent average organization risk scores for the calendar year, we propose not making any other adjustment for changes in organization enrollment in estimating budget neutrality for 2006.

Organizations continue to submit data for up to 17 months after the end of a data collection period for a payment year. This additional data submission typically increases risk scores, which, in turn, increases risk payments and decreases the budget neutrality estimate. In 2005, to account for these late data, we estimated a late data adjustment factor. For 2006, we propose not making any adjustment to take into account late data submissions. As stated above, we will use data for calendar year 2003 submitted through December 2004 in our budget neutrality calculations. This 12 month run-out of data past the end of the data collection year should ensure that our budget neutrality estimate accounts for most of the effects of late data submission.

In addition, because the average risk score of enrollees in regional PPOs is expected to be different from the average risk of beneficiaries who enroll in local MA organizations, we will make adjustments to the average risk of enrollees in our calculation. We expect to adjust the budget neutrality factor for the expected enrollment and risk scores of regional MA organizations as reflected in the FY2006 President's baseline budget.

Table II-4. Draft Community Annual Coefficients for the 2006 CMS-HCC Model with Constraints And Demographic/Disease Interactions, used in Calculation of Monthly MA Payments[1]

Note: For this notice we are providing the new disease groupings and draft coefficients for the community model and the disease hierarchies. Disease groupings will be the same across the community, long-term institutional and ESRD segments. The final coefficients for each of the segments will be provided in the Announcement of CY 2006 MA Payment Rates.

Variable	Disease Group	Community Estimate[2]	Constraint[7]
Female			
0-34 Years		600	
35-44 Years		600	
45-54 Years		900	
55-59 Years		1,400	
60-64 Years		1,800	
65-69 Years		1,400	
70-74 Years		1,800	
75-79 Years		2,300	
80-84 Years		2,700	
85-89 Years		3,200	
90-94 Years		4,200	
95 Years or Over		4,200	
Male			
0-34 Years		300	
35-44 Years		600	
45-54 Years		700	
55-59 Years		1,200	
60-64 Years		1,700	
65-69 Years		1,500	
70-74 Years		2,000	
75-79 Years		2,600	
80-84 Years		3,200	
85-89 Years		3,900	
90-94 Years		4,500	
95 Years or Over		5,400	
Medicaid and Originally Disabled Interactions with Age and Sex			
Medicaid_Female_Disabled		1,300	

Variable	Disease Group	Community Estimate[2]	Constraint[7]
Medicaid_Female_Aged		1,100	
Medicaid_Male_Disabled		800	
Medicaid_Male_Aged		1,400	
Originally Disabled_Female		1,400	
Originally Disabled_Male		1,100	
Disease Coefficients			
HCC1	HIV/AIDS	5,400	
HCC2	Septicemia/Shock	4,500	
HCC3	Central Nervous System Infection	1,200	
HCC5	Opportunistic Infections	2,400	
HCC7	Metastatic Cancer and Acute Leukemia	9,100	
HCC8	Lung, Upper Digestive Tract, and Other Severe Cancers	9,100	
HCC9	Lymphatic, Head and Neck, Brain, and Other Major Cancers	4,200	
HCC10	Breast, Prostate, Colorectal and Other Cancers and Tumors	1,200	
HCC15	Diabetes with Renal or Peripheral Circulatory Manifestation[3]	3,100	
HCC16	Diabetes with Neurologic or Other Specified Manifestation[3]	2,100	
HCC17	Diabetes with Acute Complications[3]	1,200	
HCC18	Diabetes with Ophthalmologic or Unspecified Manifestation[3]	1,200	
HCC19	Diabetes without Complication[3]	500	
HCC20	Type I Diabetes Mellitus	1,500	
HCC21	Protein-Calorie Malnutrition	3,900	
HCC22	Other Significant Endocrine and Metabolic Disorders	1,000	
HCC25	End-Stage Liver Disease	5,100	
HCC26	Cirrhosis of Liver	2,800	
HCC27	Chronic Hepatitis	1,400	
HCC31	Intestinal Obstruction/Perforation	2,200	
HCC32	Pancreatic Disease	1,800	

Variable	Disease Group	Community Estimate[2]	Constraint[7]
HCC33	Inflammatory Bowel Disease	1,500	
HCC34	Peptic Ulcer, Hemorrhage, Other Specified Gastrointestinal Disorders	1,100	
HCC37	Bone/Joint/Muscle Infections/Necrosis	3,300	
HCC38	Rheumatoid Arthritis and Inflammatory Connective Tissue Disease	1,800	
HCC44	Severe Hematological Disorders	6,000	
HCC45	Disorders of Immunity	4,400	
HCC46	Coagulation Defects and Other Specified Hematological Disorders	1,000	
HCC48	Delirium and Encephalopathy	2,000	
HCC49	Dementia/Cerebral Degeneration	1,600	
HCC51	Drug/Alcohol Psychosis	700	
HCC52	Drug/Alcohol Dependence	700	
HCC54	Schizophrenia	3,200	
HCC55	Major Depressive, Bipolar, and Paranoid Disorders	2,000	
HCC56	Reactive and Unspecified Psychosis	1,200	
HCC57	Personality Disorders	1,200	
HCC58	Depression	1,200	
HCC59	Anxiety Disorders	500	
HCC67	Quadriplegia, Other Extensive Paralysis	6,200	
HCC68	Paraplegia	5,600	
HCC69	Spinal Cord Disorders/Injuries	2,700	C1
HCC70	Cerebral Palsy and Muscular Dystrophy	700	
HCC71	Polyneuropathy	1,700	
HCC72	Multiple Sclerosis	2,600	
HCC73	Parkinson's and Huntington's Diseases	2,800	
HCC74	Seizure Disorders and Convulsions	1,200	
HCC75	Coma, Brain Compression/Anoxic Damage	2,200	C2
HCC77	Respirator Dependence/Tracheostomy Status	12,200	
HCC78	Respiratory Arrest	7,900	
HCC79	Cardio-Respiratory Failure and Shock	3,300	
HCC80	Congestive Heart Failure	2,000	

Variable	Disease Group	Community Estimate[2]	Constraint[7]
HCC81	Acute Myocardial Infarction	1,800	
HCC82	Unstable Angina and Other Acute Ischemic Heart Disease	1,800	
HCC83	Angina Pectoris/Old Myocardial Infarction	1,300	
HCC84	Coronary Atherosclerosis/Other Chronic Ischemic Heart Disease	1,000	
HCC85	Heart Infection/Inflammation, Except Rheumatic	1,100	
HCC86	Valvular and Rheumatic Heart Disease	900	
HCC87	Major Congenital Cardiac/Circulatory Defect[4]	0	
HCC89	Hypertensive Heart and Renal Disease or Encephalopathy	500	
HCC90	Hypertensive Heart Disease	400	C3
HCC91	Hypertension	400	C3
HCC92	Specified Heart Arrhythmias	1,300	
HCC95	Cerebral Hemorrhage	1,600	
HCC96	Ischemic or Unspecified Stroke	1,300	
HCC97	Precerebral Arterial Occlusion and Transient Cerebral Ischemia	400	C3
HCC98	Cerebral Atherosclerosis and Aneurysm	400	C3
HCC99	Cerebrovascular Disease, Unspecified	400	C3
HCC100	Hemiplegia/Hemiparesis	2,400	
HCC101	Monoplegia, Other Paralytic Syndromes	1,900	
HCC103	Cerebrovascular Disease Late Effects, Unspecified	1,100	
HCC104	Vascular Disease with Complications	3,500	
HCC105	Vascular Disease	1,600	
HCC107	Cystic Fibrosis	1,900	
HCC108	Chronic Obstructive Pulmonary Disease	1,900	
HCC109	Fibrosis of Lung and Other Chronic Lung Disorders	900	
HCC110	Asthma	500	
HCC111	Aspiration and Specified Bacterial Pneumonias	4,300	

Variable	Disease Group	Community Estimate[2]	Constraint[7]
HCC112	Pneumococcal Pneumonia, Emphysema, Lung Abscess	1,800	
HCC113	Viral and Unspecified Pneumonia, Pleurisy	1,600	
HCC114	Pleural Effusion/Pneumothorax	1,500	
HCC119	Proliferative Diabetic Retinopathy (D E L E T E D)[5]	--	
HCC120	Vascular Retinopathies and Hemorrhages	600	
HCC122	Glaucoma	100	
HCC125	Significant Ear, Nose, and Throat Disorders	800	
HCC130	Dialysis Status	9,300	
HCC131	Renal Failure	1,600	
HCC132	Nephritis	700	
HCC133	Urinary Obstruction and Retention	1,300	
HCC146	Uncompleted Pregnancy With Complications	600	
HCC147	Uncompleted Pregnancy With No or Minor Complications	600	
HCC148	Decubitus Ulcer of Skin	7,100	
HCC149	Chronic Ulcer of Skin, Except Decubitus	2,800	
HCC150	Extensive Third-Degree Burns	2,500	
HCC154	Severe Head Injury	2,200	C2
HCC155	Major Head Injury	900	
HCC157	Vertebral Fractures without Spinal Cord Injury	2,700	C1
HCC158	Hip Fracture/Dislocation	2,400	
HCC161	Traumatic Amputation	4,100	
HCC164	Major Complications of Medical Care and Trauma	1,700	
HCC174	Major Organ Transplant Status	5,600	
HCC176	Artificial Openings for Feeding or Elimination	4,100	
HCC177	Amputation Status, Lower Limb/Amputation Complications	3,900	
Disabled/Disease Interactions			
D_HCC5	Disabled_Opportunistic Infections	5,400	
D_HCC44	Disabled_Severe Hematological Disorders	4,400	

Variable	Disease Group	Community Estimate[2]	Constraint[7]
D_HCC51	Disabled_Drug/Alcohol Psychosis	5,400	
D_HCC52	Disabled_Drug/Alcohol Dependence	2,900	
D_HCC107	Disabled_Cystic Fibrosis	5,800	
Disease Interactions			
INT1	DM_CHF[6]	1,100	
INT2	DM_CVD	600	
INT3	CHF_COPD	1,500	
INT4	COPD_CVD_CAD	700	
INT5	RF_CHF[6]	1,600	
INT6	RF_CHF_DM[6]	4,200	

NOTES:

[1] The dollar amounts in this table will be converted to relative risk scores. That is, these dollar amounts will be divided by the national average predicted expenditures to get relative risk scores.

[2] All estimates are rounded to the nearest hundred dollars.

[3] Includes Type I or Type II Diabetes Mellitus.

[4] Included in preliminary model, but estimated coefficient had t-statistic less than 1.0, and therefore was excluded from final model.

[5] Included in 2004 and 2005 CMS-HCC models, but deleted from 2006 CMS-HCC model.

[6] Beneficiaries with the three-way interaction RF*CHF*DM are excluded from the two-way interactions DM*CHF and RF*CHF. Thus, the three-way interaction term RF*CHF*DM is not additive to the two-way interaction terms DM*CHF and RF*CHF. Rather, it is hierarchical to, and excludes these interaction terms. A beneficiary with all three conditions is not "credited" with the two-way interactions. All other interaction terms are additive.

DM = diabetes mellitus (HCCs 15-19).
CHF = congestive heart failure (HCC 80).
COPD = chronic obstructive pulmonary disease (HCC 108).
CVD = cerebrovascular disease (HCCs 95-101, and 103).
CAD = coronary artery disease (HCCs 81-84).
RF = renal failure (HCC 131).

[7] Shading between adjacent boxes in the constraint column means coefficients of HCCs are constrained to be equal. C1, C2, and C3 denote non-contiguous constraints.

SOURCE: RTI International analysis of 2002/2003 Medicare 5% sample.

Table II-5. Draft List Of Disease Groups (HCCs) with Hierarchies

DRAFT DISEASE HIERARCHIES		
If the Disease Group is Listed in This Column…		...Then Drop the Associated Disease Group(s) Listed in this Column
Disease Group (HCC)	Disease Group Label	
5	Opportunistic Infections	112,113
7	Metastatic Cancer and Acute Leukemia	8,9,10
8	Lung, Upper Digestive Tract, and Other Severe Cancers	9,10
9	Lymphatic, Head and Neck, Brain, and Other Major Cancers	10
15	Diabetes with Renal or Peripheral Circulatory Manifestation	16,17,18,19
16	Diabetes with Neurologic or Other Specified Manifestation	17,18,19
17	Diabetes with Acute Complications	18,19
18	Diabetes with Ophthalmologic or Unspecified Manifestation	19
25	End-Stage Liver Disease	26,27,34
26	Cirrhosis of Liver	27
31	Intestinal Obstruction/Perforation	34
33	Inflammatory Bowel Disease	34
44	Severe Hematological Disorders	46
51	Drug/Alcohol Psychosis	52
54	Schizophrenia	55,56,57,58,59
55	Major Depressive, Bipolar, and Paranoid Disorders	56,57,58,59
56	Reactive and Unspecified Psychosis	57,58,59
57	Personality Disorders	58,59
58	Depression	59
67	Quadriplegia, Other Extensive Paralysis	68,69,100,101,103,157
68	Paraplegia	69,100,101,103,157
69	Spinal Cord Disorders/Injuries	157
75	Coma, Brain Compression/Anoxic Damage	48
77	Respirator Dependence/Tracheostomy Status	78,79
78	Respiratory Arrest	79
80	Congestive Heart Failure	90,91
81	Acute Myocardial Infarction	82,83,84
82	Unstable Angina and Other Acute Ischemic Heart Disease	83,84
83	Angina Pectoris/Old Myocardial Infarction	84

85	Heart Infection/Inflammation, Except Rheumatic	86
89	Hypertensive Heart and Renal Disease or Encephalopathy	90,91
90	Hypertensive Heart Disease	91
95	Cerebral Hemorrhage	96,97,98,99
96	Ischemic or Unspecified Stroke	97,98,99
97	Precerebral Arterial Occlusion and Transient Cerebral Ischemia	98,99
98	Cerebral Atherosclerosis and Aneurysm	99
100	Hemiplegia/Hemiparesis	101,103
101	Monoplegia, Other Paralytic Syndromes	103
104	Vascular Disease with Complications	105,149
107	Cystic Fibrosis	108,109,110
108	Chronic Obstructive Pulmonary Disease	109,110
109	Fibrosis of Lung and Other Chronic Lung Disorders	110
111	Aspiration and Specified Bacterial Pneumonias	112,113
112	Pneumococcal Pneumonia, Empyema, Lung Abscess	113
130	Dialysis Status	131,132
131	Renal Failure	132
146	Uncompleted Pregnancy With Complications	147
148	Decubitus Ulcer of Skin	149
154	Severe Head Injury	48,75,155
161	Traumatic Amputation	177

How payments are Made with a Disease Hierarchy

EXAMPLE: If a beneficiary triggers Disease Groups 148 (Decubitus Ulcer of the Skin) and 149 (Chronic Ulcer of Skin, Except Decubitus), then DG 149 will be dropped. In other words, payment will always be associated with the DG in the first column, if a DG in the second column also occurs during the same collection period. Therefore, the MA organization's payment will be based on DG 148 rather than DG 149.

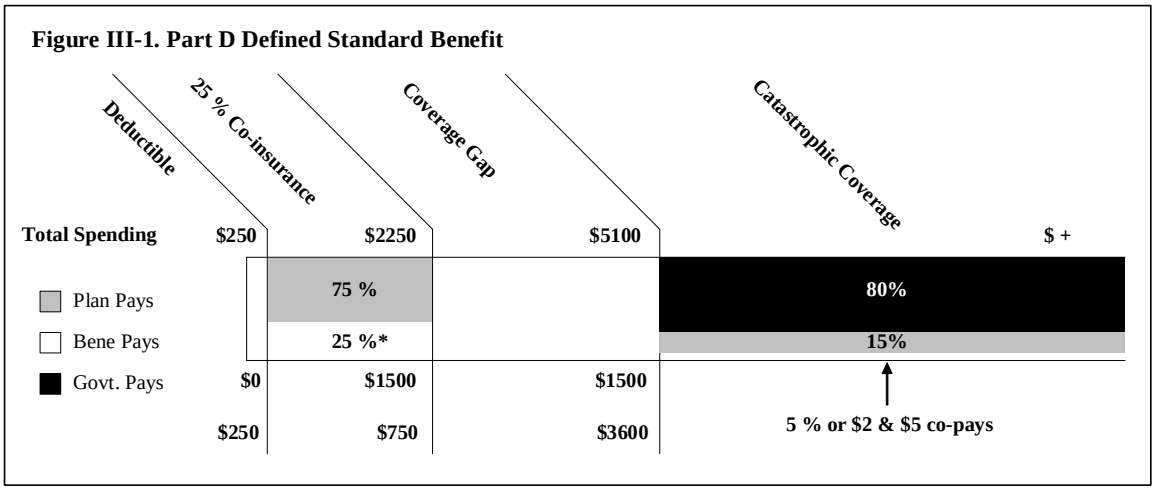
Attachment III

Overview of Payment for Medicare Advantage Prescription Drug Plans (MA-PDs) and Prescription Drug Plans (PDPs)

Overview of Part D Payments

The Medicare Part D benefit established by the Medicare Prescription Drug, Improvement and Modernization Act (MMA) of 2003 (P.L. 108-173) and codified in 42 CFR Parts 400, 403, 411, 417, and 423, provides partially government subsidized drug coverage administered by private sector Part D plans. Part D plans predominantly fall into two categories: stand-alone prescription drug plans (PDPs) and Medicare Advantage health plans that also have a prescription drug benefit (MA-PDs). Part D plans may also be offered by other entities such as PACE organizations, section 1876 cost plans, and employers. The PDPs may have three levels of risk: full risk, limited risk and fallback (no risk). Limited risk plans are subject to the same payment rules as full risk plans except that the federal government has additional risk sharing. Fallback plan rules will be established separately from this Advance Notice.

Figure III-1. Part D Defined Standard Benefit



In 2006, the Part D defined standard benefit (illustrated above) begins with a $250 deductible the beneficiary (or another party on the beneficiary's behalf) is responsible for paying. Between $250 and the initial coverage limit of $2,250, the Part D plan is responsible for 75 percent of costs and the beneficiary pays a 25 percent coinsurance. Beneficiaries are responsible for all costs between the initial coverage limit and the $3,600 out-of-pocket threshold. Catastrophic coverage begins at the attachment point or threshold of $3,600 in beneficiary out-of-pocket spending. Costs in catastrophic coverage are split three ways, with the government providing reinsurance equal to 80 percent, the Part D plan covering 15 percent, and the beneficiary paying a 5 percent co-insurance, or co-payments of $2 for generic drugs and $5 for non-generic drugs. Note that the dollar figures given are for 2006 only and will be indexed to changes in per capita Part D spending in later years.

Government payments to Part D plans are made through the following four mechanisms: 1) the direct subsidy, 2) reinsurance subsidies, 3) low-income subsidies, and 4) risk sharing arrangements.

- The direct subsidy equals the standardized bid amount, adjusted for the risk characteristics of the enrollee, minus the monthly beneficiary premium for basic benefits. Part D plan sponsors will use the bid pricing tool to compute an estimate of its average monthly revenue requirements to provide defined standard drug coverage for a Part D eligible individual with a national average risk profile (standardized bid amount).

- Reinsurance subsidies are equal to 80 percent of the allowable reinsurance costs attributable to prescription drug costs after the Part D enrollee has incurred true out-of-pocket costs that exceed the annual out-of-pocket threshold.

- Low-income subsidies are government payments on behalf of certain beneficiaries based on their income and asset levels that cover part or all of the premium subsidy amount and plan cost sharing.

- Risk sharing arrangements involve symmetrical risk corridors in which the government either pays more of plan costs or recovers payments when a plan has allowable risk corridor costs above or below a target amount by certain percentages. The target amount equals the total amount of payments (from both CMS and by or on behalf of enrollees) to that plan for all risk-adjusted standardized bid amounts less the administrative expenses (including return on investment) assumed in the standardized bids.

More detailed descriptions of the four payment mechanisms are included in the following sections on prospective payments, reconciliations and risk sharing.

Prospective Payments

For 2006, the direct, reinsurance and low-income subsidies will all be prospectively paid based on the approved plan bid for basic benefits and estimates of expected reinsurance and low-income cost sharing provided along with the bid. These payments will be reconciled to actual enrollment, risk factors, and incurred allowable reinsurance costs and low income cost sharing after the close of the coverage year. Risk sharing will also be paid after the close of the coverage year following completion of all reconciliations, and is discussed in detail in a subsequent section. We note that the American Academy of Actuaries and consultants to CMS are reviewing the risk corridor and reinsurance methodologies discussed in this notice.

Direct subsidy

The CMS will provide a direct subsidy in the form of monthly payments equal to the product of the plan's approved Part D standardized bid and the beneficiary's health status risk adjustment factor, minus the monthly beneficiary premium for basic coverage.

- The standardized bid amount is the portion of the approved bid that is attributable to basic prescription drug coverage. The risk adjustment methodology is described in more detail below.

- The monthly beneficiary premium for basic coverage is the base beneficiary premium adjusted for the difference between the plan's standardized bid amount and the national average monthly bid amount. In determining the monthly beneficiary premium, the national average bid amount may be adjusted by CMS for geographic variations in prescription drug pricing if it is determined that such price variations exist and an appropriate adjustment methodology is developed. CMS is not going to geographically adjust the national average monthly bid amount for 2006.

- The national average monthly bid amount is the average of most approved Part D standardized bid amounts weighted by enrollment in these Part D plans (As provided in the final rule, some part D plan bids –such as the bids submitted by cost plans, PACE organizations, Special Needs Plans (SNP), and Private-Fee-For-Service (PFFS) plans – are excluded from the calculation).

- The base beneficiary premium is equal to the product of the national average monthly bid amount and the beneficiary premium percentage, which is a fraction with a numerator of 25.5 percent, and a denominator of 100 percent minus the percentage of total plan revenue attributable to reinsurance payments as estimated by CMS. The percentage of total revenue attributable to reinsurance will be calculated as estimated total reinsurance payments divided by the sum of these estimated total reinsurance payments plus total payments that CMS estimates will be paid to Part D plans that are attributable to the standardized bid amount during the year, taking into account amounts paid by both CMS and enrollees.

At least one commenter to our NPRM indicated that they foresaw the calculation of the monthly beneficiary premium for basic coverage resulting in a negative premium. This would happen if the base beneficiary premium adjusted for the difference between the plan's bid and the national average monthly bid amount is less than zero. For example, if the base beneficiary premium were $35 and the national average monthly bid amount were $115 and a plan bid $75, the statutory formula would result in a negative $5 premium. In this example, the direct subsidy payment (before risk adjustment) would provide an amount $5 greater than the plan's revenue needs. The final Part D rule allows this to happen but requires that these additional dollars be applied to a supplemental Part D benefit with no additional premium, or a reduction of the approved supplemental Part D premium, if applicable.

Reinsurance subsidy

When a beneficiary exceeds the out-of-pocket threshold (in 2006, $3,600 in "true" out-of-pocket costs, or "TrOOP"), the catastrophic coverage phase of the benefit begins in which CMS reimburses 80 percent of allowable drug costs above the out-of-pocket

threshold. Allowable reinsurance costs are the subset of gross covered prescription drug costs that are attributable to basic prescription drug coverage for covered Part D drugs only and that are actually paid by the Part D sponsor or by (or on behalf of) an enrollee under the Part D plan. "Actually paid" means that the costs must be actually incurred by the Part D sponsor and must be net of any direct or indirect remuneration which includes discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers from any source, including manufacturers, pharmacies, enrollees, or any other person, that would serve to decrease the costs incurred by the Part D sponsor for the drug. Hereafter we refer to all such direct or indirect remuneration as DIR.

The allowable reinsurance costs for any Part D plan offering enhanced alternative coverage must be adjusted not only to exclude any costs attributable to benefits beyond basic prescription drug coverage, but also to exclude any costs determined to be attributable to increased utilization over the defined standard prescription drug coverage as the result of the insurance effect of enhanced alternative coverage in accordance with CMS guidelines on actuarial valuation. During 2006, CMS will make prospective monthly reinsurance payments to plans based on estimated allowable reinsurance costs submitted with a Part D plan's bid.

The CMS is developing a contract for a facilitator that will provide real time TrOOP and coordination of benefits information. The system will be ready for plan use by January 1, 2006. As indicated in the final rule, CMS expects to charge user fees of no more than $1 per beneficiary per year.

Low-income subsidy (LIS)
Part D also provides for Medicare payments to plan sponsors to subsidize some or all of the costs that would otherwise be incurred by beneficiaries for certain qualifying low-income beneficiaries, including costs associated with premiums, deductibles, coinsurances, and late enrollment penalties. Part D divides these income-related subsidies into two categories: premium assistance and cost-sharing assistance (see Table III-1 and Figure III-2 for details). For premium assistance the percentages given are in relation to the premium subsidy amount calculated for the Part D plan.

The premium subsidy amount is based on the lesser of:

- the portion of monthly beneficiary premium attributable to basic coverage (for enrollees in PDPs) or the MA monthly prescription drug benefits premium (for enrollees in MA-PDs) or

- the greater of the low-income benchmark premium amount for a region or the lowest monthly beneficiary premium for a PDP that offers basic prescription drug coverage in the region.

The low-income benchmark premium amount for a PDP region is:

- in regions where all PDPs are offered by the same PDP sponsor, the weighted average, for the PDPs in the region, of the portion of the monthly beneficiary premium attributable to basic coverage;

- in regions where there are PDPs offered by more than one PDP sponsor, a weighted average, for all PDPs and MA-PDs in the region) of the portion of the monthly beneficiary premium attributable to basic coverage (for PDPs) and the MA monthly prescription drug beneficiary premium (for MA-PDs).

For purposes of calculating the low-income benchmark premium amount for 2006, CMS assigns equal weighting to PDP sponsors (including fallback entities) and assigns MA-PD plans a weight based on prior enrollment. In 2006, new MA-PD plans will be assigned zero weight as they will have no prior enrollment (this also applies to employer sponsored plans and SNPs). PACE, private fee-for-service plan and 1876 cost plan bids are not included in this calculation for any year.

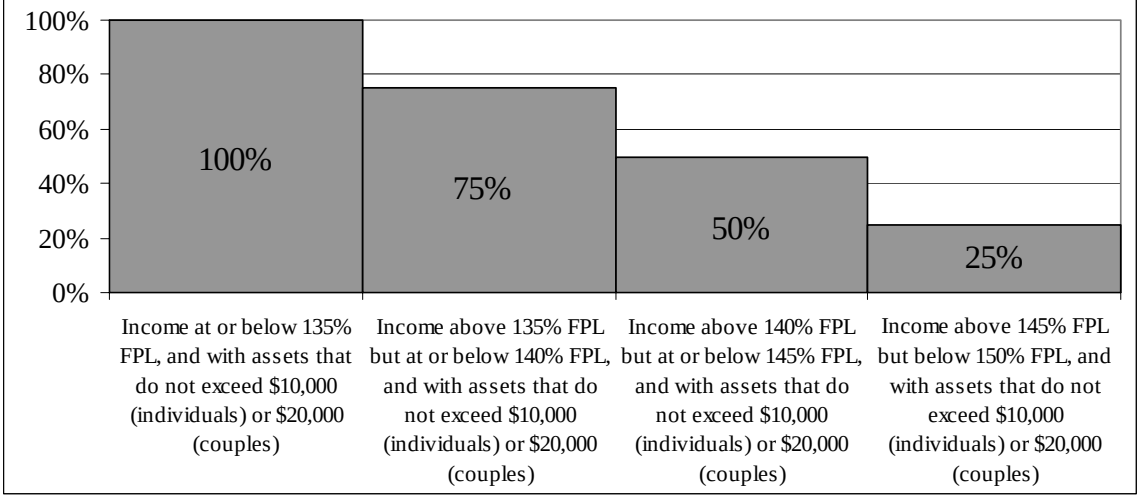
Table III-1. Premium and cost-sharing subsidy amounts for 2006

FPL & Assets	Percentage of Premium Subsidy Amount	Deductible	Copayment up to out-of-pocket limit	Copayment above out-of-pocket limit
Full-benefit dual eligible – institutionalized individual	100%*	$0	$0	$0
Full-benefit dual eligible– Income at or below 100% FPL (non-institutionalized individual)	100%*	$0	The lesser of: (1) an amount that does not exceed $1-generic/preferred multiple source and $3-other drugs, or (2) the amount charged to other full subsidy eligible individuals who are not full-benefit dual eligible individuals or whose incomes exceed 100% of the FPL.	$0
Full-benefit dual eligible –Income above 100% FPL (non-institutionalized individual)	100%*	$0	An amount that does not exceed $2- generic/preferred multiple source and $5-other drugs.	$0
Non-full benefit dual eligible beneficiary with income below 135% FPL and with assets that do not exceed $6,000 (individuals) or $9,000 (couples)	100%*	$0	An amount that does not exceed $2-generic/preferred multiple source and $5-other drugs.	$0

Non-full benefit dual eligible beneficiary with income at or below 135% FPL and with assets that exceed $6,000 but do not exceed $10,000 (individuals) or with assets that exceed $9,000 but do not exceed $20,000 (couples)	100%*	$50	15% coinsurance	An amount that does not exceed $2-generic/preferred multiple source drug or $5-other drugs
Non-full benefit dual eligible beneficiary with income at or above 135% FPL but below 150% FPL, and with assets that do not exceed $10,000 (individuals) or $20,000 (couples)	Sliding scale premium subsidy (100%-0%)	$50	15% coinsurance	An amount that does not exceed $2-generic/preferred multiple source drug or $5-other drugs.

*The percentage shown in the table is the greater of the low income benchmark premium amount or the lowest PDP premium for basic coverage in the region.
Note that Qualified Medicare Beneficiaries (QMBs), Specified Low-Income Medicare Beneficiaries (SLMBs) and Qualifying Individuals (QIs) are deemed full subsidy eligible.

Figure III-2. Sliding scale premiums for low-income eligible beneficiaries



Risk Adjustment Model

According to the MMA, payments to PDPs and MA-PDs are to be risk adjusted since they are based on a standardized bid amount which assumes an enrollee who has a risk factor of 1.0. As indicated above, Part D plan sponsors will use the bid pricing tool to compute this standardized bid amount. The starting point for this computation is the projected monthly revenue requirements to provide defined standard drug coverage for an enrollee with the plan's projected average risk factor. The underlying principles of the risk adjustment method used may be found in the research paper *Diagnostic Cost Group Hierarchical Condition Category Models for Medicare Risk Adjustment (Final Report); December 2000* found on the CMS Web site: http://www.cms.hhs.gov/researchers/projects/default.asp.

The model uses the presence of particular demographic characteristics and diagnoses to predict the following year's expected costs for an individual. The ICD-9-CM diagnoses are clustered within groups homogeneous both clinically and in costs. Each included characteristic and condition present contributes to the total prediction for an individual through a formula that sums the incremental costs. The groupings used to predict drug spending are variants of the groups used to predict Part A and B spending, and the data sources for diagnoses are the same as those used in Part C. Disease groups and draft coefficients for the Part D risk adjustment can be found on the CMS Web site at http://www.cms.hhs.gov/pdps/.

In development of the model, drug spending in dollars is used as the dependent variable of a regression model that estimates the marginal or incremental spending related to each of the explanatory variables (demographics and conditions) in the model. The model is ultimately expressed not in dollars, but as relative factors. The incremental dollars associated with each variable in the model are divided by the mean predicted dollars to produce a "relative costliness" or risk factor. Summing the risk factors for an individual yields a total risk adjustment factor that, when multiplied by a base rate, yields an individualized capitation rate, the direct subsidy described above.

Development of a risk adjustment model for drug spending is dependent on having appropriate data from which to create appropriate diagnosis groups and cost estimates. As there were no Part D data available, CMS used drug expenditure data for federal retirees with Medicare in the Federal Employee Health Benefit plan run by Blue Cross Blue Shield (BCBS). The pharmacy benefit of the BCBS plan is an uncapped benefit with a coinsurance amount for retail purchases and two tiers of copayment for mail order purchases. Only those retirees at least 65 years old were used from these data. For disabled beneficiaries, under 65, data from Medicare-Medicaid dual-eligibles were used. Other data sets were considered but none were superior to these. For both these data sets the development of the model could be done using the diagnoses from standard Medicare files and drug spending from each program's drug benefit. These files are the source of data for the model used for the first years of the Part D benefit. The BCBS spending year 2002 was used for calibration. For Medicaid, the latest available data linked to Medicare were for 2000.

Modifications to the data were necessary to remove certain drug claims from the data because the MMA specifically does not cover certain drugs. Only prescription drugs were included and Part B covered drugs were removed. Removal of the Part B drugs was straight-forward in the Medicaid data as each claim had both an NDC and amount paid. The BCBS situation was more complex. We had only total spending for each person with no paid amount on the claims. Using the Medicaid data we estimated the percentage reduction in spending associated with removal of part B drugs for people with conditions associated with high use, such as cancers and transplants. We then reduced spending for similar people in the BCBS files in the same proportion.

Other non-covered drugs, benzodiazepines and barbiturates, were intentionally left in the file because their costs proxy for the costs of substitutes. This was deemed preferable to removing the claims and costs altogether.

The model was first developed using the BCBS data. They reflect a benefit that is uniform nationally and has both retail and mail order pharmacies. The first task was to create a clinically credible model for spending. In forming the disease groupings, the large HCC clusters used for the CMS-HCC model, and the smaller constituent diagnosis groups, the DXGs were examined and tested for inclusion. Clinical and cost homogeneity, as well as cost magnitude associated with each group was examined. Pharmacist and physician consultations alternated with statistical tests in determining the diagnosis groupings. There was some reformulation and splitting of the disease groups in the move from predicting physician and hospital spending to predicting drug spending. An example is the simplification of the diabetes hierarchy. The Part A/B risk adjuster uses a hierarchy with 5 levels of diabetes; for Part D, only a distinction between uncomplicated and complicated diabetes is warranted to predict costs. When disease groups are in a hierarchy, only one, the highest one for which a code appears in the enrollee record, contributes to the risk factor. Conditions not in the same hierarchy contribute independently to the factor.

In forming the diagnosis grouper the dependent variable of the model was total spending, plan plus cost sharing. This allowed the clinicians to make reasonable judgments about the reasonableness of the cost coefficients. Though the model ultimately must predict the liability of drug plans, the structure of the cost sharing, which varies throughout the benefit range, makes it difficult to evaluate the size of plan liability coefficients. It is easier to evaluate a model that predicts the total cost of drugs needed for a condition than plan liability.

The initial model developed to predict spending omitted two groups that received special treatment at the end of the process – those who would receive the low income subsidy (LIS) and the long-term institutionalized (LTI). It was, however, necessary to bring in the Medicaid population to incorporate the disabled under 65 into the model. There were a number of problems in integrating the data sets: 1) The Medicaid group is low income and received drugs at out-of-pocket costs similar to costs under Part D LIS, not the cost sharing of BCBS; 2) They would probably spend at a different rate from those under the BCBS benefit even for the same diseases; 3) The cost data were from a different year and from many Medicaid programs. The following process was followed to convert the Medicaid data to spending patterns similar to that which would have occurred, on average, under a BCBS benefit.

The model, estimated with BCBS data for the aged, was applied to the dual eligible aged population to predict their spending as it would be under a BCBS benefit. This modeling incorporated the different demographic and risk profile of the duals in the predictions. The actual spending in the Medicaid data was then compared to the predicted spending. The ratio of the predicted to the actual spending was then used as a factor to convert the spending in the Medicaid files to levels compatible with BCBS. The conversion factor

was analyzed across the age/sex groups and, except for the sparse age 95+ groups, was quite stable.

With the data sets merged it became possible to estimate a full model across all ages and include age-specific add-ons for some diseases. One step has been omitted to this point because its relevance becomes clear only when estimating a model for plan liability. The spending data were multiplied by inflation factors that the CMS actuaries have used to project spending levels in 2006. This step is needed because the cost sharing ranges (described above) are defined in absolute dollar terms for 2006; thus, spending must be projected to levels appropriate to 2006 rather than the years of the development data. The decision to estimate a plan liability model based on the standard benefit was arrived at in consultation with industry actuaries and after studying the difficulties, both technical and operational, in modeling an unknown spectrum of possible benefit variations. Despite the discontinuous pattern of plan liability as spending varies, a model based on plan liability produces reasonable results.

The Plan Liability Model uses the grouper developed for the total spending model. The coefficients are estimated, however, on data altered to reflect plan liability. Before applying the cost sharing to create plan liability, the spending data went through another adjustment. It is generally observed that spending patterns are affected by income and prices. When insurance is present, as is the case here for drug purchases, the price to the consumer is the cost sharing. The model developed thus far has incorporated the cost sharing patterns of the BCBS benefit. The cost sharing in Part D is somewhat higher for the non-LIS population. Using estimates of the "induced demand effect" from the CMS actuaries, the spending for all people in the data was reduced to compensate for the higher cost sharing. This deduction was not made for the institutionalized, who were still excluded from the development data.

At this stage plan liability was computed for each person. As appropriate to each person's total spending, the first $250 were subtracted, 75 percent of the excess up to $2250 in spending was computed, $0 added till $5100, and 15 percent added for spending in the reinsurance range above $5100 in spending. There was no deduction from spending in the reinsurance range.

The data so structured were used to estimate plan liability coefficients for each characteristic important in the spending model. These coefficients reflected amounts that would be the plan's liability, on average, under the standard benefit. The coefficients expressed in dollars are smaller than the coefficients for the spending model as would be expected, some more changed than others. When the coefficients are expressed as relative factors, the differences will be smaller. This is because the conversion to relative factors entails dividing each coefficient by the national mean for spending or liability, as appropriate. Dividing a large spending coefficient by a large spending mean will produce a result similar to dividing the smaller liability coefficient by the smaller liability mean. The proportionality is not uniform, however. Diseases characterizing people who tend to have a large proportion of spending in the 100 percent cost sharing range, have their

factors reduced by a greater proportion than others. Much of drug spending has a zero impact on plan liability.

Both the Spending Model and the Plan Liability Model have good predictive power. The R^2 exceeds 0.20. This is higher than the explanatory power for the models predicting the more variable Part A/B costs. It is comparable to other models for drugs that we have seen reported. Analyses have been made of the predictive ratios (plan liability in the data/ predicted plan liability) for people in deciles of predicted liability. Because a substantial portion of a person's risk factor is associated with age and sex, even when diseases are accounted for, the model tends to overpay for beneficiaries who are predicted to be in the lowest deciles of costs. (There are always $0 spenders in any year, but the model will not predict $0 for the payment year.) Unlike the case for Part A/B, the model also overpredicts payment for the people in the high deciles of predicted costs. This is because the coefficients can not fully reflect the flattening of plan liability for high spenders. In the middle deciles of predicted costs there is a small degree of underprediction.

Low Income Subsidy and Institutionalization

By scaling the Medicaid spending to conform to the BCBS level of spending, the low-income effect has been removed. The CMS Office of the Actuary has estimated the effects of low cost-sharing on spending by the low-income population. The estimated percentage increase will be applied to the risk factors or the payment amounts after the base risk factors are computed.

Table III-2. Definition of the low income multipliers for Part D benefit

	Group 1	Group 1	Group 2	Group 2
Income test	Medicaid Dual <100% FPL	<135% FPL	<135% FPL	135-150% FPL
Asset test	<2× SSI	<3× SSI	>3× SSI & <$10,000 single $20,000 couple	<$10,000 single $20,000 couple
Deductible	$0	$0	$50	$50
Copay for generic drugs up to catastrophic threshold	$1	$2	—	—
Copay for brand-name drugs up to catastrophic threshold	$3	$5	—	—
Coinsurance up to catastrophic threshold	—	—	15%	15%
Coinsurance above catastrophic threshold	0%	0%	0%	0%
Copay for generic drugs above catastrophic threshold	$0	$0	$2	$2
Copay for brand-name drugs above catastrophic threshold	$0	$0	$5	$5
Premium subsidy	100%	100%	100%	Sliding scale

The low income multiplier is estimated to be 1.08 for Group 1 low income individuals (as defined above) and 1.05 for Group 2 individuals (as defined above). This multiplier is defined on a concurrent basis. (For example, if an individual were not defined as low income for January 2006 but was determined to be a Group 1 beneficiary for February 2006, the plan would receive the low income multiplier for February (and beyond) but not for January.)

An enhancement was also computed for the predicted spending by persons institutionalized in nursing facilities for more than 90 days. Spending for this group is expected to be higher because prices for the specific packages of drugs they receive are somewhat higher than the same drugs in the community. (An analysis of drug data done by IMS Health showed the price differences in the claims were small, particularly for brand name drugs that dominate the spending.) There are also effects related to compliance in acquiring and taking drugs in the institutional environment. On the other side, often patients take fewer drugs because more careful monitoring of interactions is occurring.

An analysis was done for the spending by the institutionalized by first using the base model to predict for this population and then comparing the actual spending and liability to the predicted. For the case of spending, there was a significant positive effect for the aged and the disabled who are in institutions. The effect for the disabled is greater than for the aged. It was also observed that average spending for both groups was in the 100% coinsurance range. The disabled mean was quite close to the catastrophic limit. The implications of additional demand being, to a large extent, in the range in which plans do not have incremental liability means that the effect on plan liability is much smaller than the effect on spending. The final payment adjustments for the institutionalized are smaller for the aged than for the disabled and smaller perhaps than some people expect because the final measure is plan liability rather than spending.

The long term care multiplier is 1.08 for aged individuals residing in a long term care institution and is 1.21 for Medicare disabled individuals residing in a long term institution. This multiplier, like the low income multiplier, is concurrent. We will use the Minimum Data Set (MDS) for identifying long term, institutional residents. If an individual is both a low-income subsidy eligible beneficiary and is in long-term care, then only the long-term care multiplier applies to that beneficiary.

Reconciliations and Risk Sharing

Introduction

At the conclusion of the payment year, CMS will undertake a sequence of reconciliations and risk sharing calculations for risk adjustment, low income cost sharing subsidies, reinsurance, and risk corridors. These reconciliations and risk sharing calculations are described below.

Risk Adjustment
Risk adjustment always uses one year of diagnostic data in combination with specific demographic factors to predict a future year's costs. In addition to other data requirements, plans offering Medicare Parts A and B, for instance MA and PACE organizations, demonstrations, and 1876 cost plans, are required to submit diagnosis data to support risk adjustment calculation. The diagnosis data on fee-for-service enrollees is collected by means of fee-for-service claims. This process allows the association of medical diagnoses with all Part D enrollees. We provide further detail on diagnostic data submission requirements below.

For initial payment in January 2006, risk adjustment factors will be based on diagnoses for dates of service from July 1, 2004 – June 30, 2005. The initial data collection deadline for these diagnoses is September 2, 2005. In mid-2006, we will update these factors utilizing dates of service January 1, 2005 – December 31, 2005. The mid-year data collection deadline is March 3, 2006. We expect that the mid-year factor updates will take place around July 2006, allowing all payments from that month forward to incorporate the updated factor. Retroactive adjustments for prior month's payments (January – June) will occur after the factor update has occurred.

Final reconciliation of risk adjustment for the prescription drug direct subsidy must occur prior to calculating the target amount for risk corridors. The direct subsidy component of the target amount will reflect the final reconciled direct subsidy payments actually made based on the final risk adjustment factors. Therefore, the reconciliation deadline for 2006 risk adjustment data (dates of service January 1, 2005 – December 31, 2005) will be January 31, 2007, earlier than previous risk adjustment reconciliation deadlines.

Low Income Cost-Sharing Subsidy
For qualifying low-income beneficiaries, cost-sharing amounts that would otherwise constitute beneficiary liabilities at the point of service (LICS amounts) will be paid by plan sponsors up front using LICS interim payments that CMS will advance to plans (see prospective payment above). As these costs are actually incurred during the coverage year, plans will identify incurred LICS amounts on claims. After the coverage year, CMS will reconcile interim payments with incurred amounts from claims and will make any necessary payment adjustment in 2007 (payment additions or recouping).

Reinsurance
After the end of the coverage year, CMS will reconcile reinsurance subsidies as follows:

- Identify incurred reinsurance costs above the out-of-pocket threshold at the individual beneficiary level (from claims)

- Sum incurred reinsurance costs at the plan level

- Apportion DIRs to incurred reinsurance costs by applying the ratio of covered Part D DIR to total allowed costs. (We refer to the apportioned DIR as "reinsurance DIR." "Covered Part D DIR" is defined in the DIR section under Implementation below).

- Subtract reinsurance DIR from incurred reinsurance costs, then multiply the difference by 80 percent to determine government liability.

In formula:
Reinsurance DIR = (covered Part D DIR/total allowed costs)*incurred reinsurance costs then
Adjusted reinsurance = (incurred reinsurance costs - reinsurance DIR)*0.80

Example
A plan had $1,000,000 in incurred reinsurance costs and total allowed costs of $6,100,000. Covered Part D DIR = $610,000.

Reinsurance DIR = ($610,000/$6.1m)*$1m =$100,000
Adjusted reinsurance = ($1m-$100,000)*0.80 = $720,000

The resulting adjusted reinsurance amount ($720,000 in the example) will be reconciled with prospective reinsurance payment amounts made to plans during the coverage year (see prospective payment above). Appropriate payment adjustment (payment additions or recouping) will then be made in 2007.

Risk corridor payments
Risk corridors are designed to limit exposure to unexpected expenses not already included in the reinsurance subsidy or taken into account through health status risk adjustment. The federal government and the plan share the profits or losses resulting from expenses for the standard benefit within defined symmetrical risk corridors around a target amount. Risk corridors work by determining the difference between (a) the target amount (what a plan was actually paid through the direct subsidy plus enrollee premium related to the standardized bid amount) and (b) a plan's actual allowable costs not including administrative expenses. A plans actual allowable costs are limited to those costs actually incurred or paid by the plan and must subtract out any DIR. Also if a plan provides supplemental coverage CMS takes into account how the presence of such coverage increases utilization beyond what it would be if the coverage were defined standard coverage. Finally, CMS will subtract out all federal reinsurance payments and low-income subsidy payments related to cost-sharing.

Calculating risk corridor payments can be considered as a 4-step process:

- Calculate the plan's target amount

- Calculate associated risk corridor thresholds

- Calculate adjusted allowable risk corridor costs

- Determine where costs fall with respect to the risk corridor thresholds, then calculate payment adjustment

Calculate the target amount

The target amount is the plan's total direct subsidy payments plus total beneficiary premiums (not including any negative premium amounts) related to the standardized bid amount due from enrollees or paid on their behalf plus MA rebates applied to buying down the basic premium minus administrative costsor (1.00 – administration cost percentage) * (total direct subsidy payments + total beneficiary premiums related to the standardized bid amount), where:

- the direct subsidy = (standardized bid * beneficiary risk adjustment factor) – beneficiary premium related to the standardized bid amount

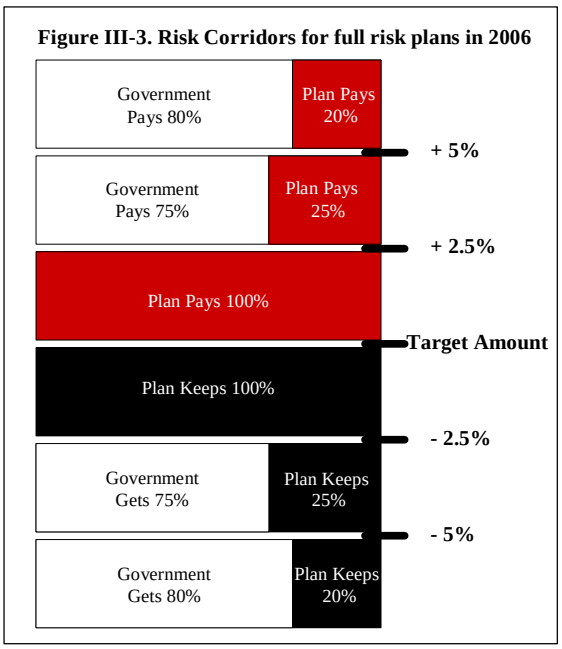
- the total direct subsidy is the sum of all monthly direct subsidy amounts paid for the entire coverage year; and

- the total beneficiary premiums (not including any negative premium amounts) related to the standardized bid amount is the sum of all monthly beneficiary premiums plus MA rebates related to the standardized bid amount, paid for the entire coverage year. Beneficiary premiums include premiums from enrollees or paid on their behalf, including low-income premium subsidies.

Example:

Direct Subsidy	$767,250
Beneficiary Premiums	$255,750
Administrative Costs	< $23,000 >
Target	$1,000,000

Calculate associated risk corridor threshold limits



As illustrated above, the first threshold upper limit is 102.5 percent of the target amount and the second threshold upper limit is 105 percent of the target amount; similarly, the first threshold lower limit is 97.5 percent of the target amount and the second threshold lower limit is 95 percent of the target amount. These percentages are for 2006.

Example (target amount = $1,000,000):
The first threshold upper limit is $1,025,000 or $1,000,000 + (.025*$1,000,000)
The second threshold upper limit is $1,050,000 or $1,000,000 + (0.050*$1,000,000)
The first threshold lower limit is $975,000 or $1,000,000 – (.025* $1,000,000)
The second threshold lower limit is $950,000 or $1,000,000 – (0.050*$1,000,000)

Calculate adjusted allowable risk corridor costs
The CMS will calculate adjusted allowable risk corridor costs from claims. These include covered prescription drug costs actually incurred and paid by the plan within the limits of the standard benefit that are not covered by reinsurance payments or low-income cost-sharing subsidies net of DIR.

Specifically, CMS will identify covered Part D drug costs from claims, then subtract the following amounts:

- From claims: patient liability amounts (e.g. deductibles and cost-sharing),LICS (equal to the plan's cost sharing not to exceed the maximum amount defined in the rule), amounts paid by non-TrOOP-eligible additional payers, and amounts identified by plans as costs related to supplemental benefits

- Induced utilization (for enhanced alternative plans only; the amount will be identified in their bids)

- Reinsurance subsidies

- Part D covered DIR dollars not allocated to reinsurance costs

The resulting difference is the adjusted allowable risk corridor costs that will be considered for payment adjustment. The statute indicates that allowable risk corridor costs must be reduced by reinsurance payments and by low-income cost-sharing subsidies, because plans are reimbursed separately for these costs. As discussed in the preamble to the final rule, since low-income premium subsidy payments are not plan costs, they are not subtracted from allowable costs for the purposes of risk corridor cost calculation.

Determine where costs fall with respect to the thresholds and calculate payment adjustment

If adjusted allowable risk corridor costs fall within 2.5 percent of the target amount (above or below it), there is no risk sharing of additional costs or "savings" compared to estimated (prepaid) amounts. But if adjusted allowable risk corridor costs are more than 2.5 percent outside the plan's target (above or below it), costs or savings will be shared in accordance with the following provisions:

- Adjusted allowable risk corridor costs > 102.5 percent ≤ 105 percent of target amount Government pays plan 75 percent of difference between adjusted allowable risk corridor costs and the 1st upper threshold limit; plan pays remainder.

Example (adjusted allowable risk corridor costs = $1,035,000):
Payment adjustment = 0.75*($1,035,000-$1,025,000) = $7,500 (government pays plan)

- Adjusted allowable risk corridor costs >105 percent of target amount Government pays plan the sum of 75 percent of difference between 2nd and 1st upper threshold limits and 80 percent of the difference between the adjusted allowable risk corridor costs and the 2nd upper threshold limit; plan pays remainder.

Example (adjusted allowable risk corridor costs = $1,063,000):
Payment adjustment = [0.75*($1,050,000-$1,025,000) + 0.80*($1,063,000-$1,050,000)] = $29,150 (government pays plan)

- Adjusted allowable risk corridor costs < 97.5 percent ≥ 95 percent of target amount Plan pays government back 75 percent of difference between 1st lower threshold limit and the adjusted allowable risk corridor costs but keeps 25 percent.

Example (adjusted allowable risk corridor costs = $973,000):
Payment adjustment = 0.75*($975,000-$973,000) = $1,500 (plan pays back to government)

- Adjusted allowable risk corridor costs < 95 percent of target amount Plan pays government back the sum of 75 percent of difference between 1st and 2nd lower threshold limits and 80 percent of the difference between the 2nd lower threshold limit and the adjusted allowable risk corridor; plan keeps remainder.

Example (adjusted allowable risk corridor costs = $945,000):
Payment adjustment = [0.75*($975,000-$950,000) + 0.80*($950,000-$945,000)] = $22,750 (plan pays back to government)

Note that in 2006, the 75 percent risk sharing for adjusted allowable risk corridor costs between the first and second upper threshold limits will change to 90 percent (or the higher percentage if negotiated as a limited risk plan) if the following two conditions have been met:

1. At least 60 percent of Part D plans that have adjusted allowable risk corridor costs for the Part D plan for the year that are above 102.5 percent of their target amount; and

2. Such plans represent at least 60 percent of part D eligible individuals enrolled in any prescription drug plan or MA-PD plan.

Note that condition 1 would exclude Fallback plans, PFFS plans, employer-sponsored plans that elect the 28% subsidy, and any plan that opts for limited risk under Section 1860D-11(f)."

Limited Risk Plans

PDPs assuming limited risk may be approved in geographic areas where access requirements for a PDP region have not otherwise been met. The statute requires that regions contain at least two qualifying plans offered by different entities, one of which must be a PDP; also, these plans must offer basic coverage or basic and supplemental benefits without any accompanying supplemental premium. In regions where access requirements are not met, the minimum number of limited risk plans needed to satisfy the requirements may be approved. Note that only PDPs may act as limited risk plans and that they must at least provide basic coverage. MA-PD plan sponsors may not assume reduced risk.

In making risk corridor payments to limited risk PDPs, we will apply the reduced risk provisions approved in their bids. In accordance with the statute, reduction in risk may be accomplished by 1) symmetrical increases in the federal risk percentages assumed within either risk corridor or 2) symmetrical narrowing of the risk corridors by reducing

the threshold risk percentages. As required under Section 423.272(c)(2) CMS may not approve any bid with a de minimis level of risk. In the preamble to the final rule we stated that our definition of de minimis in this context was a level of risk that was 10% or less of the statutory level of risk. In other words, the risk after modification cannot be less than 10% of the risk before the risk corridors were moved or federal risk percentages were increased. For example, a reduction of the first corridor from 25% to 2.5% and a reduction of the second corridor from 20% to 2%. This would also apply to the size of the corridors, e.g., one-tenth of 2.5% or one-tenth of 5%.

Part D - Implementation Issues

Prescription Drug Claims

To enable CMS to make timely and accurate plan payments, plans must submit 100 percent of claims data to CMS but only a limited number of data elements per claim. We used four criteria in determining claims submission requirements: 1) ability to make timely, accurate payment using the four legislated mechanisms (direct subsidy, low-income subsidy, reinsurance, and risk corridors); 2) minimal administrative burden on CMS, plans, and other entities including MA-PDs, PDPs, fallback plans, pharmacy benefit managers, pharmacies, and others; 3) legislative authority; and 4) validity and reliability of the data requested, such that the information will be useful.

Since multiple "claims" transactions typically take place between pharmacies, PBMs, and plans prior to final adjudication of a prescription drug claim, plans must only submit a summary record called the prescription drug event (PDE) record to CMS. This record must include covered drug costs above and below the out-of-pocket threshold and distinguish supplemental (enhanced alternative) costs from the costs of drugs provided under the standard benefit. The CMS will use these data to calculate reinsurance and risk corridor payments and to develop a second-generation Part D risk adjuster based on actual Part D experience.

Plans must also identify payers on PDE data, including LICS amounts paid by the plan at the point of service; beneficiary liability (cost-sharing) amounts; beneficiary cost-sharing for supplemental (enhanced alternative) benefits; and payments by additional third party payers other than a given Part D plan. Payments by TrOOP-eligible third parties on behalf of beneficiaries shall be included under beneficiary liability, and payments by non-TrOOP-eligible entities shall be reported separately. The CMS will use these payment data from PDE records to reconcile LICS and to validate TrOOP and entry into the catastrophic coverage phase.

In order to receive payment, plans must submit PDE records for year 2006 dates of service, including any adjustments, by the end of the third month of 2007. Specifically, prescription drug claims including adjustments for all dates of service within CY 2006 must be submitted to CMS by March 31, 2007 in order to be processed for payment reconciliation.

Reporting of Direct and Indirect Remuneration (DIR)

The final rule at 42 CFR Section 423.308 specifies that covered drug costs must be actually incurred and paid by the Part D sponsor and must be net of all direct or indirect

remuneration from any source that would serve to decrease the costs incurred by the Part D sponsor for the drug. In this notice, DIR refers to all such remuneration as described at 42 CFR Section 423.308. The DIR will be excluded from allowable reinsurance and risk corridor costs as described in the payment sections above.

Some DIR may already be reflected in the amount paid (sum of ingredient cost, dispensing fee, plus applicable sales tax) at the point of sale. However, all DIR that is not taken into account at the point of sale and thus is not accounted for on PDE records must be reported to CMS separately for exclusion from allowable costs.

Plans must report DIR not taken into account at the point of sale to CMS within six months of the end of the year. DIR dollars must be reported in full with no reduction for administrative cost or any other fees. Plans will submit DIR amounts in three categories: 1) DIR dollars for non-covered Part D drugs (statutorily-defined Part D drugs not covered by the plan); 2) DIR dollars for covered Part D drugs (statutorily-defined Part D drugs that are covered by the plan); and 3) total Part D DIR (the sum of 1 and 2). The differentiation between covered and non-covered Part D drug DIR dollars enables calculation of reinsurance and risk corridor payments based only on covered Part D drug costs.

Data Requirements
Diagnostic Data Submission for Part D Risk Adjustment
The rules for data submission for risk adjustment are the same as the rules for Part C, as described in Chapter 7 of the Medicare Managed Care Manual (http://www.cms.hhs.gov/manuals/116_mmc/mc86toc.asp).

Diagnostic data submission by 1876 cost plans and HCPPs for risk adjustment
In accordance with the SSA Section 1876(i)(3)(D), in September 2004 CMS required Section 1876 cost HMOs/CMPs to begin submitting all (medical and drug-related) diagnostic data to CMS to enable risk adjustment for their enrollees that may join Part D. We encouraged but did not require HCPPs to submit these data. We also provided for reimbursement to cost plans for data submission as an administrative expense.

Our goal in using these data is to make accurate risk adjusted Part D payments for enrollees that receive Part D coverage through Section 1876 plans that elect to offer Part D benefits, and for HCPP and Section 1876 plan enrollees that elect Part D coverage in a stand-alone PDPs. Diagnoses for dates of service 7/1/04 – 6/30/05 will be used to determine risk adjusted rates for Part D plan payments beginning 1/1/06.

We note that CMS may not have sufficient diagnostic data for making Part D risk adjusted payments where the beneficiaries have been enrolled in plans that are not required to submit diagnostic data (e.g., HCPPs). For this small group of enrollees, we are considering applying the new enrollee model for 2006 only. The CMS will identify alternative ways of risk adjusting these types of enrollees for 2007 and beyond.

Failure to provide adequate information for payment and reconciliation
In accordance with the MMA and as described in 42 CFR Section 423.322, organizations offering Part D plans must submit adequate data to enable CMS to make payment. Therefore, inadequate data submission may result in payment recovery through a lump-sum recovery; by adjusting or ceasing monthly payments throughout the remainder of a coverage year; or by adjusting monthly payments in a subsequent year. Note that payment recovery provisions apply even in the event of a change in ownership.

For example, if LICS payments exceed the costs eligible for subsidy under Section 423.782, CMS may recover payments through a lump-sum recovery or by adjusting monthly payments for the remainder of the coverage year.

Part D plans are specifically required to provide CMS with sufficient data for conducting reconciliation as discussed in Section 423.343. For risk-sharing arrangements, if the organization does not provide all rebate and PDE information data as prescribed below, we will assume or impute that the entity's adjusted allowable risks corridor costs are 50 percent of the target amount. CMS will recoup 80 percent of the difference between the 2nd threshold lower limit and the imputed adjusted allowable risk corridor costs, plus 75 percent of the difference between the 1st and 2nd threshold lower limits.

The 50 percent threshold constitutes a lower limit on government and plan liability. Also, we believe it is a reasonable limit because it would be unlikely for a plan to have costs that are less than 50 percent of their target amount.

For LIS, if the organization does not provide adequate documentation of LICS amounts on PDE records within the claims submission deadlines described below, CMS may recoup all interim LICS payments.

Throughout the coverage year, CMS will monitor plan data submission levels to detect outliers that are submitting low amounts of PDE data and may be experiencing technical or other difficulty. We will work with plans in an attempt to correct submission problems before the end of the year so they can meet reconciliation submission deadlines. However, the MMA places ultimate responsibility on the plan to submit adequate data for payment.

Part D enrollees who change plans during the coverage year
The CMS is examine different approaches to determining low income, reinsurance, and risk sharing payment amounts for individuals who change Part D plans during the payment year.

Appeals
As described in the final rule, Part D sponsors may appeal final payment decisions if the stated payment methodology has not been applied correctly. Under no circumstances may this process be used to submit new payment information after the established deadline.

Special Provisions for PACE Payment

The PACE plans are required by law to offer drugs to enrollees with no co-payments. This provision must be reconciled with the global provisions in MMA that require beneficiary out-of-pocket expenditures. Specifically, Sections 1894(b)(1)(A)(i) and 1934(b)(1)(A)(i) of the Act preclude PACE organizations from charging PACE enrollees any form of cost sharing and Section 460.186(d) of the PACE regulation precludes PACE organizations from charging a premium to any Medicaid eligible PACE enrollees. A discussion of our proposed payment methodology that accounts for the dual-eligible as well as the Medicare-only PACE enrollees is provided below, followed by our proposed premium methodology applicable to each of these categories of PACE beneficiaries.

We note that PACE organizations will need to have two separate benefit plans and two separate Part D bids. The dual eligible population will be enrolled in a standard benefit plan, and the Medicare-only population will be enrolled in an enhanced alternative plan.

CMS payment methodology applicable to dual eligible PACE enrollees

Dual eligible PACE enrollees will be deemed low-income eligible under Part D. Low-income beneficiaries are given additional cost-sharing subsidies for their Part D covered drugs. In a typical Part D plan, low-income individuals have a nominal co-payment responsibility for their Part D drugs, and the plan will provide the remainder of the usual co-payment through a low-income cost-sharing subsidy. Plans are reimbursed dollar for dollar for the cost-sharing subsidy.

However, PACE enrollees will have no co-payment responsibility under the PACE provisions. In recognition of this PACE prohibition on beneficiary co-payments, CMS proposes to cover the usual nominal co-payments for low-income beneficiaries under an additional capitated payment as provided in Section 1894(d)(2) of the Act. This section indicates that CMS may adjust Medicare payments to PACE organizations to take into account "…such other factors as the Secretary determines to be appropriate." For cost allocation purposes, CMS proposes to consider 2% of all costs below the out-of-pocket threshold to be appropriately categorized as the nominal beneficiary liability for full benefit dual eligible enrollees and therefore subject to this additional capitated payment. CMS will prospectively estimate this amount based on the cost assumptions submitted with the bid and will make an additional monthly payment to each standard benefit PACE plan for dual eligible enrollees.

To support the payment calculations, PACE plans must report the detailed drug costs for their beneficiaries. However, PACE will not need to report the payment breakdowns of those costs, because PACE will be paying 100% of the cost. CMS will use the standard benefit to array each beneficiary's costs into the standard benefit categories, i.e., deductible, initial cost sharing, coverage gap, and catastrophic coverage (reinsurance). Below we outline how CMS' intends to array the costs for dual eligible costs. The first $250 will be considered to be deductible, with 98% being LICS and 2% being attributed to additional capitated payment. The next $2,000 will be assumed to be a 75%-25% split between plan liability and beneficiary liability, divided as 23% LICS and 2% additional capitated payment. Because a supplemental cost sharing is not attributable to beneficiary

out-of-pocket spending, the normal coverage gap from $2,250 - $5,100 is extended slightly (We estimate this adjusted out-of-pocket threshold to be approximately $5204). In the coverage gap, again the LICS is 98% of all spending and the additional capitated payment accounts for 2% of the spending. All spending above the adjusted out-of-pocket threshold will be considered to be reinsurance, with the reinsurance subsidy representing 80% of the costs, plan liability 15%, and LICS 5%. There is no additional capitated payment required in this portion of the benefit, since dual eligible beneficiaries have no co-payment responsibilities under catastrophic coverage.

Premium methodology applicable to dual eligible PACE enrollees
In addition to the prohibitions on cost-sharing, PACE organizations are also precluded from imposing premiums upon any Medicaid eligible enrollee. We recognize the potential situation under which a PACE organization's bid may exceed the national average premium subsidy amount. The MMA indicates that this difference is to be borne by the beneficiary as a premium payment. Given the PACE prohibition of charging any Medicaid eligible enrollee a premium, we are considering an additional capitated payment adjustment that may be made to PACE organizations on behalf of dual eligible PACE enrollees in plans with bids above the low-income benchmark. This authority is also based on Section 1894(d)(2) of the Act. As a result, dual eligible PACE participants will not be responsible for Part D premium payments, and any premiums that would otherwise be incurred due to the bid will be accounted for as additional capitated payment amounts.

CMS payment methodology applicable to Medicare-only PACE enrollees
To support the payment calculations for Medicare-only enrollees, PACE also must report the detailed drug costs for these beneficiaries. As with the dual eligible population, PACE will not need to report the payment breakdowns of those costs, and we will map the reported costs to the benefit. The major difference is that no costs will be attributed to LICS. All cost sharing above the standard benefit will be attributed to supplemental cost sharing, which will be covered by the beneficiary premium as described below. Since there are no co-payments and no LICS, these beneficiaries will never incur any TrOOP costs and will never reach the catastrophic coverage. The calculations for these individuals will only involve allowable risk corridor costs. For any covered drug costs, the first $250 will be attributed to supplemental cost sharing and not allowable as risk corridor costs. For the next $2,000 up to the initial coverage limit, the costs will be split 75%-25% between allowable risk corridor costs and supplemental cost sharing. No costs above the initial coverage limit will be considered allowable for risk corridors; all costs above the initial coverage limit will be attributed to supplemental cost sharing.

Premium methodology applicable to Medicare-only PACE enrollees
For the Medicare-only PACE enrollees, we are proposing that PACE organizations develop a standardized bid for the basic benefit. These Medicare-only PACE enrollees will be responsible for paying the full base beneficiary premium amount Because the Medicare-only beneficiaries will never reach the catastrophic coverage, the standardized bid will only account for costs incurred up to the initial coverage limit.

A supplemental premium must also be calculated for Medicare-only PACE enrollees and supplied with the bid. This premium will apply to all Medicare-only enrollees, regardless of income level. The supplemental premium must account for all of the following costs:

1. $250 deductible,

2. 25% cost-sharing between $250 and $2250,

3. Full beneficiary responsibility for all costs above $2250.

Plans will be required to predict the cost of these amounts for all Medicare-only enrollees in aggregate in order to establish a single bid.

Special Provision for the Calculation and Payment of Reinsurance Amounts for Private Fee-For-Service Plans

As provided under Section 1860D-21(d)(4) of the MMA and Section 423.329(c)(3) of the final rule, CMS will adopt an alternative methodology for the payment of estimated reinsurance to private-fee-for-service (PFFS) plans. We propose to make interim estimated reinsurance payments to PFFS plans on a prospective monthly basis. We will base these interim estimated prospective payments on the average reinsurance amount for MA-PD plans as submitted in their Part D bids. In making this estimate, we propose to adjust the interim estimated average reinsurance payments for the projected risk of PFFS plan enrollment as compared to the MA-PD program.

We propose that final payment of estimated reinsurance to PFFS plans will be based on the average reinsurance payment actually made for payment year 2006 across the MA-PD program. We will adjust this average MA-PD reinsurance payment to take into account average reinsurance payments for populations of similar risk to the specific PFFS plan under consideration. This means the final estimated PFFS plan reinsurance amounts will be determined after final annual reinsurance payments (based on adjusted allowable reinsurance costs) to MA-PD plans are determined and MA-PD risk scores for payment year 2006 are reconciled.

Reinsurance Demonstration

We intend to use CMS's authority provided in section 402 of the Social Security Amendments of 1967 (42 U.S.C. Section1395b-1) and modified by Section 1860D-42(b) of the Act, to conduct a budget neutral Part D payment demonstration. This reinsurance demonstration proposal will require the provision of a supplemental benefit partially or completely filling in the coverage gap, with payment based on either one of the following two reinsurance options:

- Option One: Eligible Part D plans could offer an enhanced alternative drug benefit package and receive a capitated drug reinsurance payment, in addition to the normal direct subsidy, low income subsidy, and risk sharing payments. This reinsurance payment would be capitated instead of specific reinsurance payments of 80 percent of drug costs after the beneficiary incurred $3,600 in

TrOOP drug costs. The capitated reinsurance payment will be negotiated during the bidding process.

- Option Two: For eligible MA-PD plans that use MA premium rebates to cover the additional cost of enhanced alternative drug coverage, this option would permit enrollees to count supplemental benefit payments toward meeting the TrOOP spending requirement for Part D catastrophic coverage. For this option, all the supplemental benefit must be funded by MA Part A/Part B rebate dollars. To clarify, plans may not charge a supplemental premium for the supplemental benefit under this option. This is because it is not possible to distinguish A/B rebate dollars that would count toward TrOOP under this option from beneficiary premium dollars that would not count toward TrOOP.

All PDP sponsors may participate in option one. Medicare Advantage organizations offering Prescription Drug Plans (MA-PD plans) are eligible to participate in either options one or two with the exception of Program of All Inclusive Care for the Elderly (PACE) plans, cost-plans, and employer-sponsored plans.

Additional information about the demonstration will be provided both in a Federal Register notice and on the CMS Web site.

February 17, 2006

NOTE TO: Medicare Advantage Organizations, Prescription Drug Plan Sponsors, and Other Interested Parties

SUBJECT: Advance Notice of Methodological Changes for Calendar Year 2007 for Medicare Advantage (MA) Payment Rates and Part D Payment

In accordance with Section 1853(b)(2) of the Social Security Act (the Act), we are notifying you of proposed changes in the MA capitation rate methodology and risk adjustment methodology applied under Part C of the Act for CY 2007. Preliminary estimates of the national per capita MA growth percentage and other payment methodology changes for CY 2007 are also discussed. For 2007, CMS will announce the MA capitation rates on the first Monday in April, 2006, in accordance with the timetable established in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). This Advance Notice is published 45 days before that date.

For 2007, all rates will be the greater of the 2006 MA capitation rate increased by the minimum percentage increase (the greater of 2 percent or the national per capita MA growth percentage) or the 2007 fee-for-service rate. Attachment I shows the preliminary estimates of the national per capita MA growth percentage component of the minimum percentage increase.

Attachment II sets forth in detail the changes in payment methodology for 2007 for MA organizations. Attachment III provides an overview of Part D payment updates for Medicare Advantage – Prescription Drug (MA-PD) plans and Prescription Drug Plans (PDPs).

Any changes to employer/union-only group waiver plan payment for 2007 will be issued in future guidance.

In 2007, we will continue paying on a fee-for-service basis for covered clinical trial items and services provided to MA plan members.

Attachment comments or questions may be addressed to:

Deondra Moseley
Centers for Medicare & Medicaid Services
7500 Security Boulevard
S3-16-16
Baltimore, Maryland 21244

Comments also may be submitted electronically to the following address: AdvanceNotice2007@cms.hhs.gov. In order to receive consideration prior to the April 3, 2006 Announcement of MA and PDP capitation rates, comments must be received by 5:00 PM EST on March 3, 2006.

/ s /
Abby L. Block
Director
Center for Beneficiary Choices

/ s /
Solomon Mussey, A.S.A.
Acting Director
Parts C & D Actuarial Group
Office of the Actuary

Attachments

Attachment I

Preliminary Estimate of the National Per Capita Growth Percentage for Calendar Year (CY) 2007

The MMA provides that the minimum percentage increase is the higher of two percent or the national per capita MA growth percentage. The MMA also provides that, in years like 2007 when we are rebasing FFS costs, MA payment rates will be based on the greater of 100 percent of FFS costs or an increase which is the greater of two percent or the Medicare growth percentage, with no adjustment to this percentage for over- or under-estimates for years before 2004.

The current estimate of the change in the national per capita MA growth percentage for aged and disabled enrollees combined in CY 2007 is 6.9 percent. This estimate reflects an underlying trend change for CY 2007 in per capita costs of 2.5 percent and adjustments to the estimates for CY 2006, CY 2005, and CY 2004 aged MA growth percentages of 1.1 percent, 1.8 percent, and 1.3 percent respectively. Our new estimates for these years are higher than the estimates actually used in calculating the CY 2006 capitation rate book that was published April 4, 2005, and are required by Section 1853(c)(6)(C) of the Act.

The following table summarizes the estimates for the change in the national per capita MA growth percentage.

Table I-1. National Per Capita Growth Percentage

	Aged	Disabled	ESRD	Aged+Disabled
2007 Trend Change	2.3%	3.6%	-0.1%	2.5%
Revision to CY 2006 Estimate	1.2%	0.8%	2.6%	1.1%
Revision to CY 2005 Estimate	1.7%	2.5%	0.6%	1.8%
Revision to CY 2004 Estimate	1.2%	2.4%	1.6%	1.3%
Total Change	6.5%	9.6%	4.7%	6.9%

Note: The total percentage change is multiplicative, not additive and may not exactly match due to rounding.

These estimates are preliminary and could change before the final rates are announced on April 3, 2006. Further details on the derivation of the national per capita MA growth percentage will also be presented in the April 3 announcement.

Attachment II

Changes in the Payment Methodology for Original Medicare Benefits for CY 2007

Section A. Changes to the Risk Adjustment Methods for MA Organizations

1. Update of the Centers for Medicare & Medicaid Services – Hierarchical Condition Category (CMS-HCC) Risk Adjustment Model

Recalibration of the CMS-HCC Risk Adjustment Model: In 2007, CMS will implement an updated version of the current CMS-HCC risk adjustment model. Fee-for-service (FFS) claims data for the years 2002 and 2003 will be used in the recalibration of the model. (Diagnostic data for 2002 predict 2003 expenditures.) As the data are more current than the 1999 and 2000 data used for the current model, the updated model coefficients will reflect newer treatment and coding patterns in FFS Medicare.

As a result of recalibration, all segments of the risk adjustment system will be updated (the community, long-term institutional, new enrollee, and ESRD segments). For this notice we are providing the disease groupings, draft coefficients, and the disease hierarchies for the community model (see Exhibits 1 and 2). Disease groupings are the same as in past models; however, the coefficients will be different. The final coefficients for each of the segments will be provided in the "Announcement of Calendar Year (CY) 2007 Medicare Advantage Payment Rates."

The recalibration of the long-term institutionalized (LTI) segment of the model is being done with a larger sample than was used for the current model. All persons in LTI status in the prediction year (2003) who otherwise meet the criteria for inclusion in the risk adjustment modeling will be used for calibration. The effect of using a larger sample will be to refine the coefficients and better differentiate the costliness of the beneficiaries.

Update to Frailty Factors for PACE and Certain Demonstrations: Since January 2004, CMS has applied a frailty adjustment to payments to PACE organizations and certain demonstrations. The frailty adjuster was developed as a further refinement to risk adjustment to ensure that capitated payments to organizations that serve frail community-based populations were accurate.

The purpose of frailty adjustment is to better predict the Medicare expenditures for community populations with functional impairments that are not reflected in risk adjustment. The current frailty factors were estimated using the Medicare Current Beneficiary Survey (MCBS) cost and use files. Individuals were grouped according to the difficulty they experienced with Activities of Daily Living (ADLs). Their Medicare payments were predicted by the CMS-HCC model, and the difference between actual expenditures and predicted payments (i.e., "residual expenditures") was calculated. The frailty factors were derived based on the residual expenditures for each ADL group (0 ADLs, 1-2 ADLs, 3-4 ADLs, and 5-6 ADLs).

As explained above, CMS is recalibrating the CMS-HCC risk adjustment model for 2007 payment. Recalibration of the CMS-HCC model may change the predicted expenditures for the frail elderly compared to the current model, which in turn may influence the estimated frailty factors. Since the frailty adjuster is applied in conjunction with risk adjustment, the frailty factors must be consistent with the recalibrated risk adjustment model. Thus, CMS intends to recalculate the frailty factors. The new frailty factors will be published in the "Announcement of CY 2007 Medicare Advantage Payment Rates."

FFS Normalization: The FFS normalization factor, used to correct for population and coding changes between the data years used in model calibration and the payment year, will be computed to reflect a new calibration year. The FFS normalization factor is expected to be smaller than the 5% used in 2004, 2005, and 2006 because there will be fewer years between calibration and implementation.

The FFS normalization factor will no longer be applied to the rescaling factor in the ratebook. Instead, in 2007, the FFS normalization factor will be applied to the risk scores. The result of these two approaches is mathematically the same. We will announce the FFS normalization factor in the "Announcement of CY 2007 Medicare Advantage Payment Rates."

Restandardization: Due to the changes in the recalibrated risk adjustment model, county payment rates will be restandardized to reflect new average county risk scores in the FFS sector. The Office of the Actuary (OACT) intends to restandardize the 2006 rates. OACT will then project forward to get the 2007 minimum percentage increase rates using the latest growth trends for 2007. The final 2007 rate for a county will be the greater of the minimum percentage increase rate and the rebased FFS rate.

2. Implementation Issues

Elimination of Diagnostic Radiology Data from the Physician Specialty Type: In the CY 2006 Advance Notice, CMS announced the elimination of diagnostic radiology (Medicare specialty code 30) from the acceptable risk adjustment physician specialty type. In line with this announcement, diagnostic radiology has been excluded from the recalibrated risk adjustment model. This decision applies only to diagnostic radiology and does not impact other radiology codes (e.g., interventional radiology codes).

Addition of Pain Management Data from the Physician Specialty Type: Starting in 2007, CMS will include pain management (Medicare specialty code 72) as an acceptable risk adjustment physician specialty type under the CMS-HCC payment methodology. We have added pain management to the recalibrated risk adjustment model.

3. Transition Payment Blends

From 2004 through 2007, risk adjusted payment is being phased in for all MA plan payments. In 2007 the CMS-HCC model for MA plans will be applied at 100 percent

risk adjusted payment. For the Social Health Maintenance Organizations (S/HMOs), Minnesota Senior Health Options (MSHO)/ Minnesota Disability Health Options (MnDHO), Wisconsin Partnership Program (WPP) and Massachusetts Senior Care Options (SCO) demonstrations, the CMS-HCC model with a supplemental frailty adjuster will be applied in 2007 at 75 percent risk adjusted payment, with the remaining 25 percent being based on the payment methodology for these demonstrations. For Program of All-Inclusive Care for the Elderly (PACE) organizations, the CMS-HCC model with a supplemental frailty adjuster will be applied in 2007 at 75 percent risk adjusted payment, with the remaining 25 percent being based on the PACE payment methodology.

Section B. Budget Neutrality

Beginning in 2003, CMS has implemented risk adjusted payments in a budget neutral manner. Since that time, the budget neutrality amount has been calculated as the difference between payments to organizations at 100 percent of the demographic rate and payments at 100 percent of the risk adjusted rate.

As previously announced by CMS, in 2007 we will begin phasing out risk adjustment budget neutrality. The phase-out will be completed by 2011, when plans will receive no budget neutrality payment adjustment. The budget neutrality phase-out is summarized in the table below. As required by the Deficit Reduction Act of 2005, this is an acceleration of the phase-out schedule described in the February 18, 2005 CY2006 Advance Notice.

Year	Budget Neutrality Percentage
2007	55%
2008	40%
2009	25%
2010	5%
2011	0%

Section C. Regional Plan Stabilization Fund

Section 221 of the MMA added Section 1858(e) to the Act to create a new MA Regional Plan Stabilization Fund. The purpose of the fund is to provide financial incentives to MA organizations to offer MA regional PPO plans in each MA region, and to retain MA regional PPO plans in regions with relatively low MA market penetration. Specifically, the MMA authorizes CMS to make a one-year "national bonus payment" to an organization(s) that offers an MA regional PPO plan in all MA regions in a given year (if there was no such plan offered in all MA regions in the previous year). If no national bonus payment is made in a given year, CMS may use the fund to increase payments to MA regional PPO plans offered in regions that did not have any MA regional PPO plans offered in the prior year. Finally, to encourage plans to remain in regions with relatively low MA market penetration and few MA regional PPO plans, CMS may make retention payments from the fund to MA regional PPO plans.

The MA Regional Plan Stabilization Fund will initially be funded with $10 billion from the HI and SMI Trust Funds. Half of the 25 percent savings generated each year by regional PPO plans whose bids are below the benchmark is also added to the Fund. As stipulated by the MMA, these funds will be available for payments on January 1, 2007. CMS will provide additional information on the stabilization fund at a later date. Limitations to the stabilization fund can be found in §422.458.

Section D. ESRD Bidding Policy

We had planned to incorporate ESRD costs in MA plan bids beginning in 2007. However, CMS needs additional time to further evaluate different methodological approaches for incorporating ESRD costs. Therefore, for 2007, ESRD enrollee costs will not be included in the plan A/B bid. We will provide further information in the 2007 MA-PD Call Letter on how to reflect an adjustment for costs or savings for ESRD enrollees in the bid. As a result, the 2007 payment methodology for ESRD enrollees in MA plans is unchanged from 2006.

Attachment III

Overview of Payment for Medicare Advantage Prescription Drug Plans (MA-PDs) and Prescription Drug Plans (PDPs)

Section A. Weighting for the National Average Monthly Bid Amount and the Regional Low-Income Premium Subsidy Amount

In calculating the national average monthly bid in §423.279(b)(1) and the regional low-income benchmark premium amount in §423.780(b)(2), PDP plans are no longer receiving an equal weighting and MA-PD plans are no longer receiving a weight based on prior enrollment. Instead, the national average monthly bid, a weighted average of the standardized bid amounts, is calculated based on the number of Part D eligible individuals enrolled in the plan in the reference month in each PDP and MA-PD as a percent of the total number of Part D eligible individuals enrolled in all Part D plans, with the exception of MSA plans, fallbacks, MA private fee-for-service plans, specialized MA plans for special needs individuals, PACE programs under section 1894, and contracts under reasonable cost reimbursement contracts. The regional low-income benchmark premium amount, a weighted average of the Part D basic premiums, is calculated based on the number of Part D eligible-individuals enrolled in each PDP or MA-PD plan in the reference month as a percent of the total number of Part D-eligible individuals enrolled in all PDP and MA-PD plans (but not including PACE, private fee-for-service plans or 1876 cost plans) in a PDP region in the same month.

EXHIBIT 1. Draft Community Coefficients for the CMS-HCC Model with Constraints and Demographic Disease Interactions, Used in the Calculation of Monthly Medicare Advantage Payments[1]

Variable	Disease Group	Community Estimate[2]	Constraint[3]
Age/Sex			
Female 0-34 Years		$1,400	
Female 35-44 Years		1,500	
Female 45-54 Years		2,000	
Female 55-59 Years		2,400	
Female 60-64 Years		2,700	
Female 65-69 Years		1,900	
Female 70-74 Years		2,400	
Females 75-79 Years		3,000	
Female 80-84 Years		3,500	
Female 85-89 Years		4,100	
Female 90-94 Years		5,100	
Female 95 Years or Over		5,100	
Male 0-34 Years		700	
Male 35-44 Years		1,100	
Male 45-54 Years		1,300	
Male 55-59 Years		1,900	
Male 60-64 Years		2,600	
Male 65-69 Years		2,100	
Male 70-74 Years		2,700	
Male 75-79 Years		3,400	
Male 80-84 Years		4,000	
Male 85-89 Years		4,800	
Male 90-94 Years		5,400	
Male 95 Years or Over		6,200	
Medicaid Interactions with Age and Sex			
Medicaid Female, <65 Years		900	
Medicaid Female, Aged		1,100	
Medicaid Male, <65 Years		600	
Medicaid Male, Aged		1,300	
Originally-disabled[4] Interactions with Sex			
Originally-Disabled, Female		1,500	
Originally-Disabled, Male		1,200	
Disease Group			
HCC1	HIV/AIDS	6,100	
HCC2	Septicemia/Shock	5,800	
HCC5	Opportunistic Infections	2,700	
HCC7	Metastatic Cancer and Acute Leukemia	10,700	1

EXHIBIT 1. Draft Community Coefficients for the CMS-HCC Model with Constraints and Demographic Disease Interactions, Used in the Calculation of Monthly Medicare Advantage Payments[1] (continued)

Variable	Disease Group	Community	Constraint[3]
HCC8	Lung, Upper Digestive Tract, and Other Severe Cancers	10,700	1
HCC9	Lymphatic, Head and Neck, Brain, and Other Major Cancers	5,000	
HCC10	Breast, Prostate, Colorectal and Other Cancers and Tumors	1,700	
HCC15	Diabetes with Renal or Peripheral Circulatory Manifestation	3,900	
HCC16	Diabetes with Neurologic or Other Specified Manifestation	2,900	
HCC17	Diabetes with Acute Complications	2,400	
HCC18	Diabetes with Ophthalmologic or Unspecified Manifestation	1,700	
HCC19	Diabetes without Complication	1,200	
HCC21	Protein-Calorie Malnutrition	5,300	
HCC25	End-Stage Liver Disease	6,500	
HCC26	Cirrhosis of Liver	3,400	
HCC27	Chronic Hepatitis	2,000	
HCC31	Intestinal Obstruction/Perforation	2,300	
HCC32	Pancreatic Disease	2,500	
HCC33	Inflammatory Bowel Disease	1,800	
HCC37	Bone/Joint/Muscle Infections/Necrosis	3,600	
HCC38	Rheumatoid Arthritis and Inflammatory Connective Tissue Disease	2,400	
HCC44	Severe Hematological Disorders	7,400	
HCC45	Disorders of Immunity	5,500	
HCC51	Drug/Alcohol Psychosis	1,600	2
HCC52	Drug/Alcohol Dependence	1,600	2
HCC54	Schizophrenia	3,300	
HCC55	Major Depressive, Bipolar, and Paranoid Disorders	2,400	
HCC67	Quadriplegia, Other Extensive Paralysis	6,200	3
HCC68	Paraplegia	6,200	3
HCC69	Spinal Cord Disorders/Injuries	3,300	
HCC70	Muscular Dystrophy	3,000	
HCC71	Polyneuropathy	2,100	
HCC72	Multiple Sclerosis	3,100	
HCC73	Parkinson's and Huntington's Diseases	3,600	
HCC74	Seizure Disorders and Convulsions	1,800	
HCC75	Coma, Brain Compression/Anoxic Damage	2,900	4
HCC77	Respirator Dependence/Tracheostomy Status	12,100	
HCC78	Respiratory Arrest	9,400	

EXHIBIT 1. Draft Community Coefficients for the CMS-HCC Model with Constraints and Demographic Disease Interactions, Used in the Calculation of Monthly Medicare Advantage Payments[1] (continued)

Variable	Disease Group	Community	Constraint[3]
HCC79	Cardio-Respiratory Failure and Shock	4,100	
HCC80	Congestive Heart Failure	2,600	
HCC81	Acute Myocardial Infarction	2,300	
HCC82	Unstable Angina and Other Acute Ischemic Heart Disease	2,200	
HCC83	Angina Pectoris/Old Myocardial Infarction	1,500	
HCC92	Specified Heart Arrhythmias	1,900	
HCC95	Cerebral Hemorrhage	2,400	
HCC96	Ischemic or Unspecified Stroke	2,000	
HCC100	Hemiplegia/Hemiparesis	2,700	
HCC101	Cerebral Palsy and Other Paralytic Syndromes	1,400	
HCC104	Vascular Disease with Complications	4,200	
HCC105	Vascular Disease	2,100	
HCC107	Cystic Fibrosis	2,600	5
HCC108	Chronic Obstructive Pulmonary Disease	2,600	5
HCC111	Aspiration and Specified Bacterial Pneumonias	4,900	
HCC112	Pneumococcal Pneumonia, Emphysema, Lung Abscess	1,500	
HCC119	Proliferative Diabetic Retinopathy and Vitreous Hemorrhage	1,800	
HCC130	Dialysis Status	9,300	
HCC131	Renal Failure	2,500	
HCC132	Nephritis	1,200	
HCC148	Decubitus Ulcer of Skin	7,600	
HCC149	Chronic Ulcer of Skin, Except Decubitus	3,000	
HCC150	Extensive Third-Degree Burns	5,300	
HCC154	Severe Head Injury	2,900	4
HCC155	Major Head Injury	1,200	
HCC157	Vertebral Fractures without Spinal Cord Injury	3,300	
HCC158	Hip Fracture/Dislocation	2,900	
HCC161	Traumatic Amputation	4,800	
HCC164	Major Complications of Medical Care and Trauma	1,900	
HCC174	Major Organ Transplant Status	7,000	
HCC176	Artificial Openings for Feeding or Elimination	4,900	
HCC177	Amputation Status, Lower Limb/Amputation Complications	4,200	

EXHIBIT 1. Draft Community Coefficients for the CMS-HCC Model with Constraints and Demographic Disease Interactions, Used in the Calculation of Monthly Medicare Advantage Payments[1] (continued)

Variable	Disease Group	Community Estimate[2]	Constraint[3]
Disabled[4]/Disease Interactions			
D-HCC5	Disabled*Opportunistic Infections	6,100	
D-HCC44	Disabled*Severe Hematological Disorders	3,600	
D-HCC51	Disabled*Drug/Alcohol Psychosis	5,200	
D-HCC52	Disabled*Drug/Alcohol Dependence	2,300	
D-HCC107	Disabled*Cystic Fibrosis	9,000	
Disease Interactions			
INT1	DM*CHF[5]	1,300	
INT2	DM*CVD	1,000	
INT3	CHF*COPD	1,400	
INT4	COPD*CVD*CAD	1,100	
INT5	RF*CHF[5]	1,600	
INT6	RF*CHF*DM[5]	4,300	

[1] The dollar amounts in this table will be converted to relative risk scores for the April 3 Announcement of Medicare Advantage Rates. That is, these dollar amounts will be divided by the national average predicted expenditures to get relative risk scores we will report April 3.

[2] All estimates are rounded to the nearest hundred dollars.

[3] Equal values in this column indicate coefficients that have been constrained to be equal.

[4] Disabled refers to beneficiaries who are Medicare eligible and under 65 years. Originally-disabled refers to beneficiaries who are over 65, but who were eligible for Medicare due to disability.

[5] Beneficiaries with the three-way interaction RF*CHF*DM are excluded from the two-way interactions DM*CHF and RF*CHF. Thus, the three-way interaction term RF*CHF*CM is not additive to the two-way interaction terms DM*CHF and RF*CHF. Rather, it is hierarchical to, and excludes these interaction terms. A beneficiary with all three conditions is not credited with the two-way interactions. All other interaction terms are additive.

DM is diabetes mellitus (HCCs 15-19).
CHF is congestive heart failure (HCC 80).
COPD is chronic obstructive pulmonary disease (HCC 108).
CVD is cerebrovascular disease (HCCs 95, 96, 100, and 101).
CAD is coronary artery disease (HCCs 81-83).
RF is renal failure (HCC 131).

SOURCE: RTI Analysis of 2002/2003 Medicare 5% sample.

EXHIBIT 2. Draft List Of Disease Groups (HCCs) with Hierarchies

DRAFT DISEASE HIERARCHIES		
If the Disease Group is Listed in This Column…		**…Then Drop the Associated Disease Group(s) Listed in This Column**
Disease Group (HCC)	**Disease Group Label**	
5	Opportunistic Infections	112
7/8	Metastatic Cancer, Acute Leukemia, and Other Severe Cancers	9,10
9	Lymphatic, Head and Neck, Brain and Other Major Cancers	10
15	Diabetes with Renal Manifestations	16,17,18,19
16	Diabetes with Neurologic or Other Specified Manifestation	17,18,19
17	Diabetes with Acute Complications	18,19
18	Diabetes with Ophthalmologic Manifestations	19
25	End-Stage Liver Disease	26,27
26	Cirrhosis of Liver	27
51	Drug/Alcohol Psychosis	52
54	Schizophrenia	55
67/68	Quadriplegia/Paraplegia/Extensive Paralysis	69,100,101,157
69	Spinal Cord Disorders/Injuries	157
77	Respirator Dependence/ Tracheostomy Status	78,79
78	Respiratory Arrest	79
81	Acute Myocardial Infarction	82,83
82	Unstable Angina and Other Acute Ischemic Heart Disease	83
95	Cerebral Hemorrhage	96
100	Hemiplegia/Hemiparesis	101
104	Vascular Disease with Complications	105,149
111	Aspiration and Specified Bacterial Pneumonias	112
130	Dialysis Status	131,132
131	Renal Failure	132
148	Decubitus Ulcer of the Skin	149
154	Severe Head Injury, Coma, Brain Compression/Anoxic Damage	75,155

How Payments are Made with a Disease Hierarchy

EXAMPLE: If a beneficiary triggers Disease Groups 148 (Decubitus Ulcer of the Skin) and 149 (Chronic Ulcer of Skin, Except Decubitus), then DG 149 will be dropped. In other words, payment will always be associated with the DG in column 1, if a DG in column 3 also occurs during the same collection period. Therefore, the organization's payment will be based on DG 148 rather than DG 149.

February 16, 2007

NOTE TO: Medicare Advantage Organizations and Other Interested Parties

SUBJECT: Advance Notice of Methodological Changes for Calendar Year 2008 for Medicare Advantage (MA) Capitation Rates

In accordance with Section 1853(b)(2) of the Social Security Act (the Act), we are notifying you of proposed changes in the MA capitation rate methodology and risk adjustment methodology applied under Part C of the Act for CY 2008. Preliminary estimates of the national per capita MA growth percentage and other MA payment methodology changes for CY 2008 are also discussed. For 2008, CMS will announce the MA capitation rates on the first Monday in April 2007, in accordance with the timetable established in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). This Advance Notice is published 45 days before that date.

For 2008, all non-ESRD rates will be minimum percentage increase rates. As permitted under section 1853(c)(1)(D)(ii), CMS will not rebase the amount representing the actuarial value of costs under the original Medicare fee-for-service program for 2008. (CMS rebased these costs for 2007.) Attachment I shows the preliminary estimates of the national per capita MA growth percentage component of the minimum percentage increase. See Attachment II, section E2, for a discussion of ESRD rates for 2008. Attachment II sets forth in detail the changes in payment methodology for 2008 for MA organizations.

Any changes to employer/union-only group waiver plan payment for 2008 will be issued in future guidance.

Comments or questions may be submitted electronically to the following address: AdvanceNotice2008@cms.hhs.gov. Comments or questions also may be mailed to:

Anne Hornsby
Centers for Medicare & Medicaid Services
7500 Security Boulevard
S3-16-16
Baltimore, Maryland 21244

In order to receive consideration prior to the April 2, 2007 Announcement of Calendar Year (CY) 2008 Medicare Advantage Capitation Rates and Payment Policies, comments must be received by 6:00 PM EST on Friday, March 2, 2007.

/ s /
Abby L. Block
Director
Center for Beneficiary Choices

/ s /
Paul Spitalnic, A.S.A., M.A.A.A.
Director
Parts C & D Actuarial Group
Office of the Actuary

Attachments

Attachment I
Preliminary Estimate of the National Per Capita Growth Percentage for Calendar Year (CY) 2008

Section 1853(c)(1) of the Social Security Act (the Act) provides that, for years when CMS is not "rebasing" the amount representing the actuarial value of costs under original fee-for-service (FFS) Medicare, MA capitation rates will be based on the minimum percentage increase, which is the higher of two percent or the national per capita MA growth percentage, with no adjustment to this percentage for over- or under-estimates for years before 2004.

The current estimate of the change in the national per capita MA growth percentage for aged and disabled enrollees combined in CY 2008 is 4.1 percent. This estimate reflects an underlying trend change for CY 2008 in per capita costs of 3.4 percent and adjustments to the estimates for CY 2007, CY 2006, CY 2005, and CY 2004 aged and disabled MA growth percentages of 1.9 percent, -0.5 percent, -0.3 percent, and -0.5 percent, respectively. Our new estimates for these years are lower than the estimates actually used in calculating the CY 2007 capitation rate book for CY 2004 to 2006 and higher for CY 2007 than was published April 3, 2006, and are required by Section 1853(c)(6)(C) of the Act.

The following table summarizes the estimates for the change in the national per capita MA growth percentage.

Table I-1. National Per Capita MA Growth Percentage

	Aged	Disabled	ESRD	Aged+Disabled
2008 Trend Change	3.3%	4.2%	-0.1%	3.4%
Revision to CY 2007 Estimate	1.9%	2.1%	5.6%	1.9%
Revision to CY 2006 Estimate	-0.5%	-0.4%	-0.6%	-0.5%
Revision to CY 2005 Estimate	-0.3%	-0.4%	0.9%	-0.3%
Revision to CY 2004 Estimate	-0.4%	-0.4%	-1.1%	-0.5%
Total Change	4.0%	5.2 %	4.7%	4.1%

Notes: (1) The total percentage change is multiplicative, not additive and may not exactly match due to rounding.
(2) Starting in 2008, the trend change for ESRD will reflect an estimate of the trend for dialysis-only beneficiaries.

These estimates are preliminary and could change before the final rates are announced on April 2, 2007 in the Announcement of Calendar Year (CY) 2008 Medicare Advantage Capitation Rates and Payment Policies. Further details on the derivation of the national per capita MA growth percentage will also be presented in the Announcement.

Attachment II
Changes in the Payment Methodology for Original Medicare Benefits for CY 2008

Section A. Frailty Adjustment

Since 2004, CMS has applied a frailty adjustment to payments for enrollees in PACE organizations and certain demonstration plans. Frailty adjustment allows for improved prediction of Medicare expenditures for community populations with functional impairments that are not reflected in the CMS-HCC risk adjustment factors. The sections below discuss CMS' proposed changes in the calculation and application of frailty adjustment, starting in 2008.

A1. No Program-Wide Application of Frailty Adjustment

CMS has conducted research to determine whether or not to apply a frailty adjustment to all MA plans in 2008. We have determined that for 2008 there will not be program-wide application of frailty factors due to several methodological issues associated with use of survey data for calculating payments for entire program.

Background. In developing the frailty adjustment model that is currently used for enrollees in PACE organizations and certain demonstration plans, CMS adopted the approach taken by many researchers and clinicians of defining frailty as functional impairment, and using counts of difficulty in performing Activities of Daily Living (ADLs) as the core measure of functional impairment. Individuals are grouped according to their difficulties with ADLs: 0 ADLs, 1 to 2 ADLs, 3 to 4 ADLs, and 5 to 6 ADLs. The frailty adjustment model consists of payment factors that are associated with different levels of functional impairment.

CMS calibrated the current frailty factors using 1994 to 1997 data from the Medicare Current Beneficiary Surveys (MCBS). At the time we created the initial frailty model, these survey data were the only comprehensive data available that allowed CMS to link individual-level functional impairment data to Medicare claims data. Information from the MCBS survey was used to predict expenditures unexplained by the CMS-HCC model (residual expenditures calculated as the difference between actual expenditures and predicted payments). Actual frailty scores are calculated at the contract level (rather than the plan benefit package (PBP) level) using these frailty factors and an estimate of the ADL limitations of enrollees collected from Health Outcomes Survey (HOS) data. These frailty scores are added to the risk adjustment factors in payment.

Rationale for not applying frailty adjustment program-wide. Methodological concerns have led us to conclude that the application of frailty adjustment program-wide in 2008 would not improve payment accuracy.

First, the HOS data used currently to determine frailty scores for payment is sampled only at the contract level and, therefore, does not allow us to calculate accurate frailty scores at the plan benefit package (PBP) level. Because bids and plan benefit designs are made at the PBP level,

applying a contract-level frailty score would lead to inconsistent payments across plans and beneficiaries.

Second, if frailty were applied program wide, MA organizations would need to project a frailty score in their plan bids. However, when CMS pays plans, we use frailty scores calculated after the bid has been submitted. Due to the changing nature of the marketplace and the different enrollment profiles of plans from year to year, this creates a risk that the level of frailty assumed by a plan in its bid would not reflect its actual frailty score in the payment year. PACE plans do not bid on Part C benefits, and would not be affected by this issue.

CMS will continue to explore ways to incorporate factors into the CMS-HCC model that will predict costs associated with the frailty of individual beneficiaries.

A2. Update to Frailty Factors for PACE

CMS has updated and refined the current frailty adjustment factors. Effective 2008, CMS will apply these new frailty factors to PACE organization payments on a phase-in schedule (discussed at the end of this section).

CMS changed the source of data used to calibrate the frailty factors so that the methodologies used to gather ADL-related data for both calibration and payment would be similar, avoiding a bias that comes from using different data collection methodologies. As noted above, the current frailty factors were calibrated using ADL limitation information from MCBS. These MCBS data are gathered through in-person surveys. CAHPS data, which we used to recalibrate the frailty factors, and HOS data, which we use to calculate frailty scores for payment, both collect ADL information via mail surveys with telephone follow-up. We added questions regarding ADLs to the FFS CAHPS collected between March 2003 and February 2004 to obtain data from that source, used claims data for the beneficiaries in the sample from the 12 months following this period, and recalibrated the frailty factors with these data.

CMS also refined the frailty adjustment model to compute two sets of frailty factors: one for those Medicare beneficiaries who are dually eligible for Medicaid and another set for those who are not. Table II-1 below contains the new frailty factors. Medicaid beneficiaries have different cost patterns than non-Medicaid beneficiaries and this difference is incorporated into the CMS-HCC risk adjustment model. Our research shows that that there are significant differences in the relationship between unexplained expenditures from the CMS-HCC model and functional impairment for those Medicare beneficiaries who are dually eligible for Medicaid and those who are not. While the sample size of the MCBS that we used to develop the current frailty model did not allow us to reliably estimate separate models for Medicaid and non-Medicaid beneficiaries, we can do so for the recalibrated model because the CAHPS sample is much larger. The revised factors differ because the additional predicted expenditures associated with Medicaid status in the CMS-HCC model account for some portion of frailty-related spending. Using this revised model produces the appropriate factors for each population.

Table II-1. Revised Frailty Factors

ADL	Current Factor	Revised Model Factors (Non-Medicaid)	Revised Model Factors (Medicaid)
0	-0.141	-0.089	-0.183
1-2	+0.171	+0.110	+0.024
3-4	+0.344	+0.200	+0.132
5-6	+1.088	+0.377	+0.188

The revised frailty factors are generally lower for at least two reasons. The main source of the change is the decrease in home health payments mandated by the BBA, which took effect in years following the 1994-1997 MCBS data used to calibrate the current frailty factors. This decrease in home health payments partially explains the decrease in the frailty factors because, in a community setting, frailty is highly correlated to home health expenditures.

A second reason the new frailty factors are different is the survey methodology. As noted above, MCBS is a face-to-face survey, whereas CAHPS is a mail survey. Survey research has shown that respondents may be less willing to share what could be perceived as negative personal information with someone in a face-to-face interview than they would in a written, more anonymous, survey. The experience with MCBS and CAHPS bears this out: 68 percent of the MCBS sample indicated that they had no difficulty with an ADL, yet 61.5 percent of the CAHPS sample reported no difficulty with an ADL. At the other end of the scale, 4.3 percent of the MCBS respondents indicated problems with 5 or 6 ADLs compared to 6.4 percent of the CAHPS respondents. The respondents who report high numbers of ADLs in a face-to-face situation tend to be frailer and have higher costs. When respondents are given the opportunity to report limitations in ADLs anonymously, the rate of reporting increases but this broader population is less frail with lower average costs. This means that the incremental dollars associated with ADL reporting (and, therefore, the frailty factors) are lower when more respondents admit to functional impairment.

Table II-2. MCBS and CAHPS Distributions of Activities of Daily Living

ADL Categories	MCBS: % of Respondents	CAHPS: % of Respondents
0	67.9%	61.5
1-2	21.0%	23.7%
3-4	6.8%	8.4%
5-6	4.3%	6.4%

As shown in Table II-2, our results confirm the known survey bias that occurs with face-to-face interviews, as compared with mail surveys. Through the use of a mail survey, beneficiaries more accurately report their ADLs, and their residual expenditures are more accurately accounted for, thus making the frailty factors more accurate with the mail survey data (CAHPS) than with face-to-face survey data (MCBS).

CMS will transition PACE organization payments to 100 percent of the revised frailty factors over a four-year period. In each year, the monthly PACE organization payment would be based

on the A/B risk score, plus the frailty component determined under the following transition schedule:

- In 2008 (year 1): 75% of the current frailty factors and 25% of the revised frailty factors.
- In 2009 (year 2) 50% of the current frailty factors and 50% of the revised frailty factors.
- In 2010 (year 3) 25% of the current frailty factors and 75% of the revised frailty factors.
- In 2011, 100% of the revised frailty factors.

A3. Frailty Adjustment for Certain Demonstrations

Since January 2004, CMS has applied a frailty adjustment to payments for enrollees in Social Health Maintenance Organizations (S/HMOs), Minnesota Senior Health Options (MSHO)/ Minnesota Disability Health Options (MnDHO), Wisconsin Partnership Program (WPP) and Massachusetts Senior Care Options (SCO) demonstrations.

CMS will phase-out the frailty payments to these plans over a four-year period. In each year, the monthly plan payment would be based on the A/B risk score, plus the frailty component determined under the following transition schedule:

- In 2008 (year 1): 75% of the current frailty factors
- In 2009 (year 2) 50% of the current frailty factors
- In 2010 (year 3) 25% of the current frailty factors
- In 2011, 0% of the current frailty factors

Section B. Adjustment for MA Coding Intensity

Section 1853(k)(2)(B)(iv)(III) requires CMS to reflect in its risk adjustment for Part C payment "differences in coding patterns between Medicare Advantage plans and providers under part A and B to the extent that the Secretary has identified such differences." The Conference Report for the Deficit Reduction Act of 2005, which added section 1853(k), calls upon the Secretary to "conduct an analysis" in order to attempt to identify such differences in coding patterns, and that "[t]he conferees intend that any adjustments made for differences in coding patterns be made for differences resulting from inaccurate coding." The Report further provides that "[t]o the extent that the Secretary identifies any differences, they are to be incorporated into calculations of the risk rates and the budget neutrality factor in 2008, 2009, and 2010."

CMS calibrates the risk factors under the CMS-HCC model on the diagnoses and expenditure data of fee-for-service Medicare beneficiaries. Risk scores are then developed for each Medicare beneficiary (including those in managed care) using their own diagnoses. These individual risk scores are used to adjust Part C payments to MA organizations for each plan enrollee. An upward trend in fee-for-service coding results in average risk scores that are greater than 1.0 after the calibration year. Increases in risk scores over time are a result of changes in diagnostic coding over time which, in turn, can be a result of more specific coding, increased illness, or more severe manifestations of illness. In order to keep the average risk score at 1.0, CMS adjusts the CMS-HCC risk scores for these changes in fee-for-service coding patterns using a fee-for-service normalization factor (in 2007, this factor is 1.45 percent per year). A key reason for

normalizing risk scores is to keep them tied to the county ratebook, which is standardized with the average county FFS risk scores.

Because the CMS-HCC model is calibrated on fee-for-service data and the resulting risk scores are adjusted for fee-for-service normalization, MA coding patterns that differ from patterns in fee-for-service may result in risk scores that are not equivalent to the risk scores of the FFS beneficiaries used to calculate the county rates.

CMS is conducting studies designed to assess the degree of coding patterns differences that may be identified between FFS and MA and the extent to which any differences could be appropriately addressed by an adjustment to the CMS-HCC risk scores. Below is a description of two pending studies.

1. Differences in disease progression between MA and FFS. The goal of this study is to assess any differences in coding patterns by comparing overall changes in risk scores and the disease component of the risk scores for beneficiaries in FFS and in MA. This study is being conducted to test the hypothesis that MA plans code more thoroughly and, therefore, similarly situated beneficiaries appear sicker. To conduct this study, CMS will analyze the change in risk scores from 2004 to 2006 among beneficiaries in FFS and MA. We will also explore the extent to which changes in risk scores are attributable to case mix in FFS and MA plans by separately analyzing changes among continuing enrollees (stayers), leavers, and joiners. The analysis of case mix will allow us to decompose the overall trends in risk scores into the effect of changes in enrollee composition versus changes due to differences in coding patterns.

2. Differences in persistence. The goal of this study is to assess any differences in coding patterns by comparing the differences in the 'persistence' of HCCs among continuing enrollees in FFS and in MA. This study is being conducted to test the hypothesis that greater coding in MA is reflected in greater persistence in of diseases (HCCs) across years. To conduct this study, CMS will analyze rates of persistence and changes in the rates of persistence for specific diseases in the CMS-HCC model from 2004 to 2006 among beneficiaries in FFS and MA. We will explore whether persistence rates differ between FFS and MA. This analysis will specifically address rates of persistence among those who remain continuously enrolled in FFS and MA over time.

CMS will use the results of these studies and additional analysis (if any), once completed, to determine the necessity for, and if necessary the magnitude of, an adjustment to the Part C risk scores based on differences in coding patterns between MA and FFS. To the extent that these studies produce valid results that identify differences in coding prior to the April 2, 2007 Announcement, that Announcement will reflect any warranted adjustments based on these differences. If there are no conclusive results as of that date, no adjustment will be made for 2008. We invite public comment on the relative strengths of each of these studies as well as suggestions for alternative studies that could help identify differences in coding patterns.

Section C. Normalization of the Aged-Disabled CMS-HCC Model

The FFS normalization factor for the aged-disabled CMS-HCC model, used to adjust for population and coding changes between the data years used in model calibration and the payment year, has been updated to include more recent data.

Background. When we calibrate a risk adjustment model and normalize the risk scores to 1.0, we produce a fixed set of dollar expenditures and coefficients appropriate to the population and data for that calibration year. When the model with fixed coefficients is used to predict expenditures for other years, predictions for prior years are lower and predictions for succeeding years are higher than for the calibration year. Because average predicted FFS expenditures increase after the model calibration year due to coding and population changes, CMS applies a normalization factor to adjust beneficiaries' risk scores so that the average risk score is 1.0 in subsequent years.

The normalization factor is derived by first using the model to predict risk scores for the FFS population for each year in which data are available. Next, we trend the risk scores to determine the average percent change in the risk score. This amount is then compounded by the number of years between the model calibration year and the payment year to produce the normalization factor.

Factor for 2008. On April 3, 2006 CMS announced that the FFS normalization factor for 2007 is 2.9%. This factor was calculated based on an estimate of the average annual increase in predicted expenditures of 1.45 percent for the two years from 2005 (the year on which the model coefficients are denominated) to 2007. For 2008, the FFS normalization will reflect an estimate for three years, i.e., from 2005 to 2008. The preliminary estimate of the FFS normalization factor for 2008, calculated based on data from 1999 to 2006, is 4.0 percent. This figure represents more recent trends in FFS coding changes. The final FFS normalization factor will be included in the April 2, 2007 Announcement.

As in 2007, CMS will continue to apply the FFS normalization factor to the risk scores when calculating the beneficiary-level monthly payment amounts for aged and disabled enrollees.

Section D. Budget Neutrality

From 2003 through 2006, CMS implemented risk adjusted payments in a budget neutral manner by applying to the risk rates 100 percent of the Budget Neutrality (BN) factor, which is calculated as the estimated difference between payments to MA organizations at 100 percent of the demographic rates and payments at 100 percent of the risk rates. As previously announced by CMS on February 17, 2006 in the Advance Notice for 2007, and as summarized in Table II-3, the phase-out of budget-neutral risk adjusted payments began in 2007 and will be completed by 2011, when plans will receive no budget neutrality payment adjustment. For 2008, 40 percent of the BN factor will be applied to the risk rates.

Since CMS cannot calculate the BN factor until the final capitation rates are determined, the factor will be announced in the April 2, 2007 Rate Announcement. The size of the total BN factor is determined by the difference in aggregate payments made to MA organizations under the risk model and aggregate payments made under the demographic only model.

Table II-3. Schedule for Phase-out of Budget Neutral Risk Adjusted Payments

Year	Budget Neutrality Percentage
2007	55%
2008	40%
2009	25%
2010	5%
2011	0%

Section E. ESRD Bidding and Payment

Pursuant to Section 1853(a)(1)(H) of the Act, CMS has the authority to determine whether to apply the competitive bidding methodology to ESRD enrollees, and must establish "separate rates of payment" with respect to ESRD beneficiaries.

E1. ESRD Bidding Policy

For 2008, CMS will continue the policy of excluding costs for ESRD enrollees in the plan A/B bid. CMS continues to work toward including ESRD costs into MA plans bids. However, we need additional time to further evaluate different methodological approaches for incorporating ESRD costs. Therefore, for 2008, ESRD enrollee costs will not be included in the plan A/B bid. As a result, the 2008 payment methodology for ESRD enrollees in MA plans is unchanged from 2007. CMS will release Bidding Instructions for 2008 with guidance on the option of adjusting A/B mandatory supplemental premiums to reflect the costs or savings for ESRD enrollees in the basic and supplemental benefits.

E2. Refinement of Growth Trend for ESRD State Rates

Effective with the 2005 implementation of the ESRD CMS-HCC model, CMS changed how ESRD payments were made: the State rates became dialysis/transplant-only rates, and payments for functioning graft beneficiaries were determined using the county capitation rates. CMS is recalculating the State rates using more recent data and for 2008 will apply a dialysis-only growth trend for the first time. The dialysis-only trend will be applied to the State rates for 2008 and subsequent years. (See section E5 below for discussion of the proposed phase-in schedule for these new State rates).

To calculate the 2008 State rates, CMS used Medicare FFS claims data by State for beneficiaries in dialysis status between the years 2001 and 2005 to determine the average geographic adjustment (AGA) for each State and to determine the 2005 national average per capita FFS dialysis cost. CMS then adjusted the 2005 national average by each State AGA to determine revised 2005 State rates. To develop the 2008 ESRD State ratebook, CMS will apply the dialysis-only trend to this revised 2005 rate for 2007 to 2008, and will also account for claims run-out and provider cost reports and will develop growth trend factors based on 2001-2005 FFS ESRD dialysis costs by state. The final 2008 State rates will be developed by taking into account the Graduate Medical Education (GME) carve-out and the $5.25 ESRD user fee.

The distribution of changes in payment across plans using the revised State rates will depend on how many ESRD dialysis enrollees are enrolled in each plan, as well as the change in the ESRD State rates.

E3. Recalibration of the ESRD CMS-HCC Risk Adjustment Model

In 2008, CMS will implement an updated version of the current ESRD CMS-HCC risk adjustment model. Fee-for-service (FFS) claims data for the years 2002 and 2003 are used in the recalibration of the model. (Diagnostic data for 2002 predict 2003 expenditures.)

The current ESRD CMS-HCC model is calibrated on 1999 and 2000 data, and recalibrating the model on more current data results in more appropriate relative weights for each HCC because they reflect more recent coding and expenditure patterns in FFS Medicare. In addition, recalibrating updates the total costs associated with ESRD dialysis beneficiaries.

Both updates (total costs and relative cost factors) can potentially result in changes in risk scores for individual ESRD dialysis beneficiaries and for average plan ESRD risk scores. Depending on an individual beneficiary's combination of diagnoses, the newly recalibrated model may result in a different ESRD risk score for that beneficiary.

All segments of the ESRD risk adjustment model will be updated (the full-risk and new enrollee dialysis factors, the transplant factors, the post-graft full-risk community, full-risk institutional and new enrollee factors). In this notice, we are providing the relative factors for each HCC for each segment of the model (see Exhibit 1). Disease groupings are the same as in past models; however, the factors are different.

The MSP factor remains at 0.215.

E4. Normalization of ESRD CMS-HCC Model

Normalization of risk scores is done in order to maintain a 1.0 average risk score in the FFS population on which the factors were calibrated. Without normalization, risk scores rise over time in response to population and coding changes between the data years used in model calibration and the payment year. See the background discussion in Section C above for further detail on FFS normalization.

CMS is applying an ESRD normalization factor for the first time in 2008, calculated based on data from 1999-2004. For 2008, the ESRD FFS normalization factor will reflect an estimate for five years, i.e., from 2003 to 2008. The preliminary estimate of the 2008 ESRD FFS normalization factor (dialysis model) is 3.9 percent. This normalization factor will applied under the transition schedule set forth in section E5. The final FFS normalization factor will be included in the April 2, 2007 Announcement.

E5. Transition to New ESRD Payment

CMS will phase-in the revised State rates by blending payments based on the current ratebook and the ratebook based on the dialysis-only trend. Over a four-year period, we will apply the payment blend according to the schedule described below. During the transition period, we will continue to trend forward the current and the revised State rates using the same dialysis-only growth trend.

- In 2008 (year 1), CMS payments for ESRD dialysis beneficiaries enrolled in MA plans will be a blend of 75% current ratebook-based payments and 25% revised ratebook-based payments.
- In 2009 (year 2), CMS payments for ESRD dialysis beneficiaries enrolled in MA plans will be a blend of 50% current ratebook-based payment and 50% revised ratebook-based payments.
- In 2010 (year 3), CMS payments for ESRD dialysis beneficiaries enrolled in MA plans will be a blend of 25% current ratebook-based payments and 75% revised ratebook-based payments.
- In 2011, CMS payments for ESRD dialysis beneficiaries enrolled in MA plans will be based on 100% of the revised ratebook.

In States where the revised ratebook is higher than the current ratebook, we will apply the revised ESRD State rate, beginning with 2008 payments.

Section F. Transition Payment Blends

From 2004 through 2006, risk adjusted payment was phased-in for all MA plan payments, with one portion of CMS' payment to plans based on the demographic-only method and the other portion based on the CMS-HCC risk adjustment model. For 2007, Part C payments are 100 percent risk adjusted. CMS pays the Program of All-Inclusive Care for the Elderly (PACE) organizations and certain demonstrations at the announced blend for 2007 – the final year before their transition to fully risk-adjusted payments.

Starting in 2008, 100 percent of payments will be risk adjusted for PACE organizations and those plans that have been operating under demonstration authority: Social Health Maintenance Organizations (S/HMOs), Minnesota Senior Health Options (MSHO)/ Minnesota Disability Health Options (MnDHO), Wisconsin Partnership Program (WPP), and Massachusetts Senior Care Options (SCO) demonstrations. See section A3 on application of the frailty adjusters.

Section G. Regional Plan Stabilization Fund

Section 221 of the MMA added Section 1858(e) to the Act to create a new MA Regional Plan Stabilization Fund. The purpose of the fund is to provide financial incentives to MA organizations to offer MA regional PPO plans in each MA region, and to retain MA regional PPO plans in regions with relatively low MA market penetration.

Section 301 of Division B, Title III, of the Tax Relief and Health Care Act of 2006 – enacted December 20, 2006 – delayed Stabilization Fund payments until January 1, 2012.

Section H. Continuation of Clinical Trial Policy
In 2008, we will continue the policy of paying on a fee-for-service basis for clinical trial items and services covered under the September 2000 National Coverage Determination that are provided to MA plan members.

Section I. Operational Policies

Section I1. Reporting of Medicaid Status for Part C Payment
For 2008, to assign Medicaid status for Part C risk adjustment payments, CMS will begin using information regarding title XIX eligibility from the MMA Medicare/Medicaid Dual Eligible monthly submission file, which all States are required to submit to CMS under provisions of the MMA and which CMS currently uses as a source of Medicaid status for Part D. Using these files as a data source for Medicaid status under the Part C CMS-HCC model promotes consistency across Part C and Part D.

The MMA Medicare/Medicaid Dual Eligible monthly files (referred to as the "MMA State files" below) provide monthly identification of each actively enrolled Medicare/Medicare dual eligible beneficiary, including a person-month record for each Medicare/Medicaid dual eligible in a State Medicaid program in the reporting month. The MMA State files also report information on changes in the circumstances for individuals in a prior month. The MMA state files were tested during a validation period of March-May 2005 and have been in production since June 2005. The files continue to be validated monthly by a CMS contractor. The files include those eligible for comprehensive Medicaid benefits (whether eligible through the state plan or a section 1115 demonstration), as well as those for whom the State pays Medicare premiums and/or cost sharing (Qualified Medicare Beneficiaries, Specified Low-Income Medicare Beneficiaries, and Qualifying Individuals).

In 2005, when we proposed transitioning to the use of the then-new MMA State files for 2006, respondents had several concerns: the schedule for transitioning to use of the MMA State files for payment, the accuracy and reliability of the new data, and availability of a process by which plans could report Medicaid status if the CMS system did not accurately reflect the enrollees' status. Currently, CMS has used the MMA State files for well over a year in the Part D program, and we have been able to assess the completeness of the information provided by these files, compared to information obtained from the Third Party Buy-In files and plan-reported files. CMS has determined that the MMA State files more precisely identify dual eligibles. For example, there are an estimated 974,000 individuals reported on MMA files but not on Third Party-Buy In files because they are dual eligibles for whom States do not pay the Part B premium, so the State Third-Party Buy-In file does not include them. These individuals, however, do meet the criteria for Medicaid status for Part C risk adjustment.

Implementation. We are not proposing any changes to how we assign Medicaid status for payment purposes under Part D. This section only proposes changes to how we assign such status for Part C risk adjustment purposes. Currently, CMS assigns Medicaid status for Part C

risk adjustment based on two sources: (1) the Third Party Buy-In file for beneficiaries on whose behalf States report paying Part B premiums and (2) plan-reported Medicaid status.

For the payment year 2008 and beyond, CMS intends to implement the following approaches.

Full risk enrollees. CMS considers full risk Medicare beneficiaries as dually eligible if they were eligible for title XIX during any month in the year prior to the payment year. Full risk Medicare beneficiaries have 12 months of Part B in the year prior to the payment year.

- **Payment year 2008**: For risk scores applied to 2008 payment, CMS will determine Medicaid status during 2007 using the current sources of Medicaid status (plan-reported and Third Party) as well as the MMA State files.
- **Payment years starting in 2009:** CMS will no longer use plan-reported or Third Party files as sources of Medicaid status for risk scores based on data from 2008 and subsequent years (applied to payment calculations in 2009 and subsequent years). For example, for 2009 payment, we will assign Medicaid status in 2008 using data submitted on the MMA State files.

New enrollees. CMS assigns Medicaid status for new enrollees on a concurrent basis, i.e., if a newly-enrolled Medicare beneficiary is eligible for title XIX during any month during the payment year, they are considered Medicaid for that year. For new enrollees, starting with the 2008 payment year, CMS will assign concurrent Medicaid status based only on the MMA State files.

Exceptions process. In 2008, CMS will implement an exceptions process to address situations where an MMA State file record does not accurately reflect a beneficiary's status. Additional information regarding how the exceptions process will work is forthcoming.

Section I2. Standard Set of ICD-9 Diagnosis Codes for Risk Adjustment

Each year, CMS publishes on its website a list of the valid ICD-9-CM codes for the following fiscal year, based on the recommendations of the ICD-9-CM Coordination and Maintenance Committee. All final decisions on codes are made by the Director of the National Center for Health Statistics (NCHS) and the Administrator of CMS. NCHS, a component of the Centers for Disease Control, has the lead on ICD-9-CM diagnosis issues. The published code sets can be found at http://www.cdc.gov/nchs/icd9.htm. More information on the process for updating ICD-9 codes can be found at http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes/01_overview.asp#TopOfPage.

As described in Table II-4 below, starting with 2008 payment, the list of acceptable ICD-9-CM codes for the CMS-HCC, ESRD, and RxHCC risk adjustment models for risk adjustment for any given payment year will comprise the list of published NCHS/CMS codes for the three fiscal years prior to and including the payment year.

Table II-4. Phase-in Schedule for New Lists of Diagnosis Codes for Risk Adjustment

Year of Payment	Date Collection Period	Description/source of codes
2007	1/06 – 12/06	All of the following: 1) All risk model codes previously posted on CMS website, 2) IBM's list of risk adjustment codes, 3) Diagnoses codes included in the CMS-HCC and RxHCC model formats published through December 31st, 2006.
2008	1/07 – 12/07	Valid diagnoses in Fiscal Years 2006, 2007, or 2008
2009	1/08 – 12/08	Valid diagnoses in Fiscal Years 2007, 2008, or 2009
2010	1/09 – 12/09	Valid diagnoses in Fiscal Years 2008, 2009, or 2010
2011	1/10 – 12/10	Valid diagnoses in Fiscal Years 2009, 2010, or 2011

Section I3. MSA Plan Submission of Risk Adjustment Data

Section 1853(a)(1)(B)(iii) of the Act requires CMS to risk adjust payments for Medical Savings Account (MSA) plan enrollees. CMS' guidance on risk adjustment under the CMS-HCC model applies to MSA plans, including requirements for data submission. This guidance can be found on the CMS website at http://www.cms.hhs.gov/MedicareAdvtgSpecRateStats/06_Risk_adjustment.asp#TopOfPage, on the link to "Risk Adjustment Customer Support."

Section I4. Clarification on Institutional Status under Part C CMS-HCC Models

As discussed in Section F above, the transition to 100 percent risk adjusted payments is completed for all plan types in 2008. Because CMS will no longer apply the demographic-only payment method to any plan payments, organizations are no longer required to submit to CMS monthly files on enrollee institutional status (as it was defined for purposes of the Part C demographic payment).

We want to clarify how long-term institutional (LTI) status is determined for Part C risk adjusted payments. For MA plans, CMS uses the information included in the Minimum Data Set (MDS) that is reported by Medicare-certified nursing homes to determine institutional status. Beneficiaries identified as residing in a long-term institution for 90 days prior to the payment month are classified as LTI-status beneficiaries. Enrollees remain in LTI status until discharged to the community for more than 14 days.

CMS uses the Monthly Membership Report (MMR) to report LTI status to MA organizations; therefore, MA organizations may use the MMR to track the institutional status of their enrollees. Specifically, the LTI flag for Part C is provided in position 67 of the MMR. We also recommend that MA organizations review the factor code, position 189-190, which tells whether the beneficiary is community or institutional status. The MMR file layout is available in the *Medicare Advantage and Prescription Drug Plans, Plan Communications User's Guide, Version 2.0* and *Medicare Advantage and Prescription Drug Plans, Plan Communications User's Guide Appendices, Version 2.0* (dated November 16, 2006); these two documents are available on the CMS web site at http://www.cms.hhs.gov/MedicareMangCareSys/Downloads/PCUG%20v2_Main%20Guide%2011162006.pdf and

http://www.cms.hhs.gov/MedicareMangCareSys/Downloads/PCUG_Appendices%20v2_11162006.pdf, respectively.

LTI status is a concurrent indicator in the payment year. Beneficiary LTI status is determined at final reconciliation which occurs approximately six months after the payment year. However, in order to prospectively classify beneficiaries for payment status, CMS determines LTI status at a point prior to the payment year. For a given payment year, the beneficiary LTI status will be updated during the initial, mid-year, and final reconciliation risk adjustment factor updates. Plans should notify CMS of any discrepancies between LTI status as reported on the MMR and place of residence for the beneficiary.

Final Reconciliation of Institutional Status for Part C Risk Adjusted Payments. Plans have 45 calendar days after final reconciliation for a payment year to notify CMS of discrepancies in LTI status on the MMR.

Exhibit 1. Relative Factors for CMS-HSS ESRD Model

Table 1-1. Relative Factors for CMS-HCC ESRD Dialysis Model[1]

Risk factors are relative to average total Medicare expenditures per capita for dialysis patients.[2]

Variable	Disease Group	Relative Factors
Age/Sex Groups		
Female		
0-34 Years		0.699
35-44 Years		0.699
45-54 Years		0.715
55-59 Years		0.746
60-64 Years		0.749
65-69 Years		0.813
70-74 Years		0.813
75-79 Years		0.831
80-84 Years		0.850
85 Years or Over		0.872
Male		
0-34 Years		0.614
35-44 Years		0.650
45-54 Years		0.675
55-59 Years		0.699
60-64 Years		0.722
65-69 Years		0.776
70-74 Years		0.776
75-79 Years		0.790
80-84 Years		0.790
85 Years or Over		0.826
Disease Group Factors		
HCC1	HIV/AIDS	0.235
HCC2	Septicemia/Shock	0.073
HCC5	Opportunistic Infections	0.051
HCC7	Metastatic Cancer and Acute Leukemia	0.189
HCC8	Lung, Upper Digestive Tract, and Other Severe Cancers	0.189
HCC9	Lymphatic, Head and Neck, Brain, and Other Major Cancers	0.160
HCC10	Breast, Prostate, Colorectal and Other Cancers and Tumors	0.058
HCC15	Diabetes with Renal or Peripheral Circulatory Manifestation	0.080
HCC16	Diabetes with Neurologic or Other Specified Manifestation	0.080
HCC17	Diabetes with Acute Complications	0.080
HCC18	Diabetes with Ophthalmologic or Unspecified Manifestation	0.080
HCC19	Diabetes without Complication	0.079
HCC21	Protein-Calorie Malnutrition	0.050
HCC25	End-Stage Liver Disease	0.259
HCC26	Cirrhosis of Liver	0.095
HCC27	Chronic Hepatitis	0.051
HCC31	Intestinal Obstruction/Perforation	0.057
HCC32	Pancreatic Disease	0.084

HCC33	Inflammatory Bowel Disease	0.088
HCC37	Bone/Joint/Muscle Infections/Necrosis	0.115
HCC38	Disease	0.077
HCC44	Severe Hematological Disorders[3]	0.000
HCC45	Disorders of Immunity	0.113
HCC51	Drug/Alcohol Psychosis[4]	0.000
HCC52	Drug/Alcohol Dependence[4]	0.000
HCC54	Schizophrenia	0.179
HCC55	Major Depressive, Bipolar, and Paranoid Disorders	0.123
HCC67	Quadriplegia, Other Extensive Paralysis	0.229
HCC68	Paraplegia	0.229
HCC69	Spinal Cord Disorders/Injuries	0.148
HCC70	Muscular Dystrophy[3]	0.000
HCC71	Polyneuropathy	0.056
HCC72	Multiple Sclerosis	0.087
HCC73	Parkinson's and Huntington's Diseases	0.038
HCC74	Seizure Disorders and Convulsions	0.094
HCC75	Coma, Brain Compression/Anoxic Damage	0.201
HCC77	Respirator Dependence/Tracheostomy Status	0.349
HCC78	Respiratory Arrest	0.156
HCC79	Cardio-Respiratory Failure and Shock	0.088
HCC80	Congestive Heart Failure	0.086
HCC81	Acute Myocardial Infarction	0.107
HCC82	Unstable Angina and Other Acute Ischemic Heart Disease	0.107
HCC83	Angina Pectoris/Old Myocardial Infarction	0.027
HCC92	Specified Heart Arrhythmias	0.061
HCC95	Cerebral Hemorrhage	0.058
HCC96	Ischemic or Unspecified Stroke	0.058
HCC100	Hemiplegia/Hemiparesis	0.088
HCC101	Cerebral Palsy and Other Paralytic Syndromes	0.040
HCC104	Vascular Disease with Complications	0.169
HCC105	Vascular Disease	0.059
HCC107	Cystic Fibrosis	0.078
HCC108	Chronic Obstructive Pulmonary Disease	0.078
HCC111	Aspiration and Specified Bacterial Pneumonias	0.123
HCC112	Pneumococcal Pneumonia, Emphysema, Lung Abscess	0.051
HCC119	Proliferative Diabetic Retinopathy and Vitreous Hemorrhage[3]	0.000
HCC130	Dialysis Status[7]	0.000
HCC131	Renal Failure[7]	0.000
HCC132	Nephritis[7]	0.000
HCC148	Decubitus Ulcer of Skin	0.182
HCC149	Chronic Ulcer of Skin, Except Decubitus	0.110
HCC150	Extensive Third-Degree Burns[5]	0.088
HCC154	Severe Head Injury	0.201
HCC155	Major Head Injury	0.022
HCC157	Vertebral Fractures without Spinal Cord Injury	0.035
HCC158	Hip Fracture/Dislocation	0.054
HCC161	Traumatic Amputation	0.073

HCC164	Major Complications of Medical Care and Trauma[3]	0.000
HCC174	Major Organ Transplant Status	0.199
HCC176	Artificial Openings for Feeding or Elimination	0.062
HCC177	Amputation Status, Lower Limb/Amputation Complications	0.073
Medicaid Interactions With Age and Sex		
Medicaid_Female_Disabled		0.051
Medicaid_Female_Aged		0.031
Medicaid_Male_Disabled		0.043
Medicaid_Male_Aged		0.069
Originally Disabled Interactions With Sex		
Female, 65+, Originally Entitled due to ESRD/ w or wo Disability		-0.054
Male, 65+, Originally Entitled due to ESRD/ w or wo Disability		-0.047
Female, 65+, Originally Entitled due to Disability (non-ESRD)		0.056
Male, 65+, Originally Entitled due to Disability (non-ESRD)		0.032
Disabled/Disease Interactions		
D_HCC5	Disabled_Opportunistic Infections	0.081
D_HCC44	Disabled_Severe Hematological Disorders	0.050
D_HCC45	Disabled_Disorders of Immunity[4]	0.000
D_HCC51	Disabled_Drug/Alcohol Psychosis	0.190
D_HCC52	Disabled_Drug/Alcohol Dependence	0.190
D_HCC107	Disabled_Cystic Fibrosis[5]	0.149
Disease Interactions[6]		
INT1	DM_CHF	0.020
INT2	DM_CVD	0.051
INT3	CHF_COPD[4]	0.000
INT4	COPD_CVD_CAD[3]	0.000

[1]This model is used for those enrollees who have a full year of base year claims data

[2]Mean Year 2003 Total Expenditures=$60,471. Mean is over all dialysis patients including those with Medicare as secondary payer.

[3]Coefficients of variables with unconstrained coefficients less than 0 were constrained to equal 0.

[4]Coefficients of variables with coefficients with t-statistics < 1.0 were constrained to equal 0.

[5]Coefficient was constrained to equal coefficient from the CMS-HCC Aged-Disabled Community Model (2002-2003 Calibration).

[6]The interaction DM_CHF_RF (where RF = renal failure) is the same in this population as DM_CHF because all sample members have renal failure. Hence, this three-way interaction is not included.

[7]These coefficients are set to zero because beneficiaries on whom the model is calibrated have renal failure and are in dialysis status.

Table 1-2. CMS-HCC Dialysis Model for New Enrollees[1]

Variable	Relative Factors
Age/Sex Groups	
Female	
0-34 Years	0.912
35-44 Years	0.943
45-54 Years	0.974
55-59 Years	1.020
60-64 Years	1.020
65-69 Years	1.134
70-74 Years	1.162
75-79 Years	1.218
80-84 Years	1.232
85 Years or Over	1.236
Male	
0-34 Years	0.754
35-44 Years	0.894
45-54 Years	0.911
55-59 Years	0.959
60-64 Years	0.977
65-69 Years	1.090
70-74 Years	1.118
75-79 Years	1.151
80-84 Years	1.151
85 Years or Over	1.191
Medicaid Interactions With Age and Sex	
Medicaid_Female_Disabled	0.100
Medicaid_Female_Aged	0.069
Medicaid_Male_Disabled	0.087
Medicaid_Male_Aged	0.114
Originally Disabled Interactions With Sex	
Originally Disabled_Female, Age Less than 65	0.237
Originally Disabled_Female	0.237
Originally Disabled_Male, Age Less than 65	0.211
Originally Disabled_Male	0.211

Notes:

[1]New enrollees are those enrollees who do not have a full year of base year claims data.

Mean Year 2003 Total Expenditures=$60,471. Mean is over all dialysis patients including those with Medicare as secondary payer.

Table 1-3. Transplant Calculations

Under the CMS-HCC risk adjustment system of payments for ESRD patients, payment for transplants is carved out of the payments for all ESRD patients. The payment factor for a transplant is based on the average Medicare costs for transplant admissions and the two months subsequent to discharge. When CMS is notified of a transplant, three monthly payments are made. Instead of a dialysis risk factor being the basis for payment in those months, a transplant factor is used and applied to the dialysis rate book. After the three months, payment is made at the functioning graft rate or at the dialysis rate, as appropriate.

Transplant Calculations

	Kidney Only Dollars	**Kidney Plus Pancreas Dollars**	**Kidney Only Relative Factor**	**Kidney Plus Pancreas Relative Factor**
Month 1	$32,558	$55,310	6.46	10.98
Month 2	$5,106	$7,434	1.01	1.48
Month 3	$5,106	$7,434	1.01	1.48
Total	$42,770	$70,178		

Note: To compute the relative factors, the national mean of annual dialysis patient costs was converted to a monthly amount and the transplant monthly costs were divided by this number.

Mean annual dialysis costs: $60,471
Costs per month: $5,039

Table 1-4.

CMS-HCC Community and Institutional Models for Functioning Graft[1]

Additional payment factors for functioning graft status are at bottom of table.

Variable	Disease Group	Community Relative Factor	Constraints[2]	Institutional Relative Factor	Constraints[2]
Age/Sex Groups					
Female					
0-34 Years		0.223		1.240	
35-44 Years		0.224		0.879	
45-54 Years		0.304		0.879	
55-59 Years		0.370		0.879	
60-64 Years		0.422		0.879	
65-69 Years		0.298		0.945	
70-74 Years		0.371		0.885	
75-79 Years		0.468		0.822	
80-84 Years		0.546		0.757	
85-89 Years		0.637		0.694	
90-94 Years		0.788		0.617	
95 Years or Over		0.783		0.482	
Male					
0-34 Years		0.107		1.059	
35-44 Years		0.167		0.822	
45-54 Years		0.197		0.842	
55-59 Years		0.297		0.916	
60-64 Years		0.401		0.970	
65-69 Years		0.330		1.140	
70-74 Years		0.416		1.093	
75-79 Years		0.520		1.093	
80-84 Years		0.617		1.056	
85-89 Years		0.744		1.033	
90-94 Years		0.830		0.895	
95 Years or Over		0.960		0.775	
Medicaid and Originally Disabled Interactions With Age and Sex[5]					
Medicaid_Female_Disabled		0.137		0.000	
Medicaid_Female_Aged		0.177		0.000	
Medicaid_Male_Disabled		0.090		0.000	
Medicaid_Male_Aged		0.202		0.000	
Female, 65+, originally entitled due to disability		0.232		0.000	
Male, 65+, originally entitled due to disability		0.181		0.000	
Disease Group Factors					
HCC1	HIV/AIDS	0.933		0.735	
HCC2	Septicemia/Shock	0.887		0.762	
HCC5	Opportunistic Infections	0.410		0.476	
HCC7	Metastatic Cancer and Acute Leukemia	1.648		0.568	
HCC8	Lung, Upper Digestive Tract, and Other Severe Cancers	1.648		0.568	
HCC9	Lymphatic, Head and Neck, Brain, and Other Major Cancers	0.771		0.402	

HCC10	Breast, Prostate, Colorectal and Other Cancers and Tumors	0.258		0.241	
HCC15	Diabetes with Renal or Peripheral Circulatory Manifestation	0.608		0.466	
HCC16	Diabetes with Neurologic or Other Specified Manifestation	0.452		0.466	
HCC17	Diabetes with Acute Complications	0.364		0.466	
HCC18	Diabetes with Ophthalmologic or Unspecified Manifestation	0.265		0.466	
HCC19	Diabetes without Complication	0.181		0.257	
HCC21	Protein-Calorie Malnutrition	0.820		0.395	
HCC25	End-Stage Liver Disease	0.996		0.768	
HCC26	Cirrhosis of Liver	0.519		0.363	
HCC27	Chronic Hepatitis	0.303		0.363	
HCC31	Intestinal Obstruction/Perforation	0.347		0.349	
HCC32	Pancreatic Disease	0.383		0.277	
HCC33	Inflammatory Bowel Disease	0.270		0.263	
HCC37	Bone/Joint/Muscle Infections/Necrosis	0.550		0.482	
HCC38	Rheumatoid Arthritis and Inflammatory Connective Tissue Disease	0.363		0.233	
HCC44	Severe Hematological Disorders	1.136		0.477	
HCC45	Disorders of Immunity	0.841		0.443	
HCC51	Drug/Alcohol Psychosis	0.250		0.000	
HCC52	Drug/Alcohol Dependence	0.250		0.000	
HCC54	Schizophrenia	0.515		0.347	
HCC55	Major Depressive, Bipolar, and Paranoid Disorders	0.370		0.308	
HCC67	Quadriplegia, Other Extensive Paralysis	0.961		0.337	
HCC68	Paraplegia	0.961		0.291	
HCC69	Spinal Cord Disorders/Injuries	0.511		0.152	
HCC70	Muscular Dystrophy	0.466		0.000	
HCC71	Polyneuropathy	0.324		0.253	
HCC72	Multiple Sclerosis	0.472		0.174	
HCC73	Parkinson's and Huntington's Diseases	0.547		0.089	
HCC74	Seizure Disorders and Convulsions	0.280		0.165	
HCC75	Coma, Brain Compression/Anoxic Damage	0.446	C1	0.000	
HCC77	Respirator Dependence/Tracheostomy Status	1.860		1.360	

HCC78	Respiratory Arrest	1.448		0.984	
HCC79	Cardio-Respiratory Failure and Shock	0.629		0.464	
HCC80	Congestive Heart Failure	0.395		0.231	
HCC81	Acute Myocardial Infarction	0.349		0.474	
HCC82	Unstable Angina and Other Acute Ischemic Heart Disease	0.332		0.474	
HCC83	Angina Pectoris/Old Myocardial Infarction	0.231		0.296	
HCC92	Specified Heart Arrhythmias	0.295		0.198	
HCC95	Cerebral Hemorrhage	0.366		0.175	
HCC96	Ischemic or Unspecified Stroke	0.303		0.175	
HCC100	Hemiplegia/Hemiparesis	0.410		0.065	
HCC101	Cerebral Palsy and Other Paralytic Syndromes	0.212		0.000	
HCC104	Vascular Disease with Complications	0.645		0.495	
HCC105	Vascular Disease	0.324		0.164	
HCC107	Cystic Fibrosis	0.398		0.327	
HCC108	Chronic Obstructive Pulmonary Disease	0.398		0.327	
HCC111	Aspiration and Specified Bacterial Pneumonias	0.761		0.644	
HCC112	Pneumococcal Pneumonia, Emphysema, Lung Abscess	0.233		0.188	
HCC119	Proliferative Diabetic Retinopathy and Vitreous Hemorrhage	0.278		0.527	
HCC130	Dialysis Status[3]	0.000		0.000	
HCC131	Renal Failure[3]	0.000		0.000	
HCC132	Nephritis	0.182		0.290	
HCC148	Decubitus Ulcer of Skin	1.167		0.474	
HCC149	Chronic Ulcer of Skin, Except Decubitus	0.463		0.239	
HCC150	Extensive Third-Degree Burns	0.818		0.000	
HCC154	Severe Head Injury	0.446	C1	0.000	
HCC155	Major Head Injury	0.182		0.000	
HCC157	Vertebral Fractures without Spinal Cord Injury	0.501		0.109	
HCC158	Hip Fracture/Dislocation	0.450		0.000	
HCC161	Traumatic Amputation	0.736		0.224	C1
HCC164	Major Complications of Medical Care and Trauma	0.299		0.219	
HCC174	Major Organ Transplant Status	0.362		0.362	
HCC176	Artificial Openings for Feeding or Elimination	0.758		0.843	
HCC177	Amputation Status, Lower Limb/Amputation Complications	0.653		0.224	C1

Disabled/Disease Interactions					
D_HCC5	Disabled_Opportunistic Infections	0.941		0.280	
D_HCC44	Disabled_Severe Hematological Disorders	0.551		0.419	
D_HCC51	Disabled_Drug/Alcohol Psychosis	0.801		0.425	
D_HCC52	Disabled_Drug/Alcohol Dependence	0.356		0.425	
D_HCC107	Disabled_Cystic Fibrosis	1.391		0.000	
Disease Interactions					
INT1	DM_CHF[4]	0.204		0.088	
INT2	DM_CVD	0.149		0.026	
INT3	CHF_COPD	0.216		0.194	
INT4	COPD_CVD_CAD	0.174		0.042	
INT5	RF_CHF[4]	0.248		0.000	
INT6	RF_CHF_DM[4]	0.664		0.203	
Graft Factors[6]					
Aged <65, with duration since transplant of 4-9 months		3.391		3.391	
Aged 65+, with duration since transplant of 4-9 months		3.391		3.391	
Aged <65, with duration since transplant of 10 months or more		1.152		1.152	
Aged 65+, with duration since transplant of 10 months or more		1.323		1.323	

[1]To determine payments for persons with functioning grafts, the computed risk score should be applied to the appropriate cell in the CMS-HCC county risk ratebook for the aged and disabled. For payment in any month, duration is measured from the month of transplant to the first day of that month. All coefficients except for the graft factors and HCC174 were constrained to the values estimates for the 2003 Calibration CMS-HCC Aged-Disabled Community Model.
[2] _____ means coefficients of HCCs are constrained to be equal, and C1 denotes a non-continguous constraint. For the community model C1=.446; for the institutional model C1=.224.

[3]Kidney failure and Dialysis status HCCs are not captured in the model for functioning graft beneficiaries. The cost of treating their transplanted kidney is captured instead in the post-graft factors. Should a post-graft patient have failure again they would return to dialysis status and be paid under the dialysis model.
[4]Diseases in interactions are:

DM is diabetes mellitus (HCCs 15-19)
CHF is congestive heart failure (HCC 80)
COPD is chronic obstructive pulmonary disease (HCC 108)
CVD is cerebrovascular disease (HCCs 95,96,100, and 101)
RF is renal failure (HCC 131)

Beneficiaries with the three-way interaction RF*CHF*DM are excluded from the two-way interactions DM*CHF and RF*CHF. Thus, the three-way interaction term RF*CHF*DM is not additive to the two-way interaction terms DM*CHF and RF*CHF. Rather, it is hierarchical to, and excludes these interaction terms. A beneficiary with all three conditions is not "credited" with the two-way interactions. All other interaction terms are additive.

[5]These HCCs are not present in the institutional model.
[6]The graft factors are additive, similar to any other factors in the CMS-HCC model. The factor is higher during the months immediately after transplant to accoun for a high level of monitoring and services.

Table 1-5. List Hierarchies for the CMS-HCC Model

DRAFT DISEASE HIERARCHIES		
Hierarchical Condition Category (HCC)	**If the Disease Group is Listed in This Column…**	**…Then Drop the Associated Disease Group(s) Listed in This Column**
	Disease Group Label	
5	Opportunistic Infections	112
7	Metastatic Cancer and Acute Leukemia	8,9,10
8	Lung, Upper Digestive Tract, and Other Severe Cancers	9, 10
9	Lymphatic, Head and Neck, Brain and Other Major Cancers	10
15	Diabetes with Renal Manifestations or Peripheral Circulatory Manifestation	16,17,18,19
16	Diabetes with Neurologic or Other Specified Manifestation	17,18,19
17	Diabetes with Acute Complications	18,19
18	Diabetes with Ophthalmologic or Unspecified Manifestations	19
25	End-Stage Liver Disease	26,27
26	Cirrhosis of Liver	27
51	Drug/Alcohol Psychosis	52
54	Schizophrenia	55
67	Quadriplegia/Other Extensive Paralysis	68,69,100,101,157
68	Paraplegia	69,100,101,157
69	Spinal Cord Disorders/Injuries	157
77	Respirator Dependence/ Tracheostomy Status	78,79
78	Respiratory Arrest	79
81	Acute Myocardial Infarction	82,83
82	Unstable Angina and Other Acute Ischemic Heart Disease	83
95	Cerebral Hemorrhage	96
100	Hemiplegia/Hemiparesis	101
104	Vascular Disease with Complications	105,149
107	Cystic Fibrosis	108
111	Aspiration and Specified Bacterial Pneumonias	112
130	Dialysis Status	131,132
131	Renal Failure	132
148	Decubitus Ulcer of Skin	149
154	Severe Head Injury	75,155
161	Traumatic Amputation	177

How Payments are Made with a Disease Hierarchy -- EXAMPLE: If a beneficiary triggers HCCs 148 (Decubitus Ulcer of the Skin) and 149 (Chronic Ulcer of Skin, Except Decubitus), then HCC 149 will be dropped. In other words, payment will always be associated with the HCC in column 1 if a HCC in column 3 also occurs during the same collection period. Therefore, the MA organization's payment will be based on HCC 148 rather than HCC 149.

February 22, 2008

NOTE TO: Medicare Advantage Organizations, Prescription Drug Plan Sponsors, and Other Interested Parties

SUBJECT: Advance Notice of Methodological Changes for Calendar Year (CY) 2009 for Medicare Advantage (MA) Capitation Rates and Part D Payment Policies

In accordance with Section 1853(b)(2) of the Social Security Act (the Act), we are notifying you of proposed changes in the MA capitation rate methodology and risk adjustment methodology applied under Part C of the Act for CY 2009. Preliminary estimates of the national per capita MA growth percentage and other MA payment methodology changes for CY 2009 are also discussed. For 2009, CMS will announce the MA capitation rates on the first Monday in April 2008, in accordance with the timetable established in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). This Advance Notice is published 45 days before that date.

Attachment I shows the preliminary estimates of the national per capita MA growth percentage component of the minimum percentage increase, which is a key factor is determining the MA capitation rates. Attachment II sets forth the changes in payment methodology for CY 2009 for original Medicare benefits. Attachment III set forth the changes in payment methodology for CY 2009 for Part D benefits. Attachment IV presents the preliminary CMS-HCC risk adjustment factors, and Attachment V presents the annual adjustments for 2009 to the Medicare Part D benefit parameters for the defined standard benefit.

Any changes to employer/union-only group waiver plan payment for 2009 will be issued in future guidance.

Comments or questions may be submitted electronically to the following address: AdvanceNotice2009@cms.hhs.gov. Comments or questions also may be mailed to:

Anne Hornsby
Centers for Medicare & Medicaid Services
7500 Security Boulevard
S3-16-16
Baltimore, Maryland 21244

In order to receive consideration prior to the April 7, 2008 release of the Announcement of Calendar Year (CY) 2009 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies, comments must be received by 6:00 PM EST on Friday, March 7, 2008.

/ s /
Abby L. Block
Director
Center for Beneficiary Choices

/ s /
Paul Spitalnic, A.S.A., M.A.A.A.
Director
Parts C & D Actuarial Group
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Attachments

2009 ADVANCE NOTICE
TABLE OF CONTENTS

Attachment I. Preliminary Estimate of the National Per Capita Growth Percentage for Calendar Year 2009

Section 1853(c)(1) of the Social Security Act (the Act) provides that, for years when CMS is "rebasing" the amount representing the actuarial value of 100 percent of costs under original fee-for-service (FFS) Medicare, MA capitation rates will be based on the greater of 100 percent of FFS costs or an increase which is the greater of two percent or the national per capita MA growth percentage, with no adjustment to this percentage for over- or under-estimates for years before 2004. CMS is rebasing the FFS rates for 2009. See section J, Attachment II for a discussion of the proposed methodology for adjusting the FFS rates to reflect DOD and VA costs, per Section 1853(c)(1)(D)(iii) of the Act.

The current estimate of the change in the national per capita MA growth percentage for aged and disabled enrollees combined in CY 2009 is 4.8 percent. This estimate reflects an underlying trend change for CY 2009 in per capita costs of 3.4 percent and adjustments to the estimates for CY 2008, CY 2007, CY 2006, CY 2005, and CY 2004 aged and disabled MA growth percentages of 2.4 percent, –0.9 percent, 0.1 percent, –0.3 percent, and 0.2 percent, respectively. Our new estimates for these years are lower than the estimates actually used in calculating the CY 2008 capitation rate book for CYs 2005 and 2007 and higher for CYs 2004, 2006, and 2008 than was published April 2, 2007, and are required by Section 1853(c)(6)(C) of the Act.

The following table summarizes the estimates for the change in the national per capita MA growth percentage.

Table I-1. National Per Capita MA Growth Percentage

	Aged	Disabled	ESRD	Aged+Disabled
2009 Trend Change	3.4%	3.4%	1.6%	3.4%
Revision to CY 2008 Estimate	1.8%	5.7%	2.9%	2.4%
Revision to CY 2007 Estimate	–1.1%	0.2%	–3.2%	–0.9%
Revision to CY 2006 Estimate	0.3%	–1.3%	–5.1%	0.1%
Revision to CY 2005 Estimate	–0.2%	–1.2%	–1.8%	–0.3%
Revision to CY 2004 Estimate	0.2%	0.2%	–0.2%	0.2%
Total Change	4.5%	7.0%	–5.9%	4.8%

Notes: (1) The total percentage change is multiplicative, not additive and may not exactly match due to rounding.
(2) Starting in 2008, the trend change for ESRD reflects an estimate of the trend for dialysis-only beneficiaries.

These estimates are preliminary and could change before the final rates are announced on April 7, 2008 in the Announcement of Calendar Year (CY) 2009 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies. Further details on the derivation of the national per capita MA growth percentage will also be presented in the Announcement.

Attachment II. Changes in the Payment Methodology for Original Medicare Benefits for CY 2009

Section A. Recalibration of CMS-HCC Model

In 2009, CMS will implement an updated version of the aged-disabled CMS-HCC risk adjustment model, including community, institutional, and new enrollee segments of the model. Fee-for-service (FFS) claims data for the years 2004 and 2005 are used in the recalibration of the model. Disease groupings are the same as in past models; however, the factors are different.

When CMS recalibrates the CMS-HCC risk adjustment model with more recent data, an updated coefficient is calculated for each diagnosis group and demographic characteristic in the model (e.g., age, sex), which represents the marginal (additional) cost of that diagnosis group or demographic characteristic in predicting FFS per capita costs. These coefficients are then converted to relative cost factors by dividing each by the per capita cost predicted for a specific year. For the CY 2009 recalibration, CMS used predicted per capita costs for 2007. The relative factors are used to calculate risk scores for individual beneficiaries, which will average 1.0 in the denominator year.

The current CMS-HCC model is calibrated on 2002 and 2003 data, and recalibrating the model on more current data results in more appropriate relative weights for each HCC because they reflect more recent coding and expenditure patterns in FFS Medicare. In addition, recalibrating with more recent data adjusts the model for increases in predicted FFS expenditures between calibration years. Recalibration of the CMS-HCC model can result in changes in relative risk scores for individual beneficiaries and for average plan risk scores, depending on individual beneficiaries' combinations of diagnoses.

One change that was made to the model was to remove the constraints on two HCCs: Metastatic Cancer (HCC 7) and Severe Cancers (HCC 8). In the version of the model currently in use, the coefficients of HCC 7 (Metastatic Cancer) and HCC 8 (Severe Cancers) were constrained to be equal. In the past, these HCCs were constrained because there were concerns regarding the completeness of the coding for Metastatic Cancer, specifically that secondary (metastatic) cancers were sometimes incorrectly coded as primary cancers.

With the constraint removed, the estimated incremental cost of Metastatic Cancer (HCC 7) is now higher than that for Severe Cancers (HCC 8). CMS determined that there was significant clinical and expected treatment cost difference between metastatic and localized cancer (e.g., chemotherapy for metastatic cancer). Although current coding may be imperfect, there are specific diagnostic tests and indications for metastatic versus localized cancers, and allowing a payment differential will provide incentives for accurate coding. More importantly, a higher incremental payment for beneficiaries with metastatic cancer will provide for more accurate payment to Medicare Advantage plans that enroll such beneficiaries.

In Attachment IV of this Notice, we provide the relative cost factors for each HCC for each segment of the aged-disabled model.

Section B. Frailty Adjustment

B1. Frailty Adjustment Factors

CMS has recalibrated the frailty factors for CY 2009. The purpose of frailty adjustment is to predict the Medicare expenditures of community populations with functional impairments that are unexplained by the CMS-HCC risk adjustment model. Whenever CMS recalibrates the CMS-HCC risk adjustment model, the amount of unexplained Medicare expenditures can change. Thus, it is necessary to simultaneously recalibrate the frailty factors. Table II-1 presents the preliminary recalibrated frailty factors for CY 2009.

Table II-1. Preliminary Recalibrated Frailty Factors for CY 2009

ADL	2008 Factors (Non-Medicaid)	2009 Recalibrated Factors (Non-Medicaid)	2008 Factors (Medicaid)	2009 Recalibrated Factors (Medicaid)
0	–0.089	–0.093	–0.183	–0.180
1-2	+0.110	+0.112	+0.024	+0.035
3-4	+0.200	+0.201	+0.132	+0.155
5-6	+0.377	+0.381	+0.188	+0.200

CMS is not proposing to change the way we calculate the contract-level frailty score; we will use the results from each contract's 2008 HOS survey to calculate each contract-level frailty score for CY 2009.

B2. Frailty Adjustment Transition for PACE organizations

Frailty adjustment factors will be applied to payment to PACE organizations using the transition schedule published in the 2008 Announcement (published April 2, 2007). PACE frailty scores for payment year 2009 will be calculated at a blend of 70% of the frailty factors in use prior to 2008 and 30% of the recalibrated frailty factors implemented in 2009. The full transition schedule is as follows:

- In 2008 (year 1): 90% of the pre-2008 frailty factors and 10% of the 2008 frailty factors.
- In 2009 (year 2): 70% of the pre-2008 frailty factors and 30% of the 2009 frailty factors.
- In 2010 (year 3): 50% of the pre-2008 frailty factors and 50% of the most recently calibrated frailty factors.
- In 2011 (year 4): 25% of the pre-2008 frailty factors and 75% of the most recently calibrated frailty factors.
- In 2012 (year 5): 100% of the most recently calibrated frailty factors.

B3. Frailty Adjustment Transition for Certain Demonstrations

Frailty adjustment factors will be applied to payment to the following MA plan types using the phase-out schedule published in the 2008 Announcement (published April 2, 2007): Social Health Maintenance Organizations (S/HMOs), Minnesota Senior Health Options (MSHO)/ Minnesota Disability Health Options (MnDHO), Wisconsin Partnership Program (WPP) and Massachusetts Senior Care Options (SCO) plans.

The full phase out schedule is as follows:

- In 2008 (year 1): 75% of the pre-2008 frailty factors
- In 2009 (year 2) 50% of the pre-2008 frailty factors
- In 2010 (year 3) 25% of the pre-2008 frailty factors
- In 2011, 0% of the pre-2008 frailty factors

Section C. Normalization Factors

When we calibrate a risk adjustment model and normalize the risk scores to 1.0, we produce a fixed set of dollar expenditures and coefficients appropriate to the population and data for that calibration year. When the model with fixed coefficients is used to predict expenditures for other years, predictions for prior years are lower and predictions for succeeding years are higher than for the calibration year. Because average predicted fee-for-service (FFS) expenditures increase after the model calibration year due to coding and population changes, CMS applies a normalization factor to adjust beneficiaries' risk scores so that the average risk score is 1.0 in subsequent years.

The normalization factor is derived by first using the model to predict risk scores for the FFS population over a number of years. Next, we trend the risk scores to determine the annual percent change in the risk score. This amount is then compounded by the number of years between the model denominator year and the payment year to produce the normalization factor.

Starting in 2009, CMS will use a standard of five years of data in the normalization trend. Each year, CMS will drop the earliest year and add a new year of risk scores to the trend data to create the five-year dataset. By using a standard number of years, CMS intends to calculate risk score trends based on recent trends in coding, while maintaining stability in the year-to-year trends used. For the CY 2009 recalibration, trends calculated for the aged-disabled CMS-HCC, ESRD Dialysis, and the RxHCC models are developed on risk scores calculated for 2003-2007.

Below are the preliminary normalization factors for each model. The final normalization factors will be included in the April 7, 2008 Announcement.

C1. Normalization Factor for the CMS-HCC Model

The preliminary 2009 normalization factor for the aged-disabled model is 1.030. The 2009 factor will adjust for two years of FFS risk score growth, i.e., from the denominator year of 2007 to the payment year of 2009. This 2009 normalization factor of 1.030 is lower than the 2008 factor of 1.04 because the 2008 factor adjusted for three years of FFS risk score growth (2005-2008).

C2. Normalization Factor for the ESRD Dialysis Model

The preliminary 2009 normalization factor for the ESRD dialysis model is 1.019. The 2009 factor will adjust for six years of risk score growth, i.e., from the denominator year of 2003 to the payment year of 2009, and will be applied at a phased-in percentage of 50%. (As discussed in last year's Advance Notice, the ESRD Dialysis normalization factor is being applied on the same transition schedule as is the transition of the ESRD State ratebook; see Section G2.)

C3. Normalization Factor for the RxHCC Model

The preliminary 2009 normalization factor for the RxHCC model is 1.085. This normalization factor reflects a trend calculated on five years of risk score data (2003-2007). We calculated the RxHCC normalization factor by taking the actual 2007 average Part D risk score for all potential Part D plan enrollees and the annual trend applied for the two years between the calculation of actual average Part D risk score and the payment year (2007-2009).

C4. Normalization Factor for Functioning Graft Enrollees' Risk Scores

CMS applies the normalization factor for the aged-disabled CMS-HCC model to Functioning Graft enrollees' risk scores because all but one of the coefficients for the Functioning Graft model are constrained to equal the coefficients of the CMS-HCC model, and because CMS pays for Functioning Graft enrollees using the county ratebook. However, because CMS recalibrates the functioning graft coefficients along with the dialysis model, the functioning graft coefficients still have a denominator of 2005 (instead of the 2007 denominator that the CMS-HCC community and institutional coefficients will have in 2009). For that reason, CMS will add an additional year to the 2008 CMS-HCC normalization factor; the preliminary 2009 normalization factor to be applied to the 2009 risk scores of enrollees in functioning graft status is 1.058.

Section D. Budget Neutrality

From 2003 through 2006, CMS implemented risk adjusted payments in a budget neutral manner by applying to the risk rates 100 percent of the Budget Neutrality (BN) factor, which is calculated as the estimated difference between payments to MA organizations at 100 percent of the demographic rates and payments at 100 percent of the risk rates. As previously announced by CMS on February 17, 2006 in the Advance Notice for 2007, and as summarized below, the phase-out of budget-neutral risk adjusted payments began in 2007 and will be completed by 2011, when plans will receive no budget neutrality payment adjustment. For 2009, 25 percent of the BN factor will be applied to the risk rates.

Since CMS cannot calculate the BN factor until the final capitation rates are determined, the factor will be announced in the April 7, 2008 Rate Announcement.

Phase-out Schedule for Budget Neutral Risk Adjusted Payments:

The percentage of the budget neutrality factor that is applied to the risk rates is:

- 2007: 55%
- 2008: 40%
- 2009: 25%
- 2010: 5%
- 2011: 0%

Section E. Adjustment for MA Coding Intensity

Background

As promulgated by the Deficit Reduction Act (DRA), Section 1853(k)(2)(B)(iv)(III) requires CMS to reflect in its risk adjustment for Part C payment "differences in coding patterns between Medicare Advantage plans and providers under part A and B to the extent that the Secretary has identified such differences." The DRA further instructs that results of the analysis will be "incorporated into the risk scores only for 2008, 2009, and 2010." In order to comply with this section of the DRA, CMS has studied the changes in MA and FFS risk scores, the differences between those changes, and the coding patterns behind these changes.

From our research for the 2008 payment year, CMS found that MA risk scores increased approximately twice as much as FFS risk scores did for our study population between 2004 and 2006. There are a number of key reasons why risk scores in the MA and FFS sectors may rise at different rates. The composition of enrollment in each sector can have an effect on the change in the average risk score. Initially, some MA plans may have had difficulty gathering and reporting diagnosis codes as completely as FFS, so part of the differential risk score growth could be due to "catching up" to FFS. MA plans may be finding and diagnosing disease at a higher rate than FFS providers. Or, it is possible that beneficiaries enrolled in MA plans may be getting sicker faster than beneficiaries in FFS.

Our preliminary research on coding patterns, which was conducted prior to the release of the 2008 Rate Announcement, was unable to clarify enough about the coding pattern differences that result in MA and FFS risk score differences. Therefore, we did not make an adjustment for coding patterns differences in payment year 2008. We stated that we would continue to study this issue, with particular focus on the plans that have experienced significant increases in risk scores, in an effort to determine what the appropriate adjustment might be for 2009 and 2010.

CMS has continued its analysis of the coding patterns that result in differences in the MA and FFS risk scores. The findings below are based on diagnoses reported for payment years 2004-2006. CMS will update these figures by adding the (currently unavailable) 2007 risk scores to the analysis, prior to the publication of the Announcement on April 7, 2008.

Study Results

Composition effects: In order to analyze the gross difference between the change in FFS and MA risk scores, we examined the change in risk scores for three categories of enrollees: stayers, leavers, and joiners. **Stayers** were those enrollees who remained in the same sector (either FFS or MA) over the study period, **leavers** were those who left either the MA or FFS sector, either to go to the other sector or who died, and **joiners** where those who came into FFS or MA, either from the other sector or who were newly eligible to Medicare. We found that indeed some of the difference in the change in risk scores between MA and FFS was due to composition effects. Specifically, we found that:

- A significant portion of the beneficiaries who join MA are beneficiaries who are switching from FFS. In FFS, the vast majority of beneficiaries who join are newly-eligible to Medicare. The risk scores of beneficiaries who are newly eligible to Medicare

tend to be very low and these low risk scores depress FFS risk score growth relative to MA.
- Of the leavers, decedents (who have high risk scores) are a slightly larger fraction of FFS beneficiaries than of MA enrollees and, thus, the exit of high-risk score decedents restrains the year-to-year growth of average FFS risk scores by slightly more than it does MA scores.

Because most new enrollees in FFS are newly-eligible to Medicare and FFS is losing higher risk beneficiaries, overall average MA risk scores are pushed up at a faster rate than risk scores in FFS. Over the two-year period, approximately 50% of the difference between the MA and FFS sectors in the growth of risk scores is due to enrollment patterns and approximately 50% is due to the more rapid growth in risk scores for beneficiaries who stay in the same sector in consecutive years.

Focus on "stayers:" Focusing on the stayers allows us to examine differences in risk score changes that are not due to the changing composition of the enrolled population. In our analyses of the impact of coding patterns on stayers' risk scores, we did the following:
- We focused on two cohorts of stayers: those who were stayers in 2004-2005, and those who were stayers in 2005-2006. We weren't able to add the 2006-2007 cohort to the analysis prior to the release of the Advance Notice, but will do so before the release of the Announcement in April 2008.
- For each cohort, we defined MA stayers as those enrollees who were in the same contract in the July of each cohort year, as well as in each data collection year. For example, for the 2004-2005 stayer cohort, we include enrollees who were in the same contract in July 2004 and July 2005, and in all of 2003 and 2004. This criterion resulted in the exclusion of enrollees who would have been new enrollees in the data collection years, as well as those enrollees who switched contracts.
- We found that the overall risk scores of MA stayers increased by 0.032 more than those of FFS stayers over the two-year study period. As discussed below, we then broke down the change in aggregate risk scores into the changes in the disease component of the CMS-HCC risk score (the "disease score") versus the demographic component.

Focus on the disease score of stayers: The disease score is the HCC component of the risk score that plans (and FFS providers) affect by their reporting of diagnosis codes. Among stayers, we found that MA disease scores increased more quickly than FFS disease scores and that change in the disease component of the risk score accounted for approximately 90% of the difference in the change in MA versus FFS risk scores.

We found that, on average, disease scores for stayers in MA plans increased 20% faster than stayers in FFS over the two years in the study period. Specifically, FFS disease scores for stayers increased by 0.145 over the two-year period between 2004 and 2006, while the average disease score among beneficiaries who remained enrolled in a single MA contract for at least two data collection years increased by 0.174 over the same time period for a two-year difference of 0.029.

Dynamics behind changes in disease scores: CMS also analyzed the reasons why the change in MA and FFS disease scores differed among stayers. A significant portion of the difference in

disease score changes is attributable to the reporting of 26 HCCs (of the 70 HCCs in the model) that fall into one of seven hierarchies: diabetes (5 HCCs), cardiovascular disease (4 HCCs), coronary artery disease (3 HCCs), cancer (4 HCCs), quadriplegia and other central nervous system disease (4 HCCs), liver disease (3 HCCs), and dialysis/renal disease (3 HCCs). Approximately one-third of the difference in disease score change is due to increases in severity within these hierarchies, particularly within the diabetes hierarchy. The remaining difference results primarily from greater retention of reported diagnosis codes within certain hierarchies from one year to the next, especially the coronary artery disease, liver, diabetes, and renal hierarchies.

Variation among contracts: CMS research has also revealed a large amount of variation among MA contracts in the disease score change among stayers, and in the dynamics behind contracts' changing disease scores. As described above, on average, disease scores for MA stayers increased by 0.174 over the 2004-2006 study period, or 0.029 greater than the average increase of 0.145 for FFS stayers. We found that approximately 40% of the contracts in our study – those operating continuously during the 2004, 2005, and 2006 payment years – had changes in stayer disease scores that were less than the changes in FFS stayers' disease scores. Looking at enrollees, we found that 25% of the MA stayers in our analysis were enrolled in contracts where the difference between the two-year increase in stayers' disease scores and the FFS increase was at least twice the industry average.

Catch-up to FFS levels of coding: Although CMS cannot definitely determine whether "catch up" to FFS coding occurred or not, CMS recognizes that plans may have experienced some catch up, particularly during initial years of operation. In order to take any such catch up into account in our adjustment, we are proposing to:

- Adjust for MA coding only in 2009 and later (not adjust for previous year's coding patterns differences).
- Make an adjustment for contracts that have existed since at least 2005.
- Adjust risk scores for enrollees in contracts that have significant coding pattern differences from FFS.
- We are proposing to weight the impact of coding differences on disease scores in more recent years (when plans would have caught up to FFS) differently than coding patterns differences in earlier years.

More complete coding: We do not assume that the coding pattern differences that we found in our study are the result of improper coding. As discussed above, CMS understands that MA plans have made efforts to identify enrollees' conditions and may be coding more completely than FFS. However, because MA coding patterns differ from FFS coding patterns, the normalization factor (which is calculated based on FFS coding) does not currently adjust for these different coding patterns.

Impact of health status on risk score changes: As noted above, it is possible that beneficiaries enrolled in MA plans may be getting sicker faster than beneficiaries in FFS and this could be driving faster risk score growth for MA enrollees. Given the care coordination and disease management activities of MA plans, however, we do not find it reasonable to assume that MA stayers' underlying health status is getting worse at a faster rate than stayers in FFS. CMS analysis has found that MA mortality rates during the study period do not explain rising risk

scores; when applying expected mortality rates to the MA population, risk scores are expected to decrease, not increase. (In our analysis, we adjusted mortality rates for age, sex, county, Medicaid status, and institutional status.)

Calculation and Application of a Coding Intensity Measure

While our research supports the finding that MA plans have coding patterns that differ from FFS, we only have a few years to observe the differences in MA and FFS coding patterns. Therefore, for 2009 we propose to apply an MA coding adjustment factor as follows:

- Apply an adjustment to the risk scores of enrollees in those contracts for which the difference between the change in stayers' disease scores and the change in the FFS stayers' disease scores is two or more times the industry average; this threshold is approximately the same as a threshold at the plans enrolling the 25% of MA stayers with the largest change in disease score. We considered a few other options for applying an adjustment:
  - We considered applying an adjustment to those contracts above two standard deviations above the mean difference in disease score change, but the variation among plans is so great that such a threshold would eliminate most contracts.
  - We considered applying an adjustment on a contract-by-contract basis, but decided instead to apply a relatively high threshold in order to focus on the contracts that have experienced the largest changes in their stayers' disease scores, relative to FFS stayers' disease scores.

  CMS is requesting comments on the criteria for determining the threshold used to determine those contracts' payment to which we would apply an adjustment factor.

- Exclude those contracts that were not in existence until after 2005 (came into existence in 2006 or later). Contracts that existed in 2005 and earlier have at least two years of experience reporting to CMS stayers' diagnosis codes that have been used to calculate risk scores.

- Exclude contracts with under an average of 1,000 enrollees during 2005-2006. CMS considers these contracts too small to provide enough data to make reliable estimates of their coding patterns.

CMS proposes to calculate the 2009 MA coding adjustment as follows:

1. *Calculate the average annual difference between the increase in MA and FFS stayers' disease scores*. The average annual change in stayers' disease scores for a contract is calculated as the change in average disease score, averaged over as many cohorts of stayers that a contract has, e.g., CMS would calculate the annual average change in disease score for contracts that have been in existence since 2003 or earlier as the average of the change in disease score for the 2004-2005, 2005-2006, and the 2006-2007 stayer cohorts. We would then subtract the FFS annual average change in stayers' disease score to obtain the differential increase in stayers' disease scores. Changes in disease scores would be adjusted for age and survivor status.

2. *Calculate this average annual difference in the change in stayers' disease scores within that group of contracts that would fall above the threshold for applying the adjustment.* For example, we would calculate the annual average difference between MA and FFS stayers' disease score increase based only on MA data from those contracts where the difference between the change in stayers' disease scores and the change in FFS stayers' disease scores was two or more times the industry average. We would calculate the average disease score change for the set of contracts by weighting each contract's disease score change by the number of beneficiaries in each contract. We would then subtract the FFS disease score change from this weighted average. Based on the two years of data that were included in our analysis to date, the difference in the change in stayers' disease score for the contracts in this group and the FFS average is 0.050.

3. *Adjust the annual average difference in disease score change for the average percent of MA plan enrollees in the payment year who were enrolled in the same plan in the data collection year*. CMS currently estimates that this percentage of enrollees is approximately 75%, but will finalize the percentage after we add 2007 risk score data to our analysis. Based on our current estimate of 75% for the proportion of MA enrollees who are stayers, the adjustment for the contracts with the top 25% of MA enrollees with the largest difference between their change in disease score and the FFS change in disease score would be 0.0375. CMS (1) will update this calculation with 2007 data, (2) proposes to convert the adjustment amount into a percent change to risk scores in the Announcement, and (3) will consider whether to apply a straight average across the year-to-year differences, or whether to give more weight the disease score change differences in the most recent years. CMS requests comment on how we calculate the adjustment factor.

The average change in MA stayers' disease score, the change in MA stayers' disease scores for the top group of contracts, the FFS average change in disease score, the difference between MA and FFS, and the proportion of stayers we project to be enrolled in MA contracts in 2009, along with other calculations, will be updated in the Announcement.

Section F. Medicare as Secondary Payer (MSP) Adjustment Factor for Aged & Disabled Enrollees

MA capitation rates are calculated as if Medicare were always the primary payer; adjustments to the rates for situations in which Medicare is secondary are made as part of actual payment. The MSP adjuster applied to aged and disabled beneficiaries is calculated as the ratio of the actual Medicare spending for all MSP months for all MSP beneficiaries to the predicted Medicare spending for all MSP months for all MSP beneficiaries. Actual spending was calculated using the 2005 claims from the same analytic files used to recalibrate the CMS-HCC model. The predicted amount was calculated using the newly recalibrated CMS-HCC model. MSP status, which was determined using the working aged/working disabled status data in 2005, was used both for determining whom to exclude from the recalibration and for determining which beneficiaries to include in the MSP adjuster calculation.

CMS has recalculated the MSP adjuster for working aged and working disabled beneficiaries. The current adjuster of 0.215 will be revised to 0.174 in the 2009 payment year. There are two reasons for the change in the adjuster. First, CMS has refined the methodology used to calculate the adjuster. Previously, we prorated each beneficiary's MSP months using their total Medicare-paid costs during all months when beneficiary was enrolled. The new methodology includes costs only from those months in which beneficiaries have MSP status. Second, the average number of actual dollars calculated in the MSP months has decreased.

We are not proposing to change the formula for calculating the contract-level working aged/working disabled factor that is applied to each contract's total monthly payment for non-hospice/non-ESRD enrollees. We would simply change the value of the adjuster in that formula from 0.215 to 0.174.

Section G. ESRD Bidding and Payment

Pursuant to Section 1853(a)(1)(H) of the Act, CMS has the authority to determine whether to apply the competitive bidding methodology to ESRD enrollees, and must establish "separate rates of payment" with respect to ESRD beneficiaries.

G1. ESRD Bidding Policy

For 2009, CMS will continue the policy of excluding costs for ESRD enrollees in the plan A/B bid. The MA Bidding Instructions for CY 2009 will provide guidance on the option of adjusting A/B mandatory supplemental premiums to reflect the costs or savings for ESRD enrollees in the basic and supplemental benefits.

G2. Transition to New ESRD Payment

As announced in last year's Advance Notice, CMS continues the phase-in of the revised State capitation rates used to determine payments for enrollees in dialysis and transplant status. For payment year 2009, CMS will pay for ESRD dialysis and transplant enrollees using a blend of 50% of the old State ratebook (in use through 2007) and 50% of the revised State ratebook (implemented in 2008). The revised ESRD State ratebook reflects the dialysis-only trend. During the transition period, we will continue to trend forward the old and the revised State rates using the same dialysis-only growth trend. CMS is not rebasing the ESRD Dialysis State rates for 2009.

The full transition schedule is as follows. CMS payments for ESRD dialysis and transplant beneficiaries enrolled in MA plans will be:

- In 2008 (year 1): a blend of 75% old ratebook-based payments and 25% revised ratebook-based payments.
- In 2009 (year 2): a blend of 50% old ratebook-based payment and 50% revised ratebook-based payments.
- In 2010 (year 3): a blend of 25% old ratebook-based payments and 75% revised ratebook-based payments.
- In 2011: 100% of the revised ratebook.

In States where the revised dialysis rates are higher than the pre-2008 State rates, we will apply the revised ESRD State rates.

G3. ESRD Functioning Graft Payments

CMS pays for Functioning Graft enrollees with risk scores calculated using the aged-disabled CMS-HCC model coefficients, with the exception of the coefficient for HCC174 (Major Organ Transplant), which is not constrained, and the Graft factors, which are additive to the functioning graft risk scores. However, because CMS recalibrates the functioning graft coefficients along with the dialysis model, for 2009 CMS will continue to use the functioning graft coefficients published in the April 7, 2007 Advance Notice for 2008, when the ESRD dialysis model was last recalibrated. See Section C4 for a discussion of the normalization factors to be used with the functioning graft risk scores.

Section H. Regional Plan Stabilization Fund

Section 221 of the MMA added Section 1858(e) to the Act to create a new MA Regional Plan Stabilization Fund. The purpose of the fund is to provide financial incentives to MA organizations to offer MA regional PPO plans in each MA region, and to retain MA regional PPO plans in regions with relatively low MA market penetration.

Section 101 of the Medicare, Medicaid, and SCHIP Extension Act of 2007 – enacted December 18, 2007 – delayed Stabilization Fund payments until January 1, 2013.

Section I. Continuation of Clinical Trial Policy

In 2009, we will continue the policy of paying on a fee-for-service basis for clinical trial items and services provided to MA plan members that are covered under the relevant National Coverage Determinations on clinical trials.

Section J. Adjustment to FFS Capitation Rates for VA-DOD Costs

Per Section 1853(c)(1)(D)(iii) of the Act, CMS proposes to adjust to the extent appropriate the 2009 FFS rates to reflect CMS' "estimate, on a per capita basis, of the amount of additional payments that would have been made in the area involved under this title if individuals entitled to benefits under this title had not received services from facilities of the Department of Defense or the Department of Veterans Affairs."

The Office of the Actuary (OACT) proposes to compare the risk-adjusted Medicare reimbursements of dual-eligible individuals — those entitled to benefits under this title and entitled to benefits from the Department of Defense (e.g., DoD TRICARE for Life, DoD US Family Health Plan) or the Department of Veterans Affairs (VA) — with individuals entitled only under this title. In cases where groupings of dual-eligible individuals (who would possibly have services provided in VA or DoD facilities not reimbursed by Medicare) have risk-adjusted Medicare reimbursements significantly different from other Medicare-eligible individuals, we propose to adjust the MA FFS rates by excluding these individuals from the calculation. This

exclusion implicitly assumes that these individuals, if they had received all their services from Medicare-covered providers, would have the same risk-adjusted Medicare reimbursements as the remaining individuals.

MA FFS rates could be higher or lower under this adjustment. This is because the MA FFS rates are risk-adjusted rates. We note that under the current payment methodology we are missing two pieces of information on beneficiaries receiving health services through the VA or DoD:

1. The amounts Medicare would have reimbursed if these individuals had received their services from Medicare-covered providers rather than from VA/DoD providers.

2. Diagnostic information identified in VA/DoD-provided services but not identified in Medicare-covered services. Lack of diagnostic information could potentially understate individuals' risk scores.

Since the MA FFS rates are calculated using risk-adjusted reimbursements, there could be cases where the risk scores are understated to a greater extent than reimbursements leading to a reduction in the MA FFS rates in some counties.

In light of the foregoing, further information and analysis is required before making a final decision on the appropriateness of adjustments.

Section K. Operational Policies

K1. Reporting of Medicaid Status for Part C Payment

In CY 2009, CMS will complete the transition to using the MMA Medicare/Medicaid Dual Eligible monthly submission file (MMA State files) as the main source of Medicaid status for Part C plan payments. At the same time, CMS will end the use of the Third Party files as a source of Medicaid status. CMS anticipates that this change in Medicaid status source will improve – and increase – the identification of dual-eligible MA enrollees. As discussed in the 2008 Announcement (published April 2, 2007), CMS has found that the MMA State files identify approximately one million more dual eligibles than both the Third Party files and plan-reported data. (Please note that the changes discussed here only affect how we assign Medicaid status for Part C risk adjustment purposes, and that we are not changing how we identify deemed individuals for purposes of Part D payment.)

Plan Reporting. For any Medicaid period open on or after January 1, 2008, organizations may no longer submit batch "01" transactions to CMS. Instead, to request changes to Medicaid status, organizations must submit retroactive "01" transactions to IntegriGuard, as indicated in Table II-2.

Table II-2. Data sources for the assignment of Medicaid status

	Payment year 2007	Payment year 2008	Payment year 2009
New enrollees	1. Third Party Buy-In file 2. Plan-reported Medicaid • Batch "01" transactions • Retroactive "01s" through IntegriGuard	1. MMA State files 2. Plan-reported • Retroactive "01s" through IntegriGuard	1. MMA State files 2. Plan-reported • Retroactive "01s" through IntegriGuard
Full risk enrollees		1. MMA State files 2. Third Party Buy-In file 3. Plan-reported Medicaid • Batch "01" transactions • Retroactive "01s" through IntegriGuard	

Notes: Full risk enrollees. CMS considers full risk Medicare beneficiaries as dually-eligible if they were eligible for title XIX during any month in the year prior to the payment year. Full risk Medicare beneficiaries have 12 months of Part B in the year prior to the payment year.
New enrollees. CMS assigns Medicaid status for new enrollees on a concurrent basis, i.e., if a newly-enrolled Medicare beneficiary is eligible for title XIX during any month during the payment year, they are considered Medicaid for that year.

K2. Standard Set of ICD-9 Diagnosis Codes for Risk Adjustment

As discussed in the 2008 Announcement (released April 2, 2007), CMS is implementing the use of a standard set of valid codes to determine which plan-submitted diagnosis codes are acceptable for use in CMS's Risk Adjustment Processing System (RAPS). The goal is for RAPS to accept and store only those diagnoses codes that are valid. RAPS has historically accepted and stored old ICD-9 codes that had been superseded by more recent National Center for Health Statistics (NCHS) codes, i.e., invalid codes, without sending error messages to the plans. Having a standard set of valid codes for each year will make it more efficient for CMS and plans to manage risk adjustment processing, editing, and error reporting.

Starting with payment year 2009, RAPS will only accept valid ICD-9-CM codes for two fiscal years -- the fiscal year that begins prior to the payment year and the fiscal year that begins during the payment year -- for the CMS-HCC, ESRD, and RxHCC risk adjustment models. For example, for diagnoses codes to be used in 2009 final payment, i.e., for diagnoses from service dates between January 1, 2008 and December 31, 2008, RAPS will only accept codes that are valid for Fiscal Year 2008 and Fiscal Year 2009. (Please note that for the initial risk score run for payment year 2009, CMS will use valid diagnosis codes from FY 2007 and FY 2008 -- services dates between July 1, 2007 and June 30, 2008.)

Refer to Table II-3 for the implementation schedule of the new rules regarding the acceptance of diagnosis codes. Please note that Table II-3 of this Notice supersedes the table published in the April 2, 2007 Rate Announcement for 2008.

CMS is in the process of updating the "future diagnoses file" to eliminate invalid codes from that list. However, whether submitting diagnosis codes from the list of current model diagnoses or the list of future diagnoses, plans should resubmit an updated valid diagnosis code whenever they receive a RAPS error code specifying that a submitted diagnosis code is invalid. Both lists of current diagnosis codes and future diagnosis codes can be found in a zipped file on the CMS Web site at

http://www.cms.hhs.gov/MedicareAdvtgSpecRateStats/06_Risk_adjustment.asp#TopOfPage. Please refer to the HPMS memo released November 26, 2007 for a discussion of this policy and of the related RAPS error codes.

Table II-3. Acceptable diagnoses codes

Year of Payment	Date of Service	Source of codes
2007	1/06 – 12/06	The list of codes published on our website at http://www.cms.hhs.gov/MedicareAdvtgSpecRateStats/06_Risk_adjustment.asp#TopOfPage (which lists acceptable codes by year)
2008	1/07 – 12/07	The list of codes published on our website at http://www.cms.hhs.gov/MedicareAdvtgSpecRateStats/06_Risk_adjustment.asp#TopOfPage (which lists acceptable codes by year)
2009	1/08 – 12/08	Valid diagnoses in Fiscal Years 2008, 2009
2010	1/09 – 12/09	Valid diagnoses in Fiscal Years 2009, 2010
2011	1/10 – 12/10	Valid diagnoses in Fiscal Years 2010, 2011

Attachment III. Changes in the Payment Methodology for Medicare Part D for CY 2009

Section A. Benefit Design

A1. Medicare Part D Benefit Parameters: Annual Adjustments for Defined Standard Benefit in 2009

In accordance with section 1860D-2(b) of the Social Security Act (the Act), CMS must update the statutory parameters for the defined standard Part D prescription drug benefit each year. These parameters include the annual deductible, initial coverage limit, annual out-of-pocket threshold, and minimum copayments for costs above the annual out-of-pocket threshold. As required by statute, the parameters for the defined standard benefit are indexed to the percentage increase in average per capita total Part D drug expenses for Medicare beneficiaries. Accordingly, the actuarial value of the drug benefit increases along with any increase in Part D drug expenses, and the defined standard Part D benefit continues to cover a constant share of Part D drug expenses from year to year. The Part D benefit parameters are updated using two indexing methods specified by statute: (i) the annual percentage increase in average expenditures for Part D drugs per eligible beneficiary or the "annual percentage increase", and (ii) the annual percentage increase in the Consumer Price Index (CPI) (all items, U.S. city average).

As required by statute, the first indexing method, the "annual percentage increase," is used to update the following Part D benefit parameters:

(i) the deductible, initial coverage limit, and out-of-pocket threshold for the defined standard benefit;
(ii) minimum copayments for costs above the annual out-of-pocket threshold;
(iii) maximum copayments below the out-of-pocket threshold for certain low-income full subsidy eligible enrollees;
(iv) the deductible for partial low-income subsidy (LIS) eligible enrollees; and
(v) maximum copayments above the out-of-pocket threshold for partial LIS eligible enrollees.

The benefit parameters listed above will be increased by 7.54% for 2009 as summarized by Table III-1 below. This increase reflects the 2008 annual percentage trend of 5.97% as well as a multiplicative update of 1.48% for prior year revisions. Please see Attachment V for additional information on the calculation of the annual percentage increase.

Per 42 CFR 423.886(b)(3), the cost threshold and cost limit for qualified retiree prescription drug plans are updated after 2006 in the same manner as the deductible and out-of-pocket threshold for the defined standard benefit. Thus, the "annual percentage increase" will be used to update these parameters as well. The cost threshold and cost limit for qualified retiree prescription drug plans will be increased by 7.54% from their 2008 values.

The statute requires CMS to use the second indexing method, the annual percentage increase in the CPI, to update the maximum copayments below the out-of-pocket threshold for full benefit dual eligible enrollees with incomes that do not exceed 100% of the Federal poverty line. These maximum copayments will be increased by 3.18% for 2009 as summarized in Table III-1 below.

This increase reflects the 2008 annual percentage trend in CPI of 2.60%, as well as a multiplicative update of 0.57% for prior year revisions. Please see Attachment V for additional information on the calculation of the annual percentage increase in the CPI.

Table III-1. Updated Part D Benefit Parameters for Defined Standard Benefit, Low-Income Subsidy, and Retiree Drug Subsidy

Annual Percentage Increases			
	Annual percentage trend for 2008	Prior year revisions	Annual percentage increase for 2008
Applied to all parameters but (1)	5.97%	1.48%	7.54%
CPI (all items, U.S. city average): Applied to (1)	2.60%	0.57%	3.18%

Part D Benefit Parameters	2008	2009
Standard Benefit Design Parameters		
Deductible	$275	$295
Initial Coverage Limit	$2,510	$2,700
Out-of-Pocket Threshold	$4,050	$4,350
Total Covered Part D Drug Spend at OOP Threshold (2)	$5,726.25	$6,153.75
Minimum Cost-sharing in Catastrophic Coverage Portion of Benefit		
Generic/Preferred Multi-Source Drug	$2.25	$2.40
Other	$5.60	$6.00
Part D Full Benefit Dual Eligible Parameters		
Copayments for Institutionalized Beneficiaries	$0.00	$0.00
Maximum Copayments for Non-Institutionalized Beneficiaries		
Up to or at 100% FPL		
Up to Out-of-Pocket Threshold (1)		
Generic/Preferred Multi-Source Drug (3)	$1.05	$1.10
Other (3)	$3.10	$3.20
Above Out-of-Pocket Threshold	$0.00	$0.00
Over 100% FPL		
Up to Out-of-Pocket Threshold		
Generic/Preferred Multi-Source Drug	$2.25	$2.40
Other	$5.60	$6.00
Above Out-of Pocket Threshold	$0.00	$0.00
Part D Non-Full Benefit Dual Eligible Full Subsidy Parameters		
Resources ≤ $6,290 (individuals) or ≤ $9,440 (couples) (4)		
Maximum Copayments up to Out-of-Pocket Threshold		
Generic/Preferred Multi-Source Drug	$2.25	$2.40
Other	$5.60	$6.00
Maximum Copayments above Out-of-Pocket Threshold	$0.00	$0.00
Resources bet $6,290-$10,490 (ind) or $9,440-$20,970 (couples) (4)		
Deductible (3)	$56.00	$60.00
Coinsurance up to Out-of-Pocket Threshold	15%	15%
Maximum Copayments above Out-of-Pocket Threshold		
Generic/Preferred Multi-Source Drug	$2.25	$2.40
Other	$5.60	$6.00
Part D Non-Full Benefit Dual Eligible Partial Subsidy Parameters		
Deductible (3)	$56.00	$60.00
Coinsurance up to Out-of-Pocket Threshold	15%	15%
Maximum Copayments above Out-of-Pocket Threshold		
Generic/Preferred Multi-Source Drug	$2.25	$2.40
Other	$5.60	$6.00
Retiree Drug Subsidy Amounts		
Cost Threshold	$275	$295
Cost Limit	$5,600	$6,000

(1) CPI adjustment applies to copayments for non-institutionalized beneficiaries up to or at 100% FPL.

(2) Amount of total drug spending required to attain out-of-pocket threshold in the defined standard benefit if beneficiary does not have prescription drug coverage through a group health plan, insurance, government-funded health program or similar third party arrangement.

(3) The increases to the LIS deductible, generic/preferred multi-source drugs and other drugs copayments are applied to the unrounded 2008 values of $55.91, $1.04, and $3.13 respectively.

(4) The actual amount of resources allowable will be updated for contract year 2009.

Office of the Actuary
Centers for Medicare and Medicaid Services
February 22, 2007

A2. Reporting Drug Costs When Contracting with a Pharmacy Benefit Manager (PBM)
In the 2008 Part D Payment Notification issued on April 2, 2007, we stated our intent to issue a Notice of Proposed Rulemaking proposing that the pass through amount (the amount received by the pharmacy or other dispensing provider) be the only acceptable price for determining beneficiary cost-sharing and reporting drug costs to CMS in 2009 and beyond. This Notice of Proposed Rulemaking was released in the Federal Register on May 25, 2007. CMS has reviewed the comments received and expects to issue the final rule in Spring 2008. This will allow sufficient time for Part D sponsors to prepare their 2009 Part D bids in accordance with the policies established in the final rule.

Section B. Bidding

B1. Calculation of the National Average Monthly Bid Amount
CMS will complete the transition to an enrollment-weighted average for the calculation of the national average monthly bid amount in 2009. Section 1860D-13(a)(4)(B) of the Act directs CMS to calculate the national average monthly bid amount each year as a weighted average of the standardized bid amounts for each prescription drug plan (PDP) and Medicare Advantage Prescription Drug Plan (MA-PD) described in section 1851(a)(2)(A)(i) of the Act starting in 2007. When calculating the national average monthly bid amount for contract year 2006, CMS assigned equal weighting to PDP sponsors, under section 1860D-13(a)(4)(B)(ii), because CMS did not have prior enrollment for these Part D plans. MA-PD plans were assigned a weight based on their prior MA enrollments and new MA-PD plans were assigned zero weight.

In 2007, CMS implemented the Medicare Part D demonstration entitled, "Medicare Demonstration to Limit Annual Changes in Part D Premiums Due to Beneficiary Choice of Low-Cost Plans," and began a transition from the 2006 method of calculating the national average monthly bid amount to the weighted average method based on actual plan enrollments. Under this demonstration, the national average monthly bid amounts for contract years 2007 and 2008 were calculated as a composite of (i) a weighted average calculated using the 2006 weighting methodology and (ii) a weighted average calculated based on actual plan enrollments. In 2007, 80% of the national average monthly bid amount was based on the 2006 averaging methodology and 20% was based on the enrollment-weighted average. In 2008, 40% of the national average monthly bid amount is based on the 2006 averaging methodology and 60% is based on the enrollment-weighted average. Please find the weighting methodologies for contract years 2006-2009 below.

Table III-2. Weighting Blends for the National Average Monthly Bid Amount

Contract Year	2006 Weighting	Enrollment Weighting
2006	100%	0%
2007	80%	20%
2008	40%	60%
2009	0%	100%

CMS will complete the transition to the weighted average method based on actual plan enrollments in 2009. Thus for contract year 2009, 100% of the national average monthly bid amount will be based on the enrollment-weighted average. The "Medicare Demonstration to

Limit Annual Changes in Part D Premiums Due to Beneficiary Choice of Low-Cost Plans" will not be extended for contract year 2009. The 2009 national average monthly bid amount and the reference month for the plan enrollment used to determine the enrollment-weighted average will be provided in future guidance after the June bid submission deadline.

B2. Calculation of the Low-Income Benchmark Premium Amount

The Medicare Prescription Drug Improvement, and Modernization Act of 2003 (MMA) directs CMS to use a weighted average to calculate the regional low-income benchmark premium amount used in the determination of the low-income premium subsidy amount. In determining the 2006 low-income benchmark premium amounts, PDPs were weighted equally, MA-PD plans were assigned a weight based on prior enrollment as of March 31, 2005, and new MA-PD plans were assigned a zero weight. In 2007, under the "Medicare Demonstration to Transition Enrollment of Low Income Subsidy Beneficiaries," CMS calculated the regional low-income benchmark premium amounts using the same weighting methodology applied in 2006, i.e., all PDP bids were weighted equally, and MA-PD bids received weights based on plan enrollments in the reference month (June 2006).

For contract year 2008, CMS implemented a transition to the statutorily required weighting such that the regional low-income benchmark premiums would experience a smaller decrease. CMS calculated the 2008 regional benchmarks using a composite of the 2006 weighting approach (simple average) and the statutory weighting formula (weighted average).

- The first component, the simple average, was the same as the 2006 weighting methodology for the regional low-income benchmark premium amount. The PDP organization premium amounts for basic prescription drug coverage in each region would be weighted equally and the MA-PD plan premiums, after the application of Part A/B rebates, would be weighted based upon prior enrollment.
- The second component was a weighted average of the premium amounts for each PDP and MA-PD with a weighting based on each plan's prior enrollment as a percentage of all beneficiaries enrolled in those plans.

In 2008, 50% of the regional low-income benchmark amount was based on the first component, the simple average, and 50% was based on the second component, the enrollment weighted average.

CMS proposes to calculate the 2009 regional benchmarks using a composite of the 2006 weighting approach (simple average) and the statutory weighting formula (weighted average) again. However, in 2009, 25% of the regional low-income benchmark amount will be based on the first component, the simple average, and 75% will be based on the second component, the enrollment weighted average. This proposal would continue the transition to the statutorily required weighting that was started in 2008, such that the regional low-income benchmark premiums would experience a smooth glide path to the statutory weighting approach.

Under the demonstration in 2007 and 2008, CMS also implemented a policy whereby Part D plans were required to charge full-subsidy eligible beneficiaries a monthly beneficiary premium equal to the low-income premium subsidy amount, if the plan's premium exceeded the low-

income premium subsidy amount by a certain "de minimis" amount. We do not propose to extend the "de minimis" component of this demonstration to 2009. On January 8, 2008, CMS published a proposed rule titled "Option for Prescription Drug Plans to Lower Their Premiums for Low-Income Subsidy Beneficiaries." It is our intent that the policy in the final version of this rule will replace the current "de minimis" policy.

B3. Coordination of Benefits (COB) User Fees

CMS is authorized to impose user fees on Part D sponsors for the transmittal of information necessary for benefit coordination between sponsors and other entities providing prescription drug coverage. CMS may review and update this user fee annually to reflect the costs associated with COB activities. For contract year 2008, the Part D COB user fee was $1.36 per enrollee per year. Upon review of the anticipated costs of COB activities in 2009, the Part D COB user fee will increase to $2.52 per enrollee per year for contract year 2009. This COB user fee will be collected at a rate of $0.28 per enrollee per month from January to September (for an annual rate of $0.21 per enrollee per month) for a total user fee of $2.52 per enrollee per year. Part D sponsors should account for this COB user fee when developing their 2009 bids.

B4. Budget Neutrality Offsets for Reinsurance Payment Demonstration Plans in 2009

The budget neutrality offsets applied to the capitated reinsurance payments for flexible capitated, fixed capitated, and Medicare Advantage rebate option plans will remain at $10.00 per member per year for contract year 2009. The Part D Reinsurance Payment Demonstration is a budget neutral alternative payment approach that provides an incentive for Part D sponsors to offer supplemental drug coverage to Medicare beneficiaries. Under this demonstration, Medicare pays participating Part D plans a capitated reinsurance payment that is actuarially equivalent to the federal reinsurance payments that they would otherwise receive when a beneficiary reaches the catastrophic phase of the Part D benefit ($4,050 in True Out-of-pocket costs for 2008).

This demonstration must be budget neutral as stated in the Instructions for Part D Payment Demonstration released on May 10, 2005 such that the expected Medicare costs under the demonstration are no more than the expected costs to the Medicare program in the absence of the demonstration. In order to ensure budget neutrality, the capitated reinsurance payments for all plans offered under the Part D Reinsurance Payment Demonstration were offset by $10.00 per member per year in 2008.

As stated in the Federal Register Notice published on February 25, 2005 (70 FR 9360), in order to ensure budget neutrality for this payment demonstration, CMS may increase these offsets each year in order to reflect an increase in the expected costs of the demonstration. The capitated reinsurance payments for 2009 must continue to be offset by $10.00 per member per year to ensure that the Part D Reinsurance Payment Demonstration remains budget neutral. When developing the 2009 bids for flexible capitated, fixed capitated, and Medicare Advantage rebate option plans, Part D sponsors should reflect this offset amount in the direct administrative expense line item of the Bid Pricing Tool (BPT).

Section C. Risk Adjustment

C1. Normalization Factor for the RxHCC Model

Please see Section C, item C3 in Attachment II, Changes in the Payment Methodology for Original Medicare Benefits for CY 2009.

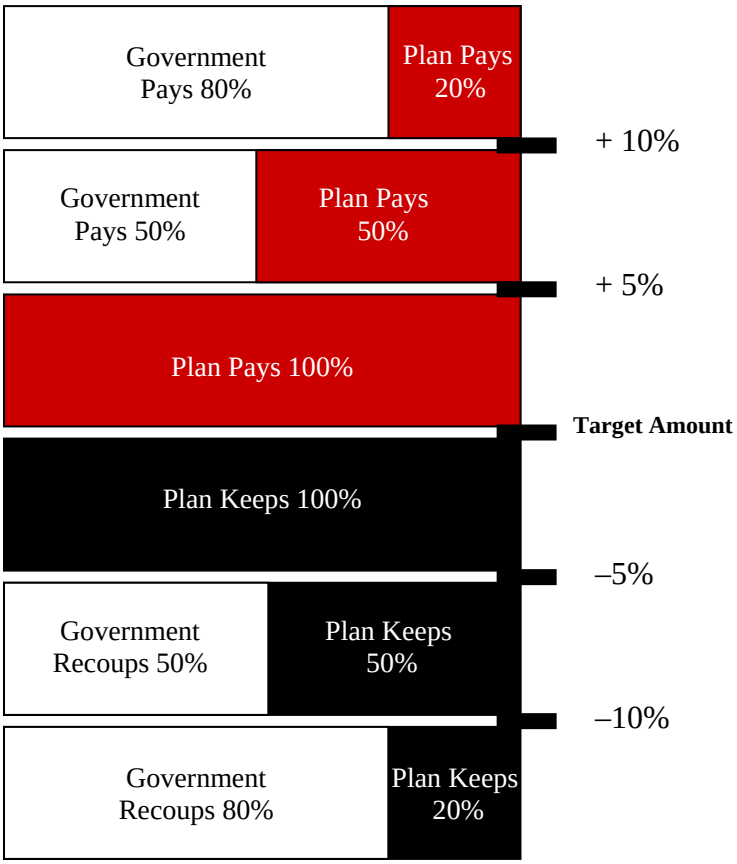
C2. Standard Set of ICD-9 Diagnosis Codes for Risk Adjustment

Please See Section K, item K2 in Attachment II, Changes in the Payment Methodology for Original Medicare Benefits for CY 2009.

Section D. Payment Reconciliation

Pursuant to section 1860D-15(e) of the Act and the regulations at 42 CFR 423.336, the risk percentages and payment adjustments for Part D risk sharing are unchanged from contract year 2008. The risk percentages for the first and second thresholds remain at 5% and 10% of the target amount respectively for 2009. The payment adjustments for the first and second corridors are 50% and 80% respectively. Please see Figure 1 below which illustrates the risk corridors for 2008-2011.

Figure 1. Part D Risk Corridors for 2008-2011



Attachment IV. Preliminary CMS-HCC Risk Adjustment Factors

Exhibit IV-1. Preliminary 2009 Community and Institutional Factors for the CMS-HCC Model

Variable	Disease Group	Community Factors	Institutional Factors
Female			
0-34 Years		0.187	1.026
35-44 Years		0.206	0.884
45-54 Years		0.275	0.888
55-59 Years		0.333	0.943
60-64 Years		0.411	0.943
65-69 Years		0.299	0.971
70-74 Years		0.368	0.931
75-79 Years		0.457	0.835
80-84 Years		0.544	0.775
85-89 Years		0.637	0.704
90-94 Years		0.761	0.614
95 Years or Over		0.771	0.457
Male			
0-34 Years		0.120	1.030
35-44 Years		0.164	0.871
45-54 Years		0.217	0.871
55-59 Years		0.249	0.978
60-64 Years		0.389	1.015
65-69 Years		0.328	1.221
70-74 Years		0.413	1.154
75-79 Years		0.517	1.143
80-84 Years		0.597	1.087
85-89 Years		0.692	1.001
90-94 Years		0.834	0.932
95 Years or Over		0.980	0.743
Medicaid and Originally Disabled Interactions with Age and Sex			
Medicaid_Female_Aged		0.179	0.091
Medicaid_Female_Disabled		0.131	0.091
Medicaid_Male_Aged		0.166	0.091
Medicaid_Male_Disabled		0.077	0.091
Originally Disabled_Female		0.204	0.023
Originally Disabled_Male		0.168	0.023
Disease Coefficients	**Description Label**		
HCC1	HIV/AIDS	0.945	0.967
HCC2	Septicemia/Shock	0.759	0.764
HCC5	Opportunistic Infections	0.300	0.288
HCC7	Metastatic Cancer and Acute Leukemia	2.276	0.824
HCC8	Lung, Upper Digestive Tract, and Other Severe Cancers	1.053	0.470

Variable	Disease Group	Community Factors	Institutional Factors
HCC9	Lymphatic, Head and Neck, Brain, and Other Major Cancers	0.794	0.368
HCC10	Breast, Prostate, Colorectal and Other Cancers and Tumors	0.208	0.182
HCC15	Diabetes with Renal or Peripheral Circulatory Manifestation[1]	0.508	0.459
HCC16	Diabetes with Neurologic or Other Specified Manifestation[1]	0.408	0.459
HCC17	Diabetes with Acute Complications[1]	0.339	0.459
HCC18	Diabetes with Ophthalmologic or Unspecified Manifestation[1]	0.259	0.459
HCC19	Diabetes without Complication[1]	0.162	0.248
HCC21	Protein-Calorie Malnutrition	0.856	0.374
HCC25	End-Stage Liver Disease	0.978	0.654
HCC26	Cirrhosis of Liver	0.406	0.384
HCC27	Chronic Hepatitis	0.406	0.384
HCC31	Intestinal Obstruction/Perforation	0.311	0.345
HCC32	Pancreatic Disease	0.403	0.309
HCC33	Inflammatory Bowel Disease	0.241	0.205
HCC37	Bone/Joint/Muscle Infections/Necrosis	0.535	0.497
HCC38	Rheumatoid Arthritis and Inflammatory Connective Tissue Disease	0.346	0.215
HCC44	Severe Hematological Disorders	1.015	0.493
HCC45	Disorders of Immunity	0.912	0.427
HCC51	Drug/Alcohol Psychosis[3]	0.274	0.000
HCC52	Drug/Alcohol Dependence[3]	0.274	0.000
HCC54	Schizophrenia	0.524	0.351
HCC55	Major Depressive, Bipolar, and Paranoid Disorders	0.353	0.293
HCC67	Quadriplegia, Other Extensive Paralysis	1.011	0.434
HCC68	Paraplegia	0.993	0.434
HCC69	Spinal Cord Disorders/Injuries	0.558	0.225
HCC70	Muscular Dystrophy[3]	0.395	0.000
HCC71	Polyneuropathy	0.327	0.225
HCC72	Multiple Sclerosis	0.599	0.145
HCC73	Parkinson's and Huntington's Diseases	0.592	0.092
HCC74	Seizure Disorders and Convulsions	0.267	0.177
HCC75	Coma, Brain Compression/Anoxic Damage[3]	0.415	0.000
HCC77	Respirator Dependence/Tracheostomy Status	1.867	1.559
HCC78	Respiratory Arrest	1.082	1.235
HCC79	Cardio-Respiratory Failure and Shock	0.578	0.445
HCC80	Congestive Heart Failure	0.410	0.228
HCC81	Acute Myocardial Infarction	0.359	0.424
HCC82	Unstable Angina and Other Acute Ischemic Heart Disease	0.284	0.424
HCC83	Angina Pectoris/Old Myocardial Infarction	0.244	0.290
HCC92	Specified Heart Arrhythmias	0.293	0.207
HCC95	Cerebral Hemorrhage	0.324	0.179
HCC96	Ischemic or Unspecified Stroke	0.265	0.179
HCC100	Hemiplegia/Hemiparesis	0.437	0.039
HCC101	Cerebral Palsy and Other Paralytic Syndromes[3]	0.180	0.000
HCC104	Vascular Disease with Complications	0.610	0.482
HCC105	Vascular Disease	0.316	0.165

Variable	Disease Group	Community Factors	Institutional Factors
HCC107	Cystic Fibrosis	0.399	0.631
HCC108	Chronic Obstructive Pulmonary Disease	0.399	0.359
HCC111	Aspiration and Specified Bacterial Pneumonias	0.703	0.573
HCC112	Pneumococcal Pneumonia, Emphysema, Lung Abscess	0.249	0.181
HCC119	Proliferative Diabetic Retinopathy and Vitreous Hemorrhage	0.252	0.497
HCC130	Dialysis Status	1.349	1.718
HCC131	Renal Failure	0.368	0.388
HCC132	Nephritis	0.125	0.253
HCC148	Decubitus Ulcer of Skin	1.153	0.485
HCC149	Chronic Ulcer of Skin, Except Decubitus	0.449	0.241
HCC150	Extensive Third-Degree Burns[3]	1.416	0.000
HCC154	Severe Head Injury[3]	0.415	0.000
HCC155	Major Head Injury[3]	0.106	0.000
HCC157	Vertebral Fractures without Spinal Cord Injury	0.443	0.161
HCC158	Hip Fracture/Dislocation[3]	0.429	0.000
HCC161	Traumatic Amputation	0.678	0.260
HCC164	Major Complications of Medical Care and Trauma	0.296	0.309
HCC174	Major Organ Transplant Status	0.705	0.920
HCC176	Artificial Openings for Feeding or Elimination	0.662	0.841
HCC177	Amputation Status, Lower Limb / Amputation Complications	0.678	0.260
Disabled/Disease Interactions			
D_HCC5	Disabled_Opportunistic Infections	0.623	1.016
D_HCC44	Disabled_Severe Hematological Disorders	1.036	0.362
D_HCC51	Disabled_Drug/Alcohol Psychosis	0.729	0.299
D_HCC52	Disabled_Drug/Alcohol Dependence	0.310	0.299
D_HCC107	Disabled_Cystic Fibrosis[3]	1.097	-
Disease Interactions			
INT1	DM_CHF[2]	0.154	0.125
INT2	DM_CVD	0.102	0.028
INT3	CHF_COPD	0.219	0.194
INT4	COPD_CVD_CAD	0.173	0.071
INT5	RF_CHF[2,3]	0.231	-
INT6	RF_CHF_DM[2]	0.477	0.358

NOTES:

[1] Includes Type I or Type II Diabetes Mellitus.

[2] Beneficiaries with the three-way interaction RF*CHF*DM are excluded from the two-way interactions DM*CHF and RF*CHF. Thus, the three-way interaction term RF*CHF*DM is not additive to the two-way interaction terms DM*CHF and RF*CHF. Rather, it is hierarchical to, and excludes these interaction terms. A beneficiary with all three conditions is not "credited" with the two-way interactions. All other interaction terms are additive.

[3] HCC or disease interaction excluded from institutional model because estimated coefficient less than 0 or t-statistic less than 1.0.

The 2007 denominator of $7,463.14 used to calculate both the community and institutional factors is the national predicted average annual cost under the model.

DM is diabetes mellitus (HCCs 15-19).
CHF is congestive heart failure (HCC 80).

COPD is chronic obstructive pulmonary disease (HCC 108).
CVD is cerebrovascular disease (HCCs 95, 96, 100, and 101).
CAD is coronary artery disease (HCCs 81-83).
RF is renal failure (HCC 131).

SOURCE: RTI International analysis of 2004/2005 Medicare 5% sample.
SOURCE: RTI International analysis of 2004/2005 Medicare 100% institutional sample.

Exhibit IV-2. Preliminary Disease Hierarchies for the CMS-HCC Model

Hierarchical Condition Category (HCC)	If the Disease Group is Listed in This Column…	…Then Drop the Associated Disease Group(s) Listed in This Column
	Disease Group Label	
5	Opportunistic Infections	112
7	Metastatic Cancer and Acute Leukemia	8, 9, 10
8	Lung, Upper Digestive Tract, and Other Severe Cancers	9, 10
9	Lymphatic, Head and Neck, Brain and Other Major Cancers	10
15	Diabetes with Renal Manifestations or Peripheral Circulatory Manifestation	16, 17, 18, 19
16	Diabetes with Neurologic or Other Specified Manifestation	17, 18, 19
17	Diabetes with Acute Complications	18, 19
18	Diabetes with Ophthalmologic or Unspecified Manifestations	19
25	End-Stage Liver Disease	26, 27
26	Cirrhosis of Liver	27
51	Drug/Alcohol Psychosis	52
54	Schizophrenia	55
67	Quadriplegia/Other Extensive Paralysis	68, 69, 100, 101, 157
68	Paraplegia	69, 100, 101, 157
69	Spinal Cord Disorders/Injuries	157
77	Respirator Dependence/ Tracheostomy Status	78, 79
78	Respiratory Arrest	79
81	Acute Myocardial Infarction	82, 83
82	Unstable Angina and Other Acute Ischemic Heart Disease	83
95	Cerebral Hemorrhage	96
100	Hemiplegia/Hemiparesis	101
104	Vascular Disease with Complications	105, 149
107	Cystic Fibrosis	108
111	Aspiration and Specified Bacterial Pneumonias	112
130	Dialysis Status	131, 132
131	Renal Failure	132
148	Decubitus Ulcer of Skin	149
154	Severe Head Injury	75, 155
161	Traumatic Amputation	177

How Payments are Made with a Disease Hierarchy -- EXAMPLE: If a beneficiary triggers HCCs 148 (Decubitus Ulcer of the Skin) and 149 (Chronic Ulcer of Skin, Except Decubitus), then HCC 149 will be dropped. In other words, payment will always be associated with the HCC in column 1 if a HCC in column 3 also occurs during the same collection period. Therefore, the MA organization's payment will be based on HCC 148 rather than HCC 149.

Exhibit IV-3. Preliminary 2009 CMS-HCC Model for New Enrollees

	Non-Medicaid & Non-Originally Disabled	Medicaid & Non-Originally Disabled	Non-Medicaid & Originally Disabled	Medicaid & Originally Disabled
Female				
0-34 Years	0.496	0.807	0.000	0.000
35-44 Years	0.652	0.963	0.000	0.000
45-54 Years	0.841	1.152	0.000	0.000
55-59 Years	0.969	1.280	0.000	0.000
60-64 Years	1.094	1.404	0.000	0.000
65 Years	0.497	0.958	1.096	1.557
66 Years	0.554	0.987	1.153	1.587
67 Years	0.595	1.028	1.194	1.628
68 Years	0.619	1.052	1.218	1.651
69 Years	0.652	1.085	1.251	1.684
70-74 Years	0.759	1.208	1.320	1.769
75-79 Years	0.955	1.357	1.430	1.832
80-84 Years	1.118	1.520	1.593	1.995
85-89 Years	1.255	1.657	1.730	2.132
90-94 Years	1.358	1.760	1.834	2.236
95 Years or Over	1.232	1.634	1.707	2.109
Male				
0-34 Years	0.344	0.675	0.000	0.000
35-44 Years	0.583	0.914	0.000	0.000
45-54 Years	0.729	1.060	0.000	0.000
55-59 Years	0.827	1.158	0.000	0.000
60-64 Years	1.033	1.365	0.000	0.000
65 Years	0.550	1.022	1.116	1.587
66 Years	0.586	1.058	1.117	1.589
67 Years	0.664	1.136	1.195	1.667
68 Years	0.664	1.136	1.195	1.667
69 Years	0.723	1.195	1.254	1.726
70-74 Years	0.855	1.322	1.392	1.859
75-79 Years	1.113	1.484	1.521	1.893
80-84 Years	1.299	1.670	1.707	2.078
85-89 Years	1.468	1.839	1.876	2.247
90-94 Years	1.630	2.001	2.038	2.409
95 Years or Over	1.638	2.009	2.046	2.417

NOTES:
The 2007 denominator of $7,463.14 used to calculate the new enrollee factors is the national predicted average annual cost under the model.

Three sets of interaction coefficients were constrained to be equal (Male, Age 67 & Male, Age 68; Medicaid, Male, Age 65 & Medicaid, Male, Ages 66 to 69; Originally Disabled, Female, Age 65 & Originally Disabled, Female, Ages 66 to 69). These constraints are necessary so that predicted expenditures, and risk scores for all demographic groups, vary in a reasonable way, as shown in the table of mutually exclusive demographic groups.

SOURCE: RTI International analysis of 2004/2005 Medicare 5% sample.

Attachment V. Medicare Part D Benefit Parameters for the Defined Standard Benefit: Annual Adjustments for 2009

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) directs CMS to update the statutory parameters for the defined standard Part D drug benefit each year. These parameters include the standard deductible, initial coverage limit, and catastrophic coverage threshold, and minimum copayments for costs above the annual out-of-pocket threshold. In addition, CMS is statutorily required to update the parameters for the low income subsidy benefit and the cost threshold and cost limit for qualified retiree prescription drug plans eligible for the Retiree Drug Subsidy. Included in this notice are (i) the methodologies for updating these parameters, (ii) the updated parameter amounts for the Part D defined standard benefit and low-income subsidy benefit for 2009, and (iii) the updated cost threshold and cost limit for qualified retiree prescription drug plans.

As required by statute, the parameters for the defined standard benefit formula are indexed to the percentage increase in average per capita total Part D drug expenses for Medicare beneficiaries. Accordingly, the actuarial value of the drug benefit increases along with any increase in drug expenses, and the defined standard Part D benefit continues to cover a constant share of drug expenses from year to year.

All of the Part D benefit parameters are updated using one of two indexing methods specified by statute: (i) the annual percentage increase in average expenditures for Part D drugs per eligible beneficiary, and (ii) the annual percentage increase in the Consumer Price Index (CPI) (all items, U.S. city average).

I. Annual Percentage Increase in Average Expenditures for Part D Drugs Per Eligible Beneficiary

Section 1860D-2(b)(6) of the Social Security Act defines the "annual percentage increase" as "the annual percentage increase in average per capita aggregate expenditures for covered Part D drugs in the United States for Part D eligible individuals, as determined by the Secretary for the 12-month period ending in July of the previous year using such methods as the Secretary shall specify." The following parameters are updated using the "annual percentage increase":

Deductible: From $275 in 2008 and rounded to the nearest multiple of $5.

Initial Coverage Limit: From $2,510 in 2008 and rounded to the nearest multiple of $10.

Out-of-Pocket Threshold: From $4,050 in 2008 and rounded to the nearest multiple of $50.

Minimum Cost-Sharing in the Catastrophic Coverage Portion of the Benefit: From $2.25 per generic or preferred drug that is a multi-source drug, and $5.60 for all other drugs in 2008, and rounded to the nearest multiple of $0.05.

Maximum Copayments below the Out-of-Pocket Threshold for certain Low Income Full Subsidy Eligible Enrollees: From $2.25 per generic or preferred drug that is a multi-source drug, and $5.60 for all other drugs in 2008, and rounded to the nearest multiple of $0.05.

Deductible for Low Income (Partial) Subsidy Eligible Enrollees: From $56[1] in 2008 and rounded to the nearest $1.

Maximum Copayments above the Out-of-Pocket Threshold for Low Income (Partial) Subsidy Eligible Enrollees: From $2.25 per generic or preferred drug that is a multi-source drug, and $5.60 for all other drugs in 2008, and rounded to the nearest multiple of $0.05.

II. Annual Percentage Increase in Consumer Price Index, All Urban Consumers (all items, U.S. city average)

Section 1860D-14(a)(4) of the Social Security Act specifies that the annual percentage increase in the CPI, All Urban Consumers (all items, U.S. city average) as of September of the previous year is used to update the maximum copayments below the out-of-pocket threshold for full benefit dual eligible enrollees with incomes that do not exceed 100% of the Federal poverty line. These copayments are increased from $1.05 per generic or preferred drug that is a multi-source drug, and $3.10 for all other drugs in 2008[2], and rounded to the nearest multiple of $0.05 and $0.10, respectively.

III. Calculation Methodology

Annual Percentage Increase

For the 2007 and 2008 contract years, the annual percentage increases, as defined in section 1860D-2(b)(6) of the Social Security Act, were based on the National Health Expenditure (NHE) prescription drug per capita estimates because sufficient Part D program data was not available. For the 2009 contract year benefit parameters, Part D program data is used to calculate the annual percentage trend as follows:

$$\frac{\textit{August}\ 2007 - \textit{July}\ 2008}{\textit{August}\ 2006 - \textit{July}\ 2007} = \frac{\$2{,}659.37}{\$2{,}509.48} = 1.0597$$

In the formula, the average per capita cost for August 2006 – July 2007 ($2,509.48) is calculated from actual Part D prescription drug event (PDE) data and the average per capita cost for August 2007 – July 2008 ($2,659.37) is calculated based on actual Part D PDE data incurred from August – December, 2007 and projected through July, 2008.

[1] Consistent with the statutory requirements of 1860D-14(a)(4)(B) of the Social Security Act, the update for the deductible for low income (partial) subsidy eligible enrollees is applied to the unrounded 2008 value of $55.91.
[2] Consistent with the statutory requirements of 1860D-14(a)(4)(A) of the Social Security Act, the copayments are increased from the unrounded 2008 values of $1.04 per generic or preferred drug that is a multi-source drug, and $3.13 for all other drugs.

The 2009 benefit parameters reflect the 2008 annual percentage trend as well as a revision to the prior estimates for the 2006 and 2007 annual percentage increases. Based on the updated NHE prescription drug per capita costs, the 2007 and 2008 increases are now estimated to be 6.45% and 6.59%, respectively. Accordingly, the 2009 benefit parameters reflect a multiplicative update of 1.47% (1.0645/1.0529 * 1.0659/1.0619 – 1) for prior year revisions. In summary, the 2008 parameters outlined in section I are updated by 7.54% for 2009 as summarized by Table V-1.

Table V-1. Annual Percentage Increase

Annual percentage trend for July 2008	5.97%
Prior year revisions	1.48%
Annual percentage increase for 2008	7.54%

Note: Percentages are multiplicative, not additive.
Values are carried to additional decimal places and may not agree to the rounded values presented above.

Annual Percentage Increase in Consumer Price Index, All Urban Consumers (all items, U.S. city average)

The annual percentage increase in the CPI as of September of the previous year referenced in section 1860D-14(a)(4)(A)(ii) is interpreted to mean that, for contract year 2009, the September 2008 CPI should be used in the calculation of the index. To ensure that plan sponsors and CMS have sufficient time to incorporate the cost-sharing requirements into benefit, marketing material and systems development, the methodology to calculate this update includes an estimate of the September 2008 CPI based on the projected amount included in the President's FY2009 Budget. The September 2007 value is from the Bureau of Labor Statistics. The annual percentage trend in CPI for contract year 2009 is calculated as follows:

$$\frac{\text{Projected September 2008 CPI}}{\text{Actual September 2007 CPI}} \textit{ or } \frac{213.9}{208.5} = 1.026$$

(Source: President's FY2009 Budget and Bureau of Labor Statistics, Department of Labor)

The 2009 benefit parameters reflect the 2008 annual percentage trend in the CPI, as well as a revision to the prior estimate for the 2007 annual percentage increase. The 2008 parameter update reflected an annual percentage trend in CPI of 2.17%. Based on the actual reported CPI for September 2007, the September 2007 CPI increase is now estimated to be 2.76%. Thus, the 2009 update reflects a multiplicative 0.57% (1.0276/1.0217 – 1) correction for prior year revisions. In summary, the cost sharing items outlined in section II are updated by 3.18% for 2009 as summarized by Table V-2.

Table V-2. Cumulative Annual Percentage Increase in CPI

Annual percentage trend for September 2008	2.60%
Prior year revisions	0.57%
Annual percentage increase for 2008	3.18%

Note: Percentages are multiplicative, not additive.
Values are carried to additional decimal places and may not agree to the rounded values presented above.

IV. Part D Payment Demonstration Adjustment

The fixed capitated option of the Part D Payment Demonstration includes a catastrophic benefit that begins at the total drug expense corresponding to the out-of-pocket threshold in the Defined Standard Benefit. For 2009, this amount is increased from $5,726.50 in 2008 to $6,153.75. Specifically, this is the minimum amount of total covered Part D drug expenditures that will have occurred when the beneficiary reaches the out-of-pocket threshold of $4,350 in 2009 in the defined standard benefit. This expense level is determined arithmetically as a function of the 2009 out-of-pocket threshold (as opposed to being indexed directly).

V. Retiree Drug Subsidy Amounts

As outlined in §423.886(b)(3) of the regulations implementing the Part D benefit, the cost threshold and cost limit for qualified retiree prescription drug plans that end in years after 2006 are adjusted in the same manner as the annual Part D deductible and out-of-pocket threshold are adjusted under §423.104(d)(1)(ii) and (d)(5)(iii)(B), respectively. Specifically, they are adjusted by the "annual percentage increase" as defined previously in this document and the cost threshold is rounded the nearest multiple of $5 and the cost limit is rounded to the nearest multiple of $50. The cost threshold and cost limit are defined as $265 and $5,350, respectively, for plans that end in 2007, and, as $275 and $5,600, respectively, for plans that end in 2008. For 2009, the cost threshold is increased to $295, and the cost limit is increased to $6,000.

February 20, 2009

NOTE TO: Medicare Advantage Organizations, Prescription Drug Plan Sponsors, and Other Interested Parties

SUBJECT: Advance Notice of Methodological Changes for Calendar Year (CY) 2010 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies

In accordance with Section 1853(b)(2) of the Social Security Act (the Act), we are notifying you of planned changes in the MA capitation rate methodology and risk adjustment methodology applied under Part C of the Act for CY 2010. Preliminary estimates of the national per capita MA growth percentage and other MA payment methodology changes for CY 2010 are also discussed. For 2010, CMS will announce the MA capitation rates on the first Monday in April 2009, in accordance with the timetable established in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). This Advance Notice is published 45 days before that date.

Attachment I shows the preliminary estimates of the national per capita MA growth percentage, which is a key factor in determining the MA capitation rates. Attachment II sets forth the changes in payment methodology for CY 2010 for original Medicare benefits. Attachment III set forth the changes in payment methodology for CY 2010 for Part D benefits. Attachment IV presents the annual adjustments for 2010 to the Medicare Part D benefit parameters for the defined standard benefit.

Comments or questions may be submitted electronically to the following address: AdvanceNotice2010@cms.hhs.gov. Comments or questions also may be mailed to:

Deondra Moseley
Centers for Medicare & Medicaid Services
7500 Security Boulevard
S2-22-25
Baltimore, Maryland 21244

In order to receive consideration prior to the April 6, 2009 release of the Announcement of Calendar Year (CY) 2010 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies, comments must be received by 6:00 PM Eastern time on Friday, March 6, 2009.

/ s /
Abby L. Block
Director
Center for Drug and Health Plan Choice

/ s /
Paul Spitalnic, A.S.A., M.A.A.A.
Director
Parts C & D Actuarial Group
Office of the Actuary

Attachments

2010 ADVANCE NOTICE
TABLE OF CONTENTS

Attachment I. Preliminary Estimate of the National Per Capita Growth Percentage for Calendar Year 2010

Section 1853(c)(1), (j)(1), and (k)(1) of the Social Security Act (the Act) provides that, for years when CMS is not "rebasing" the amount representing the actuarial value of costs under original fee-for-service (FFS) Medicare, MA capitation rates will be based on the prior year's capitation rate, updated by the national per capita MA growth percentage, with no adjustment to this percentage for over- or under-estimates for years before 2004. CMS is not rebasing the FFS rates for 2010.

The current estimate of the change in the national per capita MA growth percentage for aged and disabled enrollees combined in CY 2010 is 0.5 percent. This estimate reflects an underlying trend change for CY 2010 in per capita costs of -1.1 percent and adjustments to the estimates for prior years as indicated in the table below. Our new estimates are lower than the estimates actually used in calculating the CY 2009 capitation rate book for CYs 2005 and, 2007 and 2008 and higher for CYs 2004, 2006, and 2009 than was published April 7, 2008, and are required by Section 1853(c)(6)(C) of the Act.

The following table summarizes the estimates for the change in the national per capita MA growth percentage.

Table I-1. National Per Capita MA Growth Percentage

	Aged	Disabled	ESRD	Aged+Disabled
2010 Trend Change	- 1.2%	- 0.5%	0.1%	- 1.1%
Revision to CY 2009 Estimate	1.8%	1.6%	1.9%	1.8%
Revision to CY 2008 Estimate	- 0.4%	- 0.5%	1.0%	- 0.4%
Revision to CY 2007 Estimate	- 0.1%	- 1.9%	0.9%	- 0.4%
Revision to CY 2006 Estimate	0.0%	0.6%	1.8%	0.1%
Revision to CY 2005 Estimate	- 0.1%	- 0.3%	3.3%	- 0.1%
Revision to CY 2004 Estimate	0.6%	0.9%	- 7.2%	0.6%
Total Change	0.6%	- 0.1%	1.4%	0.5%

Notes: (1) The total percentage change is multiplicative, not additive, and may not exactly match due to rounding.

(2) Starting in 2008, the trend change for ESRD reflects an estimate of the trend for dialysis-only beneficiaries. The ESRD national growth percentage could be higher than shown because it is subject to the greater of 2 percent or the national growth percentage.

These estimates are preliminary and could change before the final rates are announced on April 6, 2009 in the Announcement of Calendar Year (CY) 2010 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies. Further details on the derivation of the national per capita MA growth percentage will also be presented in the Announcement.

Attachment II. Changes in the Payment Methodology for Original Medicare Benefits for CY 2010

Section A. Frailty Adjustment

Frailty adjustments to plan payments are made to compensate plans for the costs of their enrollees due to frailty that are not captured by the CMS-HCC risk adjustment model. The methodology for calculating frailty payments is described in the 2004 Advance Notice and Announcement (published in 2003); updates to the frailty model are discussed in the 2008 Advance Notice and Announcement (published in 2007). CMS is required by law to make frailty adjustments to Part C payments made to PACE organizations; CMS also made frailty adjustments to payments to certain demonstrations.

A1. Frailty Adjustment Transition for PACE organizations

Frailty adjustment factors will be applied to payment to PACE organizations using the transition schedule published in the 2008 and 2009 Announcements. PACE frailty scores for payment year 2010 will be calculated at a blend of 50% of the frailty factors in use prior to 2008 and 50% of the recalibrated frailty factors implemented in 2009. ADL distributions from the 2008 HOS-M survey will be applied to each of these factors to calculate contract-level frailty scores. The full transition schedule is as follows:

- In 2008 (year 1): 90% of the pre-2008 frailty factors and 10% of the 2008 frailty factors.
- In 2009 (year 2): 70% of the pre-2008 frailty factors and 30% of the 2009 frailty factors.
- In 2010 (year 3): 50% of the pre-2008 frailty factors and 50% of the 2009 frailty factors.
- In 2011 (year 4): 25% of the pre-2008 frailty factors and 75% of the most recently calibrated frailty factors.
- In 2012 (year 5): 100% of the most recently calibrated frailty factors.

A2. Frailty Adjustment Transition for Certain Demonstrations

Frailty adjustment factors will be applied to payment to the following MA plan types using the phase-out schedule published in the 2008 and 2009 Announcements: Social Health Maintenance Organizations (S/HMOs), Minnesota Senior Health Options (MSHO)/ Minnesota Disability Health Options (MnDHO), Wisconsin Partnership Program (WPP) and Massachusetts Senior Care Options (SCO) plans. ADL distributions from the 2008 HOS-M or HOS survey will be applied to each of the 2007 frailty factors to calculate contract-level frailty scores. The frailty scores will be applied in payment at the appropriate phase-out percentage.

The full phase out schedule is as follows:

- In 2008 (year 1): 75% of the pre-2008 frailty factors
- In 2009 (year 2) 50% of the pre-2008 frailty factors
- In 2010 (year 3) 25% of the pre-2008 frailty factors
- In 2011, 0% of the pre-2008 frailty factors

Section B. Normalization Factors

When we calibrate a risk adjustment model and normalize the risk scores to 1.0, we produce a fixed set of dollar expenditures and coefficients appropriate to the population and data for that calibration year. When the model with fixed coefficients is used to predict expenditures for other years, predictions for prior years are lower and predictions for succeeding years are higher than for the calibration year. Because average predicted fee-for-service (FFS) expenditures increase after the model calibration year due to coding and population changes, CMS applies a normalization factor to adjust beneficiaries' risk scores so that the average risk score is 1.0 in subsequent years.

The normalization factor is derived by first using the model to predict risk scores for the FFS population over a number of years. Next, we trend the risk scores to determine the annual percent change in the risk score. This annual trend is then compounded by the number of years between the model denominator year and the payment year to produce the normalization factor.

Starting in payment year 2009, CMS uses a standard of five years of data in the normalization trend. Each year, CMS drops the earliest year and adds a new year of risk scores to the trend data to create the five-year dataset. By using a standard number of years, CMS calculates risk score trends based on recent trends in coding, while maintaining stability in the year-to-year trends used. For the CY 2010 normalization factors, trends calculated for the aged-disabled CMS-HCC, ESRD Dialysis, and the RxHCC models are developed on risk scores calculated for 2004-2008.

Below are the preliminary normalization factors for each model. The final normalization factors will be published in the 2010 Announcement, to be released April 6, 2009.

B1. Normalization Factor for the CMS-HCC Model

The preliminary 2010 normalization factor for the aged-disabled model is 1.041. This normalization factor reflects a trend calculated on five years of risk score data (2004-2008). The 2010 factor will adjust for three years of FFS risk score growth, i.e., from the denominator year of 2007 to the payment year of 2010.

B2. Normalization Factor for the ESRD Dialysis Model

The preliminary 2010 normalization factor for the ESRD dialysis model is 1.039. This normalization factor reflects a trend calculated on five years of risk score data (2004-2008). The 2010 factor will adjust for seven years of risk score growth, i.e., from the denominator year of 2003 to the payment year of 2010, and will be applied at a phased-in percentage of 75%. (As discussed in the 2008 and 2009 Advance Notices, the ESRD Dialysis normalization factor is being applied on the same transition schedule as is the transition of the ESRD State ratebook; see Section E1.)

B3. Normalization Factor for Functioning Graft Enrollees' Risk Scores

The preliminary 2010 normalization factor for the Functioning Graft portion of the ESRD risk adjustment model is 1.072. The 2010 factor will adjust for five years of FFS risk score growth, i.e., from the denominator year of 2005 to the payment year of 2010.

B4. Normalization Factor for the Rx Hierarchical Condition Category (RxHCC) Model
For 2010, we intend to change the methodology used to calculate the Part D normalization factor. For 2008 and 2009, we calculated the Part D normalization factor by trending to the payment year from the latest available Part D risk score for all potential enrollees, i.e., all individuals who are eligible for enroll in Part D, not just those who are actually enrolled. Starting in 2010, we intend to normalize Part D risk scores based on Part D enrollees. This change will help ensure that the average enrollee risk score equals 1.0 and keep the beneficiary premium at the appropriate proportion of aggregate plan payment: approximately 25.5 percent from beneficiary plan premiums and 74.5 percent from the government. We are developing the 2010 Part D normalization factor by trending from the latest available Part D risk score for all actual enrollees in Part D. The preliminary 2010 normalization factor for the RxHCC model is 1.146. This normalization factor reflects a trend calculated on five years of risk score data (2004-2008). We calculated the RxHCC normalization factor by taking the 2008 average Part D risk score for Part D enrollees and the annual trend applied for the two years between the calculation of actual average Part D risk score (2008) and the payment year (2010).

Section C. Budget Neutrality

From 2003 through 2006, CMS implemented risk adjusted payments in a budget neutral manner by applying to the risk rates 100 percent of the Budget Neutrality (BN) factor, which is calculated as the estimated difference between payments to MA organizations at 100 percent of the demographic rates and payments at 100 percent of the risk rates.

As CMS previously announced in the 2007 Advance Notice (published on February 17, 2006), and as summarized below, the phase-out of budget-neutral risk adjusted payments began in 2007 and will be completed by 2011, when plans will receive no budget neutrality payment adjustment. For 2010, 5 percent of the BN factor will be applied to the risk rates.

Since CMS cannot calculate the BN factor until the final capitation rates are determined, the factor will be announced in the 2010 Rate Announcement, to be published on April 6, 2009.

Phase-out Schedule for Budget Neutral Risk Adjusted Payments:

The percentage of the budget neutrality factor that is applied to the risk rates is:

- 2007: 55%
- 2008: 40%
- 2009: 25%
- 2010: 5%
- 2011: 0%

Section D. Adjustment for MA Coding Pattern Differences

BACKGROUND.
Section 1853(k)(2)(B)(iv)(III) requires, that in risk adjusting Part C payments in 2010, CMS make an adjustment to reflect "differences in coding patterns between Medicare Advantage plans and providers under part A and B to the extent that the Secretary has identified such differences." In order to comply with this requirement, CMS has conducted extensive research to analyze

changes in MA and original fee-for-service Medicare (FFS) risk scores, differences between those changes, and coding patterns behind these changes.

RESULTS OF CODING PATTERN DIFFERENCE ANALYSIS:

Based on our careful and in depth review of the data, CMS has found that MA risk scores have increased more than twice as much as FFS risk scores. This trend was established based on our study data from 2004 and 2007 and our preliminary 2008 risk score data shows that this trend is continuing.

As discussed in previous Advance Notices, part of the differential in FFS and MA risk score increases can be attributed to changes in the population of enrollees, i.e., the risk scores of beneficiaries leaving ("leavers") or joining ("joiners") either FFS or MA plans have an impact on the overall average risk score in each sector. Specifically, we found that:

- A significant portion of the beneficiaries who join MA are beneficiaries who are switching from FFS. In FFS, the vast majority of beneficiaries who join are newly-eligible to Medicare. The risk scores of beneficiaries who are newly eligible to Medicare tend to be very low and these low risk scores depress FFS risk score growth relative to MA.
- Of the leavers, decedents (who have high risk scores) are a slightly larger fraction of FFS beneficiaries than of MA enrollees and, thus, the exit of high-risk score decedents restrains the year-to-year growth of average FFS risk scores by slightly more than it does MA scores.

Because most new enrollees in FFS are newly-eligible to Medicare, and FFS is losing higher-risk beneficiaries, there has been downward pressure on the average FFS risk scores compared to those in MA. Approximately 50% of the difference between the MA and FFS sectors in the growth of risk scores is due to enrollment patterns and approximately 50% is due to the more rapid growth in risk scores for beneficiaries who stay in the same sector in consecutive years.

We have continued to analyze coding pattern differences with a particular focus on "disease scores" and "stayers." The "disease score" is the HCC portion of the risk score that plans and FFS providers affect by their reporting of diagnoses codes. "Stayers" are those beneficiaries who remained in MA for at least two years and, therefore, (1) whose risk score in a payment year was calculated using diagnoses submitted by an MA plan in the previous year and (2) whose change in disease score is due entirely to MA diagnosis reporting. We compared the coding patterns of these beneficiaries with those who stayed in FFS for at least two years. Based on our careful consideration of this data, we have concluded that there exists a difference in coding patterns between MA and FFS.

CMS has found that MA stayer disease scores increase faster then FFS stayer disease scores, even after adjusting for age distribution and survivor status. The absolute difference in disease score growth between MA and FFS was about 0.015 in 2004-2005 and in 2005-2006. This difference in disease score growth increased to 0.025 in 2006-2007. We will have the results for the 2007-2008 cohort prior to the publication of the 2010 Announcement.

In compliance with Section 1853(k)(2)(B)(iv)(III), we are planning to use the methodology specified below to make an adjustment to Part C risk scores in 2010.

CALCULATION OF THE 2010 CODING PATTERN DIFFERENCE ADJUSTMENT FACTOR:

CMS intends to apply a coding pattern difference adjustment in 2010 that takes into account differences in disease score growth. We are planning to adjust for differences in disease score growth for the period 2007-2010, which constitutes three years of growth (2007-2008, 2008-2009, and 2009-2010) and is consistent with the payment years specified in statute for which CMS must adjust risk scores.

CMS is planning to calculate the 2010 MA coding pattern difference adjustment as follows:

1. Calculate difference factor. The difference factor is calculated as the average annual difference in MA and FFS stayer disease score growth. CMS calculates this average difference across as many stayer cohorts as are available.
   - Create Stayer cohorts
     - For each cohort, we defined MA stayers as those beneficiaries who were in a Part C plan in the July of each cohort year, as well as in each respective data collection year. For example, for the 2004-2005 stayer cohort, we include beneficiaries who were in a Part C plan in July 2004 and July 2005, and in all of 2003 and 2004 (the respective data collection years).
     - Similarly, we defined FFS stayers as those beneficiaries who were in FFS in the July of each cohort year and in each of the respective data collection years.
     - We have created MA and FFS stayer cohorts for 2004-2005, 2005-2006, and 2006-2007.
     - The data to allow us to create a 2007-2008 cohort will be available after the Advance Notice is released. We plan to add these data to our calculations of the MA coding pattern difference adjustment factor.
   - Calculate the difference in disease score growth between MA and FFS for each cohort: We calculate the change in the average disease score change for each MA and FFS cohort, and then subtract the FFS disease scores growth from the MA disease score growth. The following adjustments are made in calculating the difference in disease score growth:
     - We rebase each disease score so that the 1.0 in any given year is the FFS average. For example, we divide the 2004 FFS and MA disease scores by the 2004 FFS average risk score, and the 2005 FFS and MA disease scores by the 2005 FFS average risk scores. Rebasing puts the MA and FFS disease scores on the same scale so that comparisons can be made across years.
     - We adjust the resulting difference for age and survivor status: Because the age distribution in FFS is not the same as that in MA, and because disease score growth varies by age, we are adjusting the results to account for age differences between the two sectors. We then recalculate the average change in disease score.
   - The average annual difference in disease score growth is calculated as the average across each cohort's difference in disease score growth, weighted by the number of MA stayers in each cohort year. We turn the average annual difference into a percentage by dividing through by the average of the rebased risk score in year 2 of each cohort year.

- The average annual difference factor based on the three existing cohorts is 1.75%. We plan to add the results of the 2007-2008 cohort to the analysis and announce the updated difference factor in the 2010 Announcement in April 2009.

2. Calculate MA enrollment duration factor (EDF)
   - The EDF is the average length of time that beneficiaries have been enrolled in the MA program as defined below.
   - The EDF accounts for the fact that MA enrollees have been enrolled in Medicare Advantage for varying lengths of time.
   - Tabulate the EDF over the past three (3) years. Ideally, we would make these calculations for those beneficiaries who are enrolled in MA in payment year 2010. Since the enrollees in the payment year are unknown at the time of calculation of this factor, we approximate this count by tabulating the EDF over three (3) years for those enrolled in the January prior to the payment year.
   - In order to tabulate the EDF, we start with the number of full risk enrollees in MA in the current year (in this case, 2009) and count the number who were also in an MA plan for at least seven (7) months in the previous (data collection) year (in this case, 2008). We then add to this count the number of beneficiaries who were enrolled in MA in 2009, at least seven (7) months in 2008, and at least seven (7) months in 2007. We continue this summation back for a total of three (3) years to obtain the aggregate years of MA enrollment.
   - We then divide the total number of enrollment years by the number of full risk enrollees in the starting year who were enrolled at least seven (7) months in the year before the starting year to obtain the average enrollment length of time, or EDF.
   - The preliminary EDF for three (3) years, tabulated for enrollees in January 2009, is 2.45.

3. Apply the EDF to the difference factor to obtain MA coding pattern difference factor
   - Based on calculations using the three existing cohorts, the coding difference adjustment factor for three years would be 4.29% (1.75% * 2.45). We will update the MA coding pattern difference factor when we obtain results from the 2007-2008 cohort and will announce the final adjustment factor in the 2010 Announcement.

4. Operationalize MA coding pattern difference factor in order to apply factor to all enrollees in the payment year.
   - We will adjust coding difference factor by the percent of enrollees who are stayers in the year prior to the payment year (to approximate the proportion in the payment year), in order to obtain an adjustment factor which we can apply to all enrollees in the payment system.
   - The stayer percentage that we are planning to use is the percent of stayers enrolled in Part C plans in January 2009. The preliminary percentage is 87.3%.
   - **The adjustment applied to Part C risk scores, using data from the existing three cohorts, would be a reduction of 3.74%.** We plan to update this MA coding pattern

difference adjustment factor with data from the 2007-2008 cohort and announce the final adjustment factor in the 2010 Announcement in April 2009.

While we are planning to adjust for differences in disease score growth for the three-year period 2008-2010, we also are considering other possible alternative approaches that would involve adjusting for disease score growth over a different numbers of years.

For payment year 2010, we considered an adjustment for differences in disease score growth since 2004, the first year of comprehensive risk adjustment. This would represent disease score growth over a six year period, i.e., 2004 to 2010. An adjustment on this basis would represent the broadest measure of differences in coding patterns. In our 2009 Advance Notice, we proposed to base an adjustment, that we ultimately did not make in that year, on just one year's worth of differential disease score growth.

We invite comments on our decision to adjust for differences in disease score growth for the three-year period 2008-2010, as well as alternative approaches involving a greater or smaller number of years. We will consider all comments carefully, and may adopt any of these approaches in the final notice.

The MA coding pattern difference adjustment will be taken into account when we calculate budget neutrality for 2010.

We consider the MA coding pattern difference adjustment as a needed statutory correction to payments for 2010, as required by the DRA. In the future, the adjustment will no longer be needed once we have enough years of encounter data from Part C plans so that we can calibrate the Part C risk adjustment model on plan data. Once we are able to calibrate the Part C risk adjustment model on plan data, we would also develop the model normalization factor based on plan coding trends, which we anticipate will be adequate to maintain an average risk score of 1.0. We will be releasing guidance in 2009 regarding the collection of encounter data from Part C plans.

Section E. ESRD Payment

Pursuant to Section 1853(a)(1)(H) of the Act, CMS has the authority to establish "separate rates of payment" with respect to ESRD beneficiaries.

E1. Transition to New ESRD Payment

As announced in the 2008 and 2009 Advance Notices, CMS continues the phase-in of the revised State capitation rates used to determine payments for enrollees in dialysis and transplant status. For payment year 2010, CMS will pay for ESRD dialysis and transplant enrollees using a blend of 25% of the old State ratebook (in use through 2007) and 75% of the revised State ratebook (implemented in 2008). The revised ESRD State ratebook reflects the dialysis-only trend. During the transition period, we will continue to trend forward both the old and the revised State rates using the same dialysis-only growth trend. CMS is not rebasing the ESRD Dialysis State rates for 2010.

The full transition schedule is as follows. CMS payments for ESRD dialysis and transplant beneficiaries enrolled in MA plans will be:

- In 2008 (year 1): a blend of 75% old ratebook-based payments and 25% revised ratebook-based payments.
- In 2009 (year 2): a blend of 50% old ratebook-based payment and 50% revised ratebook-based payments.
- In 2010 (year 3): a blend of 25% old ratebook-based payments and 75% revised ratebook-based payments.
- In 2011: 100% of the revised ratebook.

In States where the revised dialysis rates are higher than the blended State rates, we will apply the revised ESRD State rates.

E2. ESRD Functioning Graft Payments

CMS pays for Functioning Graft enrollees with risk scores calculated using the aged-disabled CMS-HCC model coefficients, with the exception of the coefficient for HCC174 (Major Organ Transplant), which is not constrained, and the Functioning Graft factors, which are additive to the functioning graft risk scores. Because CMS recalibrates the functioning graft coefficients along with the dialysis model, for 2010 CMS will continue to use the functioning graft coefficients published in the 2008 Advance Notice (published April 2, 2007), when the ESRD dialysis model was last recalibrated. See Section B3 for a discussion of the normalization factors to be used with the functioning graft risk scores.

Section F. IME Phase Out

Section 161 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) requires CMS to phase out indirect medical education (IME) amounts from MA capitation rates. PACE programs are excluded from the IME payment phase out. Payment to teaching facilities for indirect medical education expenses for MA plan enrollees will continue to be made under fee-for-service Medicare.

For purposes of making this adjustment, we will be calculating IME in the 2010 FFS rates. This amount will serve as the basis for the 2010 amount that we will carve out of the rates. Effectively, the maximum reduction that any specific county capitation rate can experience in any year beginning with 2010 due to this IME phase out provision is 0.60% of the total FFS rate. In the second year, the maximum cumulative reduction any specific county can experience due to IME phase out is 1.20% of the FFS rate. And in the third year the maximum cumulative reduction is 1.8%, and so on. The absolute effect of the IME phase out on each county will be determined by the amount of IME included in the rate. We will recalculate the IME amount in rebasing years. In non-rebasing years, we will grow the IME amount by the national growth percentage. To help plans identify the impact, CMS will separately identify the amount of IME for each county rate in the 2010 ratebook. We will also publish the rates with and without the IME reduction for the year.

Section G. Location of Network Areas for PFFS Plans in Plan Year 2011

Section 162(a)(1) of MIPPA amended section 1852(d) of the Act by creating a new requirement for certain MA PFFS plans to establish contracts with providers. Specifically, for plan year 2011 and subsequent plan years, MIPPA requires that MA PFFS plans that are operating in a network area (as defined in section 1852(d)(5)(B) of the Act) must meet the access standards described in

section 1852(d)(4)(B) of the Act through contracts with providers. These PFFS plans may no longer meet access standards by establishing payment rates that are not less than the rates that apply under Original Medicare and having providers deemed to be contracted as described in §422.216(f).

"Network area" is defined in section 1852(d)(5)(B) of the Act, for a given plan year, as the area that the Secretary identifies (in the announcement of the risk and other factors to be used in adjusting MA capitation rates for each MA payment area for the previous plan year) as "having at least 2 network-based plans (as defined in section 1852(d)(5)(C) of the Act) with enrollment as of the first day of the year in which the announcement is made." For purposes of this requirement, we interpret "having" a network-based plan with enrollment an area to mean having a network-based plan in the area that is generally open to enrollment. Thus, an area that has only one network-based plan that is generally open to enrollment, along with other limited enrollment network-based plans, such as a plan limited to members of an employer group or special needs population, would not meet this test.

"Network-based plan" is defined in section 1852(d)(5)(C) of the Act as (1) an MA plan that is a coordinated care plan as described in section 1851(a)(2)(A)(i) of the Act, excluding non-network regional PPOs; (2) a network-based MSA plan; or (3) a section 1876 cost plan. The types of coordinated care plans that meet the definition of a network-based plan are HMOs, PSOs, local PPOs, as well as regional PPOs in those areas where it is meeting access requirements through written contracts with providers.

As required by MIPPA, for purposes of identifying the location of the network areas for plan year 2011, we determined whether at least two network-based plans with enrollment as of January 1, 2009 exist in each of the counties in the U.S., including its 5 territories and the District of Columbia. In some cases, network areas consist of partial counties and are identified by zip codes. The list of network areas for plan year 2011 can be downloaded from the following website: http://www.cms.hhs.gov/PrivateFeeforServicePlans/.

An existing PFFS plan may have some counties (or partial counties) in its current service area that meet the definition of a network area and other counties (or partial counties) that do not. As we stated in our guidance document located at: http://www.cms.hhs.gov/ManagedCareMarketing/Downloads/MIPPA_Imp_memo091208Final.pdf, , CMS will not permit an MA organization offering a PFFS plan to operate a mixed model where some counties (or partial counties) in the plan's service area are considered network areas and other counties (or partial counties) that are non-network areas (where there are no network-based plan options or only one other network-based plan).

For plan year 2011 and subsequent plan years, the MA organization must establish a unique plan with a service area consisting of the counties (or partial counties) that are network areas and another plan with a service area consisting of the counties (or partial counties) that are non-network areas. The MA organization must file separate plan benefit packages for the PFFS plan that will operate in network areas and the plan that will operate in non-network areas.

PFFS plans operating in network areas in 2011 must establish networks of contracted providers to furnish services in these areas in accordance with section 1852(d)(4)(B) of the Act in order to meet Medicare access to services requirements. PFFS plans may not use alternate methods to meet access requirements in network areas. If an existing PFFS plan is not able to establish a

network of contracted providers that CMS determines to be adequate in a network area, then the plan must exit from that area in plan year 2011. If an MA organization is not able to establish a network of contracted providers that CMS determines to be adequate in a network area, then it may not offer a PFFS plan in that area in plan year 2011 and subsequent years. PFFS plans operating in non-network areas can continue to meet access requirements by establishing payment rates that are not less than the rates that apply under Original Medicare (see §422.114(a)(2)(i)) and having providers deemed to be contracted as provided under §422.216(f).

Implementation of this MIPPA requirement will result in a significant change to the way many PFFS plans will meet access requirements beginning in 2011. CMS will not accept Notices of Intent and applications for non-network PFFS products for those counties (or partial counties) determined to be network areas. As indicated above, the list of network areas for plan year 2011 can be downloaded from the PFFS website.

Regardless of whether a PFFS plan meets access requirements exclusively through deeming or is subject to the requirement that it establish a network of providers with signed contracts, providers who do not have a contract with the PFFS plan continue to have the option of accepting a PFFS plan's terms & conditions of payment and becoming a deemed provider as described in §422.216(f).

Section H. Continuation of Clinical Trial Policy

In 2010, we will continue the policy of paying on a fee-for-service basis for clinical trial items and services provided to MA plan members that are covered under the relevant National Coverage Determinations on clinical trials.

Section I. Adjustment to FFS Per Capita Costs for VA-DOD Costs

Section 1853(c)(1)(D)(iii) of the Act directs the Secretary to make an appropriate adjustment to the payment rates to reflect CMS' "estimate, on a per capita basis, of the amount of additional payments that would have been made in the area involved under this title if individuals entitled to benefits under this title had not received services from facilities of the Department of Defense or the Department of Veterans Affairs."

To approximate an adjustment to the county fee for service (FFS) payment rates, the Office of the Actuary (OACT) first analyzed the cost impact of removing dual-eligibles from the Medicare claims and enrollments.[1] Specifically, OACT calculated the ratio of standardized per capita costs of all Medicare beneficiaries excluding dual-eligibles (or non-veterans) to all Medicare beneficiaries (or all beneficiaries) for each county. The analysis was based on FFS data for calendar years 2004-2006.

OACT then multiplied 2009 FFS rates by the ratios calculated and analyzed the resulting change in rates for each county. OACT looked at the rate changes between the 2009 FFS rates calculated for all beneficiaries and the rates calculated for the non-veterans only. The rate changes do not reflect the impact of any FFS rate minimums. OACT found that the impact for

[1] For this analysis, dual-eligibles are defined as those Medicare beneficiaries who are also eligible to receive care through the Veterans Health Administration (VHA). CMS received eligibility data from the VHA, but because of regulatory requirements, CMS has not yet received eligibility data from the DoD.

adjusting total FFS costs to non-veteran FFS costs produces results that approximate a normal curve - the distribution is symmetric (approximately half of the counties would receive an increase, and half of the counties would receive a decrease) – and - although there are limited outliers - most of the values are tightly clustered about the mean, which is -$0.56 (i.e., a rate reduction of $0.56). This analysis shows that the differences in costs between non-veterans and all beneficiaries are more attributable to normal, random variation than to distinctly different costs for these two populations.

When payment rate minimums are applied, the number of affected counties is further reduced. Of the 2,991 counties currently receiving the minimum payment (i.e., "M" counties) only 45 counties would have FFS rate increases large enough to raise their payment above the current minimum; of these, only 21 counties would have payment rate increases of more than $12.50. For the remaining 136 counties (i.e., "S" counties), 75 counties would have payment rate increases; of these, only 33 counties would receive increases of more than $12.50.

Based on the above analysis, OACT concludes that there is insufficient evidence to incorporate any VA adjustment into the rate making process for 2010. This conclusion is based on the view that the differences observed between the two populations appear to be normal, random variations and not indicative of true underlying differences of the FFS costs between the total and the non-veteran population. OACT plans to revisit this analysis for future plan years. Once data from DoD is received, OACT will reassess the appropriateness of a rate adjustment (per section 1853(c)(1)(D)(iii) of the Act) that encompasses the impact of both VA and DoD dual-eligible populations.

Section J. Calculation and Source Data of MSP Factor

Currently, CMS makes a contract-level payment adjustment to MA payments to account for the lower expected cost to plans for enrollees who are working aged (WA) and working disabled (WD). This is referred to as the Medicare Secondary Payer (MSP) adjustment. As with FFS Medicare, MA organizations are expected to avoid costs or collect from the primary insurers for such individuals.

Under the current methodology for calculating the contract level MSP adjustment, each MA organization surveys the March cohort of its aged and disabled members and reports to CMS those with coverage primary to Medicare due to WA and WD status. The MSP status of non-responders to the survey is determined from the Common Working File (CWF). Using this information, CMS calculates a contract-level MSP payment adjustment factor.

CMS has established a centralized COB operation by consolidating under a single contractor entity, the COB contractor, the performance of all activities that support the collection, management, and reporting of other insurance coverage of Medicare beneficiaries. CMS requires the COB contractor to maintain a comprehensive health care insurance profile on all Medicare beneficiaries. As a result of these activities, CMS now has a comprehensive in-house source of MSP information. These COB data are the source data for all Medicare FFS and Part D MSP activities.

Given that Medicare now has a comprehensive in-house source of MSP information, beginning for payment year 2010, CMS will no longer require that MA organizations conduct, nor will we

use the results of, the plan surveys. Rather, CMS will adjust for MSP status at the beneficiary level in the MARx payment system using the COB data.

Attachment III. Changes in the Payment Methodology for Medicare Part D for CY 2010

Section A. Benefit Design

A1. Medicare Part D Benefit Parameters: Annual Adjustments for Defined Standard Benefit in 2010

In accordance with section 1860D-2(b) of the Social Security Act (the Act), CMS must update the statutory parameters for the defined standard Part D prescription drug benefit each year. These parameters include the annual deductible, initial coverage limit, annual out-of-pocket threshold, and minimum copayments for costs above the annual out-of-pocket threshold. As required by statute, the parameters for the defined standard benefit are indexed to the percentage increase in average per capita total Part D drug expenses for Medicare beneficiaries. Accordingly, the actuarial value of the drug benefit increases along with any increase in Part D drug expenses, and the defined standard Part D benefit continues to cover a constant share of Part D drug expenses from year to year. The Part D benefit parameters are updated using two indexing methods specified by statute: (i) the annual percentage increase in average expenditures for Part D drugs per eligible beneficiary or the "annual percentage increase", and (ii) the annual percentage increase in the Consumer Price Index (CPI) (all items, U.S. city average).

As required by statute, the first indexing method, the "annual percentage increase," is used to update the following Part D benefit parameters:

(i) the deductible, initial coverage limit, and out-of-pocket threshold for the defined standard benefit;
(ii) minimum copayments for costs above the annual out-of-pocket threshold;
(iii) maximum copayments below the out-of-pocket threshold for certain low-income full subsidy eligible enrollees;
(iv) the deductible for partial low-income subsidy (LIS) eligible enrollees; and
(v) maximum copayments above the out-of-pocket threshold for partial LIS eligible enrollees.

The benefit parameters listed above will be increased by 3.13% for 2010 as summarized by Table III-1 below. This increase reflects the 2009 annual percentage trend of 5.79% as well as a multiplicative update of -2.52% for prior year revisions. Please see Attachment V for additional information on the calculation of the annual percentage increase.

Per 42 CFR 423.886(b)(3), the cost threshold and cost limit for qualified retiree prescription drug plans are updated after 2006 in the same manner as the deductible and out-of-pocket threshold for the defined standard benefit. Thus, the "annual percentage increase" will be used to update these parameters as well. The cost threshold and cost limit for qualified retiree prescription drug plans will be increased by 3.13% from their 2009 values.

The statute requires CMS to use the second indexing method, the annual percentage increase in the CPI, to update the maximum copayments below the out-of-pocket threshold for full benefit dual eligible enrollees with incomes that do not exceed 100% of the Federal poverty line. These maximum copayments will be increased by 2.06% for 2010 as summarized in Table III-1 below.

This increase reflects the 2009 annual percentage trend in CPI of 0.36%, as well as a multiplicative update of 1.70% for prior year revisions. Please see Attachment V for additional information on the calculation of the annual percentage increase in the CPI.

Table III-1. Updated Part D Benefit Parameters for Defined Standard Benefit, Low-Income Subsidy, and Retiree Drug Subsidy

Annual Percentage Increases

	Annual percentage trend for 2009	Prior year revisions	Annual percentage increase for 2009
Applied to all parameters but (1)	5.79%	-2.52%	3.13%
CPI (all items, U.S. city average): Applied to (1)	0.36%	1.70%	2.06%

Part D Benefit Parameters

	2009	2010
Standard Benefit Design Parameters		
Deductible	$295	$305
Initial Coverage Limit	$2,700	$2,780
Out-of-Pocket Threshold	$4,350	$4,500
Total Covered Part D Drug Spend at OOP Threshold (2)	$6,153.75	$6,356.25
Minimum Cost-sharing in Catastrophic Coverage Portion of Benefit		
Generic/Preferred Multi-Source Drug	$2.40	$2.50
Other	$6.00	$6.20
Part D Full Benefit Dual Eligible Parameters		
Copayments for Institutionalized Beneficiaries	$0.00	$0.00
Maximum Copayments for Non-Institutionalized Beneficiaries		
Up to or at 100% FPL		
Up to Out-of-Pocket Threshold (1)		
Generic/Preferred Multi-Source Drug (3)	$1.10	$1.10
Other (3)	$3.20	$3.30
Above Out-of-Pocket Threshold	$0.00	$0.00
Over 100% FPL		
Up to Out-of-Pocket Threshold		
Generic/Preferred Multi-Source Drug	$2.40	$2.50
Other	$6.00	$6.20
Above Out-of Pocket Threshold	$0.00	$0.00
Part D Non-Full Benefit Dual Eligible Full Subsidy Parameters		
Resources ≤ $6,600 (individuals) or ≤ $9,910 (couples) (4)		
Maximum Copayments up to Out-of-Pocket Threshold		
Generic/Preferred Multi-Source Drug	$2.40	$2.50
Other	$6.00	$6.20
Maximum Copayments above Out-of-Pocket Threshold	$0.00	$0.00
Resources bet $6,600-$11,010 (ind) or $9,910-$22,010 (couples) (4)		
Deductible (3)	$60.00	$60.00
Coinsurance up to Out-of-Pocket Threshold	15%	15%
Maximum Copayments above Out-of-Pocket Threshold		
Generic/Preferred Multi-Source Drug	$2.40	$2.50
Other	$6.00	$6.20
Part D Non-Full Benefit Dual Eligible Partial Subsidy Parameters		
Deductible (3)	$60.00	$62.00
Coinsurance up to Out-of-Pocket Threshold	15%	15%
Maximum Copayments above Out-of-Pocket Threshold		
Generic/Preferred Multi-Source Drug	$2.40	$2.50
Other	$6.00	$6.20
Retiree Drug Subsidy Amounts		
Cost Threshold	$295	$305.00
Cost Limit	$6,000	$6,200

(1) CPI adjustment applies to copayments for non-institutionalized beneficiaries up to or at 100% FPL.

(2) Amount of total drug spending required to attain out-of-pocket threshold in the defined standard benefit if beneficiary does not have prescription drug coverage through a group health plan, insurance, government-funded health program or similar third party arrangement.

(3) The increases to the LIS deductible, generic/preferred multi-source drugs and other drugs copayments are applied to the unrounded 2009 values of $60.13, $1.08, and $3.23 respectively.

(4) The actual amount of resources allowable will be updated for contract year 2010.

Section B. Bidding

B1. Reporting Drug Costs When Contracting with a Pharmacy Benefit Manager (PBM)

For contract years 2006 – 2009, Part D sponsors that contracted with a pharmacy benefit manager (PBM) were permitted to report either the amount paid to the PBM or the amount paid to the pharmacy when calculating beneficiary cost sharing, reporting drug costs on prescription drug event (PDE) records, and developing Part D bids. In order to ensure transparency in bid development and the reporting of drug costs, Part D sponsors were required each year to submit an attestation, the "Attestation of Pricing Approach", which identified for each Part D plan the pricing approach that was used in the development of the Part D bid and also would be used to calculate beneficiary cost-sharing and report drug costs to CMS.

In the Final Rule with Comment, "Revisions to the Medicare Advantage and Prescription Drug Benefit Programs", published on January 12, 2009, CMS revised various Part D definitions to clarify that, effective contract year 2010, Part D sponsors must use the amount paid to the pharmacy (or other dispensing provider) as the basis for reporting drug costs to CMS. Under this rule, Part D sponsors are required to use the amount paid to the pharmacy as the basis for: (i) calculating beneficiary cost sharing; (ii) accumulating gross covered drug costs; (iii) calculating true out-of-pocket (TrOOP) costs; (iv) reporting drug costs on Prescription Drug Event (PDE) records; and (v) developing Part D bids. Therefore, Part D sponsors will no longer be permitted to use the amount paid to the PBM to determine beneficiary cost sharing and report drug cost. This policy creates a uniform definition of drug costs for all Part D sponsors and ensures that Part D sponsors' administrative costs are excluded from the drug costs used to determine beneficiary cost sharing and Part D reinsurance and risk corridor payments.

As a result of this regulatory change, effective contract year 2010, Part D sponsors must use the negotiated amount paid to the dispensing provider at the point of sale as the basis for drug costs in the development of Part D bids. For Part D sponsors that contract with a PBM, amounts paid to the PBM for the drug that exceed the amounts paid to the pharmacy must be included in the administrative expense component of the bid. All Part D sponsors are strongly encouraged to include provisions in their contracts with PBMs that ensure compliance with this policy and other CMS reporting requirements. Please note that starting contract year 2010, Part D sponsors will not be required to submit the Attestation of Pricing Approach because all sponsors will use the amount paid to the pharmacy for developing Part D bids and reporting drug costs to CMS.

B2. Reinsurance Payment Demonstration Plans

In 2006, CMS implemented the Part D Reinsurance Payment Demonstration in response to concerns in the MMA Conference Committee Report that the reinsurance provisions of the Part D benefit as they relate to the True Out-Of-Pocket (TrOOP) threshold established in section 1860D-2(b)(4)(B) of the Act, could create a disincentive for Part D sponsors to provide enhanced alternative prescription drug coverage. As an incentive for Part D sponsors to offer supplemental drug coverage to Medicare beneficiaries, Medicare pays participating Part D plans under the Part D Reinsurance Payment Demonstration a capitated reinsurance payment that is actuarially equivalent to the federal reinsurance payments they would otherwise receive when a beneficiary reaches the catastrophic phase of the Part D benefit ($4,500 in TrOOP costs for 2010).

Given that 2010 is the last scheduled year for the Part D Reinsurance Payment Demonstration, CMS will not accept any new or expanded applications for reinsurance demonstration plans to be

offered in 2010. However, flexible capitated, fixed capitated, and Medicare Advantage rebate option plans that were offered in 2009 may continue through 2010.

This demonstration must be budget neutral such that the expected Medicare costs under the demonstration are no more than the expected costs to the Medicare program in the absence of the demonstration. In order to ensure budget neutrality, the capitated reinsurance payments for all plans offered under the Part D Reinsurance Payment Demonstration will be offset by $10.77 per member per year in 2010. When developing the 2010 bids for flexible capitated, fixed capitated, and Medicare Advantage rebate option plans, Part D sponsors should reflect this offset amount in the direct administrative expense line item of the Bid Pricing Tool (BPT).

Section C. Risk Adjustment

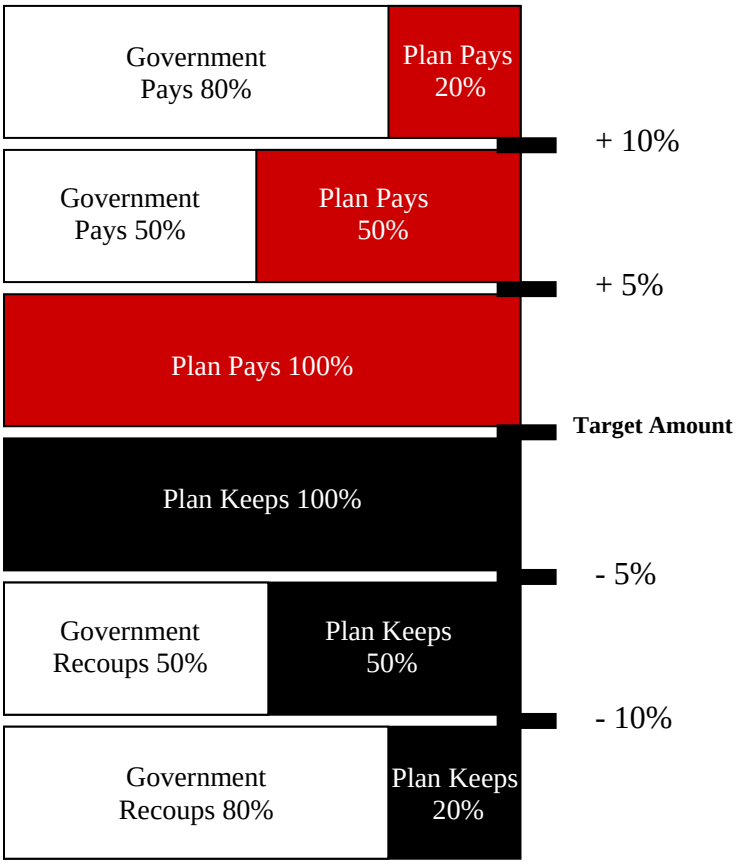
C1. Normalization Factor for the RxHCC Model

Please see Section B, item B4 in Attachment II, Changes in the Payment Methodology for Original Medicare Benefits for CY 2010.

Section D. Payment Reconciliation

Pursuant to section 1860D-15(e) of the Act and the regulations at 42 CFR 423.336, the risk percentages and payment adjustments for Part D risk sharing are unchanged from contract year 2009. The risk percentages for the first and second thresholds remain at 5% and 10% of the target amount respectively for 2010. The payment adjustments for the first and second corridors are 50% and 80% respectively. Please see Figure 1 below which illustrates the risk corridors for 2008-2011.

Figure 1. Part D Risk Corridors for 2008-2011



Risk sharing when a plan's adjusted allowable risk corridor costs (AARCC) exceed the target amount:
For the portion of a plan's adjusted allowable risk corridor costs (AARCC) that is between the target amount and the first threshold upper limit (105% of the target amount), the Part D sponsor pays 100% of this amount. For the portion of the plan's AARCC that is between the first threshold upper limit and the second threshold upper limit (110% of the target amount), the government pays 50% and the plan pays 50%. For the portion of the plan's AARCC that exceeds the second threshold upper limit, the government pays 80% and the plan pays 20%.

Risk sharing when a plan's adjusted allowable risk corridor costs (AARCC) are below the target amount:
If a plan's adjusted allowable risk corridor costs (AARCC) are between the target amount and the first threshold lower limit (95% of the target amount), the plan keeps 100% of the difference between the target amount and the plan's AARCC. If a plan's AARCC are between the first threshold lower limit and the second threshold lower limit (90% of the target amount), the government recoups 50% of the difference between the first threshold lower limit and the plan's AARC. The plan would keep 50% of the difference between the first threshold lower limit and the plan's AARC as well as 100% of the difference between the target amount and first threshold lower limit. If a plan's AARCC are less than the second threshold lower limit, the government recoups 80% of the difference between the plan's AARCC and the second threshold lower limit

as well as 50% of the difference between the first and second threshold lower limits. In this case, the plan would keep 20% of the difference between the plan's AARCC and the second threshold lower limit, 50% of the difference between the first and second threshold lower limits, and 100% of the difference between the target amount and the first threshold lower limit.

Attachment IV.
Medicare Part D Benefit Parameters for the Defined Standard Benefit: Annual Adjustments for 2010

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) directs CMS to update the statutory parameters for the defined standard Part D drug benefit each year. These parameters include the standard deductible, initial coverage limit, and catastrophic coverage threshold, and minimum copayments for costs above the annual out-of-pocket threshold. In addition, CMS is statutorily required to update the parameters for the low income subsidy benefit and the cost threshold and cost limit for qualified retiree prescription drug plans eligible for the Retiree Drug Subsidy. Included in this notice are (i) the methodologies for updating these parameters, (ii) the updated parameter amounts for the Part D defined standard benefit and low-income subsidy benefit for 2010, and (iii) the updated cost threshold and cost limit for qualified retiree prescription drug plans.

As required by statute, the parameters for the defined standard benefit formula are indexed to the percentage increase in average per capita total Part D drug expenses for Medicare beneficiaries. Accordingly, the actuarial value of the drug benefit increases along with any increase in drug expenses, and the defined standard Part D benefit continues to cover a constant share of drug expenses from year to year.

All of the Part D benefit parameters are updated using one of two indexing methods specified by statute: (i) the annual percentage increase in average expenditures for Part D drugs per eligible beneficiary, and (ii) the annual percentage increase in the Consumer Price Index (CPI) (all items, U.S. city average).

I. Annual Percentage Increase in Average Expenditures for Part D Drugs Per Eligible Beneficiary

Section 1860D-2(b)(6) of the Social Security Act defines the "annual percentage increase" as "the annual percentage increase in average per capita aggregate expenditures for covered Part D drugs in the United States for Part D eligible individuals, as determined by the Secretary for the 12-month period ending in July of the previous year using such methods as the Secretary shall specify." The following parameters are updated using the "annual percentage increase":

Deductible: From $295 in 2009 and rounded to the nearest multiple of $5.

Initial Coverage Limit: From $2,700 in 2009 and rounded to the nearest multiple of $10.

Out-of-Pocket Threshold: From $4,350 in 2009 and rounded to the nearest multiple of $50.

Minimum Cost-Sharing in the Catastrophic Coverage Portion of the Benefit: From $2.40 per generic or preferred drug that is a multi-source drug, and $6.00 for all other drugs in 2009, and rounded to the nearest multiple of $0.05.

Maximum Copayments below the Out-of-Pocket Threshold for certain Low Income Full Subsidy Eligible Enrollees: From $2.40 per generic or preferred drug that is a multi-source drug, and $6.00 for all other drugs in 2009, and rounded to the nearest multiple of $0.05.

Deductible for Low Income (Partial) Subsidy Eligible Enrollees: From $60[2] in 2009 and rounded to the nearest $1.

Maximum Copayments above the Out-of-Pocket Threshold for Low Income (Partial) Subsidy Eligible Enrollees: From $2.40 per generic or preferred drug that is a multi-source drug, and $6.00 for all other drugs in 2009, and rounded to the nearest multiple of $0.05.

II. Annual Percentage Increase in Consumer Price Index, All Urban Consumers (all items, U.S. city average)

Section 1860D-14(a)(4) of the Social Security Act specifies that the annual percentage increase in the CPI, All Urban Consumers (all items, U.S. city average) as of September of the previous year is used to update the maximum copayments below the out-of-pocket threshold for full benefit dual eligible enrollees with incomes that do not exceed 100% of the Federal poverty line. These copayments are increased from $1.10 per generic or preferred drug that is a multi-source drug, and $3.20 for all other drugs in 2009[3], and rounded to the nearest multiple of $0.05 and $0.10, respectively.

III. Calculation Methodology

Annual Percentage Increase

For the 2007 and 2008 contract years, the annual percentage increases, as defined in section 1860D-2(b)(6) of the Social Security Act, were based on the National Health Expenditure (NHE) prescription drug per capita estimates because sufficient Part D program data was not available. Beginning with the 2009 contract year, the annual percentage increases are based on Part D program data. For the 2010 contract year benefit parameters, Part D program data is used to calculate the annual percentage trend as follows:

$$\frac{\text{August 2008} - \text{July 2009}}{\text{August 2007} - \text{July 2008}} = \frac{\$2{,}829.52}{\$2{,}674.62} = 1.0579$$

In the formula, the average per capita cost for August 2007 – July 2008 ($2,674.62) is calculated from actual Part D prescription drug event (PDE) data and the average per capita cost for August 2008 – July 2009 ($2,829.52) is calculated based on actual Part D PDE data incurred from August – December, 2008 and projected through July, 2009.

The 2010 benefit parameters reflect the 2009 annual percentage trend as well as a revision to the prior estimates for prior years' annual percentage increases. Based on updated NHE prescription drug per capita costs and PDE data, the 2007, 2008 and 2009 increases are now estimated to be

[2] Consistent with the statutory requirements of 1860D-14(a)(4)(B) of the Social Security Act, the update for the deductible for low income (partial) subsidy eligible enrollees is applied to the unrounded 2009 value of $60.13.
[3] Consistent with the statutory requirements of 1860D-14(a)(4)(A) of the Social Security Act, the copayments are increased from the unrounded 2009 values of $1.08 per generic or preferred drug that is a multi-source drug, and $3.23 for all other drugs.

6.42%, 5.33% and 6.12%. Accordingly, the 2010 benefit parameters reflect a multiplicative update of -2.52% for prior year revisions. In summary, the 2009 parameters outlined in section I are updated by 3.13% for 2010 as summarized by Table IV-1.

Table IV-1. Annual Percentage Increase

Annual percentage trend for July 2009	5.79%
Prior year revisions	(2.52%)
Annual percentage increase for 2009	3.13%

Note: Percentages are multiplicative, not additive. Values are carried to additional decimal places and may not agree to the rounded values presented above.

Annual Percentage Increase in Consumer Price Index, All Urban Consumers (all items, U.S. city average)

The annual percentage increase in the CPI as of September of the previous year referenced in section 1860D-14(a)(4)(A)(ii) is interpreted to mean that, for contract year 2010, the September 2009 CPI should be used in the calculation of the index. To ensure that plan sponsors and CMS have sufficient time to incorporate the cost-sharing requirements into benefit, marketing material and systems development, the methodology to calculate this update includes an estimate of the September 2009 CPI. The annual percentage trend in CPI for contract year 2010 is calculated as follows:

$$\frac{\text{Projected September 2009 CPI}}{\text{Actual September 2008 CPI}} \text{ or } \frac{219.6}{218.8} = 1.004$$

The 2010 benefit parameters reflect the 2009 annual percentage trend in the CPI, as well as a revision to the prior estimate for the 2008 annual percentage increase. The 2009 parameter update reflected an annual percentage trend in CPI of 2.60%. Based on the actual reported CPI for September 2008, the September 2008 CPI increase is now estimated to be 4.94%. Thus, the 2010 update reflects a multiplicative 1.70% correction for prior year revisions. In summary, the cost sharing items outlined in section II are updated by 2.06% for 2010 as summarized by Table IV-2.

Table IV-2. Cumulative Annual Percentage Increase in CPI

Annual percentage trend for September 2009	1.004%
Prior year revisions	1.70%
Annual percentage increase for 2009	2.06%

Note: Percentages are multiplicative, not additive. Values are carried to additional decimal places and may not agree to the rounded values presented above.

IV. Part D Payment Demonstration Adjustment

The fixed capitated option of the Part D Payment Demonstration includes a catastrophic benefit that begins at the total drug expense corresponding to the out-of-pocket threshold in the Defined Standard Benefit. For 2010, this amount is increased from $6.153.75 in 2009 to $6,356.25. Specifically, this is the minimum amount of total covered Part D drug expenditures that will have occurred when the beneficiary reaches the out-of-pocket threshold of $4,500 in 2010 in the

defined standard benefit. This expense level is determined arithmetically as a function of the 2010 out-of-pocket threshold (as opposed to being indexed directly).

V. Retiree Drug Subsidy Amounts

As outlined in §423.886(b)(3) of the regulations implementing the Part D benefit, the cost threshold and cost limit for qualified retiree prescription drug plans that end in years after 2006 are adjusted in the same manner as the annual Part D deductible and out-of-pocket threshold are adjusted under §423.104(d)(1)(ii) and (d)(5)(iii)(B), respectively. Specifically, they are adjusted by the "annual percentage increase" as defined previously in this document and the cost threshold is rounded the nearest multiple of $5 and the cost limit is rounded to the nearest multiple of $50. The cost threshold and cost limit are defined as $275 and $5,600, respectively, for plans that end in 2008, and, as $295 and $6,000, respectively, for plans that end in 2009. For 2010, the cost threshold is increased to $305, and the cost limit is increased to $6,200.

February 19, 2010

NOTE TO: Medicare Advantage Organizations, Prescription Drug Plan Sponsors, and Other Interested Parties

SUBJECT: Advance Notice of Methodological Changes for Calendar Year (CY) 2011 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2011 Call Letter

In accordance with Section 1853(b)(2) of the Social Security Act (the Act), we are notifying you of planned changes in the MA capitation rate methodology and risk adjustment methodology applied under Part C of the Act for CY 2011. Preliminary estimates of the national per capita MA growth percentage and other MA payment methodology changes for CY 2011 are also discussed. For 2011, CMS will announce the MA capitation rates on the first Monday in April 2010, in accordance with the timetable established in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA).

Attachment I shows the preliminary estimates of the national per capita MA growth percentage, which is a key factor in determining the MA capitation rates. Attachment II sets forth the changes in payment methodology for CY 2011 for original Medicare benefits. Attachment III set forth the changes in payment methodology for CY 2011 for Part D benefits. Attachment IV presents the annual adjustments for CY 2011 to the Medicare Part D benefit parameters for the defined standard benefit. Attachment V presents the preliminary CMS-HCC and RxHCC risk adjustment factors. Attachment VI provides the draft CY 2011 Call Letter for Medicare Advantage (MA) organizations (MAOs); section 1876 cost-based contractors; prescription drug plan (PDP) sponsors; demonstrations; Programs of All-Inclusive Care for the Elderly (PACE) organizations; and employer and union-sponsored group plans, including employer/union-only group waiver plans (EGWPs). The Call Letter contains information these plan sponsor organizations will find useful as they prepare their bids for the new contract year.

The Advance Notice/Call Letter has been drafted assuming current law. If new legislation is enacted after this Notice is released and before the April Rate Announcement is published, CMS will incorporate changes in the Rate Announcement.

Comments or questions may be submitted electronically to the following address: AdvanceNotice2011@cms.hhs.gov. Comments or questions also may be mailed to:

Deondra Moseley
Centers for Medicare & Medicaid Services
7500 Security Boulevard
S2-22-25
Baltimore, Maryland 21244

In order to receive consideration prior to the April 5, 2010 release of the Announcement of Calendar Year (CY) 2011 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies, comments must be received by 6:00 PM Eastern time on Friday, March 5, 2010.

/ s /
Jonathan Blum
Acting Director
Center for Drug and Health Plan Choice

/ s /
Paul Spitalnic, A.S.A., M.A.A.A.
Director
Parts C & D Actuarial Group
Office of the Actuary

Attachments

2011 ADVANCE NOTICE
TABLE OF CONTENTS

Attachment I. Preliminary Estimate of the National Per Capita Growth Percentage for Calendar Year 2011

Section 1853 (k)(1)(B) of the Social Security Act (the Act) provides that, for years when CMS is "rebasing" the amount representing the actuarial value of costs under original fee-for-service (FFS) Medicare, the MA capitation rate for a payment area will be based on the greater of the adjusted average per capita cost or the prior year's capitation rate for the area updated by the national per capita MA growth percentage (with no adjustment to this percentage for over- or under-estimates for years before 2004). CMS is rebasing the FFS rates for CY 2011.

The current estimate of the change in the national per capita MA growth percentage for aged and disabled enrollees combined in CY 2011 is 1.38 percent. This estimate reflects an underlying trend change for CY 2011 in per capita costs of 1.75 percent and, as required under section 1853(c)(6)(C) of the Act, adjustments to the estimates for prior years as indicated in the table below. Our new estimates are lower than the estimates actually used in calculating the CY 2010 capitation rate book for CYs 2004, 2005, 2006, and 2008 and higher for CYs 2007, 2009, and 2010 than were published April 6, 2009. Section 1853(c)(1)(D)(i) of the Act, as added by sections 4101(e) and 4102(d) of the Health Information Technology for Economic and Clinical Health Act (HITECH Act), requires that electronic health record (EHR) incentive payments be excluded from the calculation of the adjusted average per capita cost.

The following tables summarize the estimates for the change in the national per capita MA growth percentage for aged/disabled rates (Table I-1) and ESRD rates (Table I-2).

Table I-1. National Per Capita MA Growth Percentage – Aged/disabled

	Aged	Disabled	Aged+Disabled
2011 Trend Change	1.69%	2.07%	1.75%
Revision to CY 2010 Estimate	0.19%	0.45%	0.20%
Revision to CY 2009 Estimate	0.23%	2.37%	0.56%
Revision to CY 2008 Estimate	-0.42%	0.44%	-0.30%
Revision to CY 2007 Estimate	0.10%	-0.26%	0.04%
Revision to CY 2006 Estimate	-0.39%	-0.42%	-0.41%
Revision to CY 2005 Estimate	0.06%	-1.36%	-0.13%
Revision to CY 2004 Estimate	-0.31%	-0.32%	-0.31%
Total Change	1.13%	2.95%	1.38%

Notes: The total percentage change is multiplicative, not additive, and may not exactly match due to rounding.

For 2011, CMS will retabulate the ESRD State rates with fee-for-service costs based on 2008 data and a recalibrated ESRD risk model. The table below shows the dialysis-only national

growth percentage for each year between 2008 and 2011. The final rate for 2011 will be the greater of the estimated 2011 fee-for-service amount or the CY 2010 dialysis-only rate standardized with the recalibrated coefficients and increased by 2 percent.

Table I-2. National Per Capita MA Growth Percentage -- ESRD

	ESRD
2011 Trend Change	3.78%
2010 Trend Change	1.24%
2009 Trend Change	3.65%
Total Trend	8.90%

Notes: The total percentage change is multiplicative, not additive, and may not exactly match due to rounding.

These estimates are preliminary and could change before the final rates are announced on April 5, 2010 in the Announcement of Calendar Year (CY) 2011 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies. Further details on the derivation of the national per capita MA growth percentage will also be presented in the April 5, 2010 Announcement.

Attachment II. Changes in the Payment Methodology for Original Medicare Benefits for CY 2011

Section A. Recalibration and Clinical Update of the CMS-HCC Risk Adjustment Model

The CMS-HCC risk adjustment model is used to adjust payments for Part C benefits offered by MA plans and PACE organizations to aged/disabled beneficiaries. The CMS-HCC model includes both diseases and demographic factors. There are separate sets of coefficients for beneficiaries in the community, beneficiaries in long term care institutions, and new enrollees. The CMS-HCC model was first used for payment in 2004 and has been recalibrated two times since then (2007 and 2009).

In 2011, CMS will implement an updated version of the CMS-HCC risk adjustment model, including the coefficients for the community, institutional, and new enrollee segments of the model. The 2011 model will encompass both updates to the data years used to recalibrate the model and a clinical revision of the diagnoses included in each hierarchical condition category (HCC).

CMS recalibrated the CMS-HCC risk adjustment model using data from FFS claims, specifically, 2006 diagnoses were used to predict 2007 expenditures. In addition to using more recent data years in recalibrating the model, CMS also undertook a clinical update that involved reviewing the assignment of all ICD-9 diagnoses codes to diagnosis groupings that are used as the building blocks of the condition categories (CC). In consultation with a panel of outside clinicians, CMS reviewed the ICD-9 codes grouped with other clinically similar ICD-9 codes. These diagnosis groupings were then mapped to condition categories based on similar clinical characteristics and severity, and cost implications. Both the panel of clinicians and analyses of cost data informed the creation of condition categories.

Coefficients for condition categories were estimated by regressing the total expenditure for A/B benefits for each beneficiary onto their demographic factors and condition categories, as indicated by their diagnoses. Resulting dollar coefficients represent the marginal (additional) cost of the condition or demographic factor (e.g., age/sex group, Medicaid status, disability status).

Changes to the condition categories – additions, deletion, and revisions – are based on each category's ability to predict costs for Medicare Parts A and B benefits. Condition categories that don't predict costs well –because the coefficient is small, the t-value is low, the number of beneficiaries with a certain condition is small so the coefficient is unstable, or the condition doesn't have well specified diagnostic coding – are not included in the model. HCCs in the current model are subject to revision, regrouping, or deletion.

In a final step, hierarchies were imposed on the condition categories, assuring that more advanced and costly forms of a condition are reflected in a higher coefficient.

There were no changes in the demographic factors used in the CMS-HCC model, although we used the more recent and comprehensive sources of Medicaid – MMA State files, Territory-reported, and plan-reported -- in calibrating the model.

In order to use the risk adjustment model to calculate risk scores for payment, we create relative factors for each demographic factor and HCC in the model. We do this by dividing all the dollar coefficients by the average per capita predicted expenditure for a specific year (i.e., the "denominator year"). For 2011, CMS used the predicted per capita costs for 2009. The relative factors are used to calculate risk scores for individual beneficiaries, which will average 1.0 in the denominator year for the FFS population. The denominator, which is used to create relatives for all segments of the CMS-HCC model, is $8,034.71.

Differences between the current model and the revised model will occur for several reasons. Changes in the marginal cost attributable to an HCC, relative to changes in the average cost, can alter the relative factor associated with that HCC. Similarly, changes in the marginal cost attributable to an HCC, relative to changes in the marginal costs attributable to all other HCCs, can also result in changes in the relative factor associated with that HCC. In addition, changes in the relative factors will result from changes in the assignment of ICD-9 codes to HCCs, as well as the addition or deletion of HCCs to the model.

Although the recalibrated model retains an average 1.0 risk score, individual beneficiaries' risk scores may change, as may plan average risk scores, depending on each individual beneficiaries' combination of diagnoses.

Changes to model

The 2011 model has 87 HCCs, up from 70. The increase in HCCs is a result of new HCCs added to the model and the splitting of several existing HCCs. Below we discuss the major changes in HCCs.

<u>HCCs added to the model</u>:

HCCs related to two levels of severity of dementia have been added to the CMS-HCC model: dementia with complications and dementia without complications. Dementia HCCs were added to the model due to the high costs associated with the condition.

Two new HCCs related to metabolic disorders were added: "Other significant endocrine and metabolic disorders" and "Morbid Obesity." Although BMI codes have been used inconsistently, we believe that they will become more important in coding.

In addition, we have added "Fibrosis of the Lung and Other Chronic Lung Disorders" and "Exudative Macular Degeneration."

Changes to existing HCCs:

A number of diseases that are currently included in HCCs with other related conditions have been broken out into their own HCCs. These conditions include quadriplegia, cerebral palsy, ALS and other motor neuron disease, and athereosclerosis of the extremities with ulceration or gangrene. Additional conditions that have been broken out into separate HCCs are pressure ulcers and kidney disease. Four HCCs for pressure ulcers are included in the model. However, these four HCCs are constrained to be equal to each other. The reason for this decision is that the diagnoses codes for the severity of pressure ulcers are new in FY2010 and were not available for the data years when we recalibrated the model. Instead, the model was recalibrated using pressure ulcer diagnoses codes available in the 2006 data – codes that did not specify severity. As more data become available, we expect these factors will be differentiated.

The current trio of kidney-related diseases – dialysis status, renal failure, and nephritis – are broken out further by dividing "Renal Failure" into "Acute Renal Failure" and five severity levels of chronic kidney disease (CKD). Since CKD coding is developing, we have constrained the CKD HCCs to equal the same coefficient.

The 2011 model consolidates the number of diabetes HCCs from the five HCCs in the current model to three: diabetes with acute complications, diabetes with chronic complications, and diabetes without complications.

Disease interactions: The coefficients for the community model continue to have six disease interactions, the net result of the following changes: three disease interactions were removed, three were added, two were retained, and one was modified.

- The disease interactions retained from the current model are: Diabetes*CHF and CHF*COPD
- The Renal*CHF interaction term has been modified in that "renal disease" now encompasses all kidney-related HCCs, instead of just renal failure.
- The disease interactions that were removed are: Diabetes*CVD, COPD*CVD*CAD, and Renal Failure*CHF*diabetes.
- New disease interaction terms are: Sepsis*Cardiorespiratory failure, Cancer*Immune disorders, and COPD*Cardiorespiratory failure.

The institutional set of coefficients now has twelve disease interactions instead of five. It retains two interactions from the current model -- Diabetes*CHF and CHF* COPD – and adds ten new disease interaction terms:

- COPD*Cardiorespiratory failure
- Sepsis*Pressure Ulcer
- Sepsis*Artificial Openings for Feeding or Elimination
- Artificial Openings for Feeding or Elimination*Pressure Ulcer
- COPD*Aspiration and Specified Bacterial Pneumonias

- Aspiration and Specified Bacterial Pneumonias*Pressure Ulcer
- Sepsis*Aspiration and Specified Bacterial Pneumonias
- Schizophrenia*COPD
- Schizophrenia*CHF
- Schizophrenia*Seizure Disorders and Convulsions

Disabled interactions: The community set of coefficients retains all five existing disabled-disease interactions and adds two additional disabled-disease interactions: Disabled*Chronic Pancreatitis and Disabled*Complications of Specified Implanted Device or Graft.

The institutional set of coefficients retains one of the four disabled-disease interactions – Disabled*Opportunistic infections – and adds five new disabled-disease interactions:

- Disabled*CHF
- Disabled*Pressure Ulcer
- Disabled*Chronic Ulcer of the Skin, Except Pressure Ulcer
- Disabled*Bone/Joint Muscle Infections/Necrosis
- Disabled*Multiple Sclerosis

CMS continues to include Medicaid as a demographic factor in the CMS-HCC risk adjustment model, which incorporates attributes of title XIX eligible beneficiaries, including low income status. CMS also considered including a factor reflecting the costs of low income Medicare beneficiaries who are not Medicaid eligible, using data on those beneficiaries who have qualified for the low income subsidy under Part D (but who are not Medicaid eligible). When included in the model, the coefficient for this additional low income factor was quite low. Further, a low t-value (< 2) indicated that the predictive power of the coefficient was not reliable. Thus, we did not include a factor for low income (but not Medicaid eligible) in the updated CMS-HCC model.

In Attachment V of this Notice, we provide draft relative factors for each HCC in each segment of the aged-disabled model. Table 1 in Attachment provides the draft factors of the community and institutional segments of the CMS-HCC model. Table 2 provides the new enrollee factors. Table 3 provides the updated hierarchies for the revised HCCs, and Table 4 provides a comparative list of current and revised HCCs.

Section B. New Enrollee Risk Scores for Chronic SNPs

New enrollee risk scores are demographic-only risk scores and are used as in payment for beneficiaries who are not full risk (do not have 12 months of Part B in the data collection period). MA organizations that offer chronic condition Special Needs Plans (SNPs) have expressed concern that the new enrollee risk scores do not reflect the full risk of their enrollees, given that these beneficiaries must have certain conditions to be enrolled in these plans. For 2011, CMS will develop a methodology that will allow us to adjust new enrollee risk scores for beneficiaries enrolled in chronic condition SNPs to take into account the condition(s) that

enrollees in these particular SNPs must have as a condition of enrollment. CMS will release the final methodology in the 2011 Announcement.

Section C. Normalization Factors

When we calibrate a risk adjustment model and normalize the risk scores to 1.0, we produce a fixed set of dollar expenditures and coefficients appropriate to the population and data for that calibration year. When the model with fixed coefficients is used to predict expenditures for other years, predictions for prior years are lower and predictions for succeeding years are higher than for the calibration year. Because average predicted expenditures increase after the model calibration year due to coding and population changes, CMS applies a normalization factor to adjust beneficiaries' risk scores so that the average risk score is 1.0 in subsequent years.

The normalization factor is derived by first using the model to predict risk scores over a number of years. Next, we trend the risk scores to determine the annual percent change in the risk score. This annual trend is then compounded by the number of years between the model denominator year and the payment year to produce the normalization factor.

Below are the preliminary normalization factors for each model. The final normalization factors will be published in the 2011 Announcement, to be released April 5, 2010.

C1. Normalization Factor for the CMS-HCC Model

The preliminary 2011 normalization factor for the aged-disabled model is 1.031.

To calculate the normalization factor for the CMS-HCC risk adjustment model, CMS used the risk adjustment model to be implemented in 2011 to calculate five years of risk scores for the FFS population. For the 2011 normalization factor, CMS used risk scores from 2005-2009 to calculate an annual trend, which was then compounded for two years, to adjust for two years of FFS risk score growth, i.e., from the denominator year of 2009 to the payment year of 2011.

C2. Normalization Factor for the ESRD Dialysis Model

The preliminary 2011 normalization factor for the ESRD dialysis model is 1.008.

To calculate the normalization factor for the CMS-HCC ESRD dialysis model, CMS uses the ESRD risk adjustment model to be implemented in 2011 and calculates five years of dialysis risk scores for the FFS population. For the 2011 normalization factor, CMS used risk scores from 2005-2009 to calculate an annual trend. The 2011 factor will adjust for two years of risk score growth, i.e., from the denominator year of 2009 to the payment year of 2011, and will be applied at a phased-in percentage of 100%. (As discussed in the 2008 Advance Notice, the ESRD Dialysis normalization factor is being applied on the same transition schedule as is the transition of the ESRD State ratebook; see Section G1.)

C3. Normalization Factor for Functioning Graft Enrollees' Risk Scores

The preliminary 2011 normalization factor for the Functioning Graft segment of the ESRD risk adjustment model is the same as that used for the CMS-HCC model: 1.031.

We calculate the functioning graft normalization factor using the same annual trend that we use in calculating the normalization factor for the aged/disabled risk scores under the CMS-HCC model because the functioning graft model uses the same factors as the CMS-HCC model, with the exception of several HCCs that are modified for this population of beneficiaries.

C4. Normalization Factor for the Rx Hierarchical Condition Category (RxHCC) Model

The preliminary 2011 normalization factor for the RxHCC model is 1.029. This normalization factor reflects a trend calculated on three years of risk score data (2006-2008).

In 2011, we intend to normalize Part D risk scores based on Part D enrollees, as we did in 2010. This helps ensure that the average enrollee risk score equals 1.0 and keeps the base beneficiary premium at the appropriate proportion of aggregate plan payment: approximately 25.5 percent from the base beneficiary premium and 74.5 percent from the government. To calculate the normalization factor for the RxHCC risk adjustment model, CMS used the risk adjustment model to be implemented in 2011 and calculated three years of risk scores for the population of Medicare beneficiaries enrolled in Part D plans. We used only three years of data for the trend because we only had Part D enrollees' risk scores for 2006 through 2008. We then compounded the annual trend for three years, to adjust for three years of Part D risk score growth, i.e., from the denominator year of 2008 to the payment year of 2011.

Section D. Aged/Disabled MSP Factor

MA capitation rates are calculated as if Medicare were always the primary payer; adjustments to the rates for situations in which Medicare is secondary are made as part of actual payment. The MSP adjustment factor is applied as a reduction to payment for working aged and working disabled beneficiaries. The MSP factor is calculated as the ratio of the actual Medicare spending for all MSP beneficiary months to the predicted amount of Medicare spending that the model predicts for these MSP beneficiary months. Actual spending was calculated using the 2007 claims from the same analytic files used to recalibrate the CMS-HCC model. The predicted amount was calculated using the newly recalibrated CMS-HCC model. MSP status was determined using the working aged/working disabled status indicator from the Medicare Enrollee Database (EDB) for 2007.

CMS has recalculated the MSP adjustment factor for working aged and working disabled beneficiaries. The current aged/disabled MSP factor of 0.174 will be revised; the preliminary 2011 aged/disabled MSP factor is 0.163.

Section E. Frailty Adjustment

E1. Frailty Adjustment Factors

CMS has recalibrated the frailty factors for CY 2011. The purpose of frailty adjustment is to predict the Medicare expenditures of community populations with functional impairments that are unexplained by the CMS-HCC risk adjustment model. Whenever CMS recalibrates the CMS-HCC risk adjustment model, the amount of unexplained Medicare expenditures can change. Thus, it is necessary to simultaneously recalibrate the frailty factors. For 2011, only payments made to PACE organizations will be adjusted for frailty. Table II-1 below and Appendix V presents the preliminary recalibrated frailty factors for CY 2011.

Table II-1. Preliminary Recalibrated Frailty Factors for CY 2011

ADL	2009 Factors (Non-Medicaid)	2011 Recalibrated Factors (Non-Medicaid)	2009 Factors (Medicaid)	2011 Recalibrated Factors (Medicaid)
0	-0.093	-0.079	-0.180	-0.201
1-2	+0.112	+0.118	+0.035	+0.000
3-4	+0.201	+0.187	+0.155	+0.105
5-6	+0.381	+0.335	+0.200	+0.121

CMS is not proposing to change the way we calculate the contract-level frailty score; we will use the results from each contract's 2010 HOS-M survey to calculate each contract-level frailty score for CY2011.

E2. Frailty Adjustment Transition for PACE organizations

Frailty adjustment will be applied to payment to PACE organizations using the transition schedule published in the 2008 Announcement (published April 2, 2007). PACE frailty scores for payment year 2011 will be calculated at a blend of 25% of the frailty factors in use prior to 2008 and 75% of the recalibrated frailty factors for 2011. The full transition schedule is as follows:

- In 2008 (year 1): 90% of the pre-2008 frailty factors and 10% of the 2008 frailty factors.
- In 2009 (year 2): 70% of the pre-2008 frailty factors and 30% of the 2009 frailty factors.
- In 2010 (year 3): 50% of the pre-2008 frailty factors and 50% of the 2009 frailty factors.
- In 2011 (year 4): 25% of the pre-2008 frailty factors and 75% of the 2011 frailty factors.
- In 2012 (year 5): 100% of the most recently calibrated frailty factors.

E3. Frailty Adjustment Transition for Certain Demonstrations

Frailty adjustment will no longer be applied to payment to the following MA plan types, per the phase-out schedule published in the 2008 Announcement (published April 2, 2007): Social Health Maintenance Organizations (S/HMOs), Minnesota Senior Health Options (MSHO)/ Minnesota Disability Health Options (MnDHO), Wisconsin Partnership Program (WPP) and Massachusetts Senior Care Options (SCO) plans.

The full phase out schedule is as follows:

- In 2008 (year 1): 75% of the pre-2008 frailty factors
- In 2009 (year 2): 50% of the pre-2008 frailty factors
- In 2010 (year 3): 25% of the pre-2008 frailty factors
- In 2011: 0% of the pre-2008 frailty factors

Section F. Adjustment for MA Coding Pattern Differences

CMS calibrates the CMS-HCC model using FFS data, and the relative factors reflect the FFS pattern of coding. CMS adjusts for the trend in the rate of increase of diagnoses codes submitted by FFS providers with the application of a normalization factor that is updated annually and that reduces risk scores with the goal that the average remains 1.0 in each payment year. Because MA coding patterns differ from those in FFS, MA risk scores increase more quickly and are, therefore, higher than they would be if MA plans coded in the same manner as FFS providers. Beginning in 2010, CMS instituted a separate adjustment to the Part C risk scores to account for differential coding patterns between MA and FFS. The adjustment for 2010 of 3.41% was based on our estimate of how much lower plans' 2010 risk scores would have been if the disease scores (the portion of the risk score attributable to diagnostic coding) for MA enrollees who stayed in an MA plan during the period 2007 to 2010 ("MA stayers") had grown at the same rate as FFS beneficiaries' risk scores during this period. In calculating the adjustment for MA coding differences, CMS removed the impact of differences in rising risk scores that are attributed to enrollment into and disenrollment out of MA plans, aging and other demographic changes, and adjusted for age and sex effects on disease coding changes.

For 2011, CMS is again proposing a coding pattern adjustment of 3.41%. As with the 2010 adjustment, this proposed adjustment reflects our estimate of differential disease score growth between MA and FFS over a three-year period. We are soliciting comments on whether CMS should revise the methodology to adjust for differential growth between 2007 and 2011. In addition, we are soliciting comments on whether our estimate of the annual differential in disease score growth should be calculated with more recent cohorts. Both of these revisions to the methodology would increase the coding pattern adjustment.

Section G. Budget Neutrality

From 2003 through 2006, CMS implemented risk adjusted payments that were budget neutral to the demographic payments made prior to, and throughout the transition to, full risk adjusted payments by applying to the risk rates 100 percent of the Budget Neutrality (BN) factor. The BN factor was calculated as the estimated difference between payments to MA organizations at 100 percent of the demographic rates and payments at 100 percent of the risk rates.

As specified by the Deficit Reduction Act of 2005, and as implemented under section 1853(k)(2)(C), the phase-out of budget-neutral risk adjusted payments began in 2007 and will be completed in 2011, when plans will receive no budget neutrality payment adjustment. As shown in the phase out schedule below, 0 percent of the BN factor will be applied to the risk rates in 2011.

Phase-out Schedule for Budget Neutral Risk Adjusted Payments:

The percentage of the BN factor that is applied to the risk rates is:

- 2007: 55%
- 2008: 40%
- 2009: 25%
- 2010: 5%
- 2011: 0%

Section H. ESRD Payment

Pursuant to Section 1853(a)(1)(H) of the Act, CMS has the authority to establish "separate rates of payment" with respect to ESRD beneficiaries.

H1. Transition to New ESRD Payment

As first announced in the 2008 Advance Notice, CMS continues the phase-in of the revised State capitation rates used to determine payments for enrollees in dialysis and transplant status.

The full transition schedule is as follows:

- In 2008 (year 1): a blend of 75% old ratebook-based payments and 25% revised ratebook-based payments.
- In 2009 (year 2): a blend of 50% old ratebook-based payment and 50% revised ratebook-based payments.
- In 2010 (year 3): a blend of 25% old ratebook-based payments and 75% revised ratebook-based payments.
- In 2011: 100% of the revised 2008 ratebook.

H2. ESRD State Rates

For 2011, CMS has revised the underlying dialysis rates based on FFS costs. To calculate dialysis State rates, CMS used Medicare FFS claims data by State for beneficiaries in dialysis status between the years 2006 and 2008 to determine the average geographic adjustment (AGA) for each State and to determine the 2008 national average per capita FFS dialysis cost. CMS then adjusted the 2008 national average by each State AGA to determine revised 2008 State rates and trended these rates to 2011 using the ESRD dialysis growth trend. To determine the 2011 ESRD rates, CMS will take the greater of the revised 2008 ESRD dialysis-only State rates grown by the ESRD growth trend to 2011 or the 2010 dialysis only rate restandardized by the new dialysis risk model grown by 2%. The final 2011 State rates will be developed by taking into account the MIPPA '08 carve-out of indirect medical education (IME) and the $5.25 ESRD user fee.

The distribution of changes in payment across plans using the revised State rates will depend on how many ESRD dialysis beneficiaries are enrolled in each plan, as well as the change in the ESRD State rates.

H3. Recalibration and Clinical Update of ESRD Risk Adjustment Models

The ESRD Risk Adjustment Model uses the same HCCs that are incorporated in the CMS-HCC model used for the risk scores of aged/disabled beneficiaries. Using these same HCCs, the ESRD model segments are calibrated using the appropriate ESRD population. Therefore, the resulting coefficients reflect cost and diagnosis coding for this subgroup of beneficiaries. Unlike the CMS-HCC model we exclude (i.e., constrain to zero) the relative factors for kidney-related HCCs and interaction terms. All of the components of the ESRD model were recalibrated for 2011:

- Dialysis: The ESRD dialysis risk adjustment model is a single set of coefficients for both community and institutional enrollees in dialysis status. The ESRD dialysis model is calibrated using diagnoses and expenditure data for all beneficiaries in FFS who are in dialysis status.
- Dialysis new enrollee: The set of demographic-only new enrollee factors are estimated for beneficiaries in dialysis status that do not have 12 months of Part B in the data collection year. The dialysis new enrollee factors are estimated using data from all FFS beneficiaries in dialysis status.
- Transplant: Transplant factors are estimated for the first three months following a transplant. The first month's factor is the largest, with months 2 and 3 smaller.
- Functioning graft: the functioning graft set of HCCs is identical to the CMS-HCC model, with the addition of a set of postgraft "add on" factors that take into account the cost of immunosuppressant drugs for this population.

- Functioning graft new enrollee: This segment of the ESRD model uses the same factors as the CMS-HCC new enrollee model, with the addition of a set of postgraft "add on" factors that take into account the cost of immunosuppressant drugs for this population.

H4. ESRD MSP Factor

Using the same methodology as used to recalculate the aged/disabled MSP factor, CMS has recalculated the MSP adjuster for ESRD beneficiaries. The current ESRD MSP adjustment factor of 0.215 will be revised; the preliminary 2011 ESRD MSP factor is 0.189. CMS will continue to apply the ESRD MSP adjustment to individual-level payments.

Section I. IME Phase Out

Section 161 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) requires CMS to phase out indirect medical education (IME) amounts from MA capitation rates. PACE programs are excluded from the IME payment phase out. Payment to teaching facilities for indirect medical education expenses for MA plan enrollees will continue to be made under fee-for-service Medicare.

For purposes of making this adjustment, we will calculate base 2011 FFS rates including the IME amount. This amount will serve as the basis for the 2011 amount that we will carve out of the rates. The absolute effect of the IME phase-out on each county will be determined by the amount of IME included in the FFS rate. By statute, however, the maximum reduction for any specific county in 2011 is 1.2% of the FFS rate. To help plans identify the impact, CMS will separately identify the amount of IME for each county rate in the 2011 ratebook. We will also publish the rates with and without the IME reduction for the year.

Section J. EHR Incentives

Section 1853(l)(1) of the Act, as added by section 4101(c) of the HITECH Act, provides for incentive payments to qualifying MA organizations for certain of their affiliated eligible professionals (EPs) and hospitals that are meaningful users of certified EHR technology during the relevant EHR reporting period for a payment year. These incentive payments to qualifying MA organizations may be available as early as calendar year 2011, payable in 2012. CMS has issued a proposed rule that would implement these provisions, CMS-0033-P, which was published on January 13, 2010.

Section K. Physician Quality Reporting Initiative (PQRI) and E-Prescribing

Payments to physicians who have contracted with MAOs generally are governed by the terms of the contract. In the case of payments to a contracting physician (whether the contract is deemed or signed) under a PFFS plan meeting access requirements by paying what Medicare would pay, the MAO is required to pay the contractor the full amount he or she would receive if the enrollee

were a Medicare beneficiary not enrolled in an MA plan. This would include bonus and incentive amounts if the physician would receive them in connection with treating a Medicare beneficiary not enrolled in an MA plan.

Physicians who have not contracted with an MAO, but who provide covered professional services to an enrollee of an MA plan offered by an organization are similarly required to be paid the amount they would receive for a non-MA enrollee, and thus would be eligible for both the Physician Quality Reporting Initiative (PQRI) bonus payment from the organization to the extent they are due such payments under the original Medicare program. This rule would also apply to payments made by a cost-contracting HMO for plan-covered services to a non-contracting physician. When a physician is determined by original Medicare to have satisfied the requirements and qualified for an incentive under the PQRI, he or she should expect to receive a bonus check from any MAOs or cost-contracting HMOs which he or she has billed as a non-contracted provider, or for which he or she has provided covered professional services under a PFFS plan that meets access standards by paying the Medicare payment rate. The amount of the PQRI payment is calculated just as it is calculated for original Medicare, that is to say a percentage (2% for 2009 and 2010) of Medicare allowed charges for covered professional services submitted to the plan during the reporting period.

When a physician is determined by Medicare to be a successful e-prescriber and qualifies for the 2% incentive under the 2009 E-prescribing Incentive Program, MAOs and cost-contracting HMOs are required to pay non-contracted physicians, and in the case of PFFS plans meeting access standards through payment, contracting physicians, 2% of the Medicare allowed charges for any applicable, covered professional services rendered in 2009 to a member of their plan. Such payments are due whether or not the non-contracting or PFFS-contracting physician has participation status under the original Medicare program. This policy also applies to non-physician practitioners who would qualify for such payments from original Medicare.

Similar to the manner in which we released 2007 and 2008 PQRI files through HPMS, a file of the providers entitled to 2009 PQRI and e-prescribing payments will be provided in the fall of 2010. (See HPMS PQRI notices dated 6/27/08 and 10/26/09.) Bonus and incentive payments for claims incurred in a given year are payable the following year in a lump sum. Additional technical guidance will be provided at the time data files are released.

Section L. Clinical Trial Policy

Medicare Advantage plans must cover all Medicare services including clinical trials. Under the authority in section 1853(c)(7) of the Act to "adjust" payment "appropriately," CMS since 2001 has provided for fee-for-service reimbursement for clinical trial costs, and permitted MA organizations to designate that such payments be made directly to the providers furnishing such services to MA enrollees. Under this arrangement, MA enrollees generally are required under the MA plan to pay FFS levels of cost sharing for the services related to clinical trials. MA plans

may reduce cost sharing related to clinical trials; however few, if any, have chosen to do so. In addition, to date, CMS has not required plans to apply these cost share amounts to the beneficiaries' out-of-pocket maximum.

In 2011, we will continue the policy of paying on a fee-for-service basis for clinical trial items and services provided to MA plan members that are covered under the relevant National Coverage Determinations on clinical trials. However, starting in 2011, as a condition for CMS making payment for MA enrollees' clinical trial costs on a fee-for-service basis, MA plans will be required to reimburse beneficiaries for cost sharing incurred for clinical trials services that exceeds the MA plans' in- network cost sharing for the same category of service. In addition, starting in 2011, clinical trial cost sharing must also be included in the out-of-pocket maximum calculation.

Section M. Adjustment to FFS Per Capita Costs for VA-DOD Costs

Section 1853(c)(1)(D)(iii) of the Act directs the Secretary to make an appropriate adjustment to the payment rates to reflect CMS' "estimate, on a per capita basis, of the amount of additional payments that would have been made in the area involved under this title if individuals entitled to benefits under this title had not received services from facilities of the Department of Defense (DoD) or the Department of Veterans Affairs." In the 2010 Advance Notice dated February 20, 2009, the Office of the Actuary (OACT) concluded that there was insufficient evidence to incorporate any VA adjustment into the rate making process and did not have DoD data to analyze.

OACT has since obtained TRICARE eligibility data from the DoD. TRICARE is the DoD's health care program that covers eligible Uniformed Services beneficiaries for medical care. The vast majority of TRICARE beneficiaries are enrolled in the TRICARE For Life (TFL) option which pays secondary to Medicare. Another TRICARE option available to TRICARE/Medicare dual-eligibles is the Uniformed Services Family Health Plan (USFHP). The USFHP is available to TRICARE members who live near selected civilian medical facilities through which the Plan delivers care. Non-emergency care must be obtained through the USFHP hospital and doctor network. USFHP is primary to Medicare (with very few exceptions) and bills are not generally submitted to Medicare.

In lieu of obtaining cost, use and diagnosis data at the beneficiary level, the methodology is the same as was used to analyze the VA data last year. The analysis was performed separately for all DoD and USFHP only enrollees and compares the average FFS costs to determine if there are significant differences between the DoD groups and the total Medicare population. To approximate an adjustment to the county fee for service (FFS) payment rates, OACT analyzed

the cost impact of removing the dual-eligibles from the Medicare claims and enrollment[1]. Specifically, OACT calculated the ratio of standardized per capita costs of all Medicare beneficiaries excluding dual-eligibles (non-DoD) to all Medicare beneficiaries (or all beneficiaries) for each county. The calculations were based on FFS data for calendar years 2004-2006.

OACT analyzed the ratios in counties with at least 10 members in the respective groups and found that there was no statistical significance of the DoD ratios but the USFHP-only ratios were significant. Accordingly, adjustments will be made to counties with at least 10 USFHP members. The adjustment will be to adjust the FFS rates by the ratios calculated. Based on applying the adjustments to the 2009 FFS rates, the average monthly FFS rate will increase in 138 affected counties by approximately $1.85, with a range of a decrease of $0.10 to an increase of $12.04 and fifteen counties will experience increases in FFS rates of $5.00 or more.

Section N. Location of Network Areas for PFFS Plans in Plan Year 2012

Section 162(a)(1) of MIPPA amended section 1852(d) of the Act by creating a new requirement for MA organizations offering certain non-employer MA PFFS plans to enter into signed contracts with a sufficient number of providers to meet the access standards applicable to coordinated care plans. Specifically, for plan year 2011 and subsequent plan years, MIPPA requires that non-employer MA PFFS plans that are offered in a network area (as defined in section 1852(d)(5)(B) of the Act) must meet the access standards described in section 1852(d)(4)(B) of the Act through signed contracts with providers. These PFFS plans may no longer meet access standards by establishing payment rates that are not less than the rates that apply under Original Medicare and having providers deemed to be contracted as described in 42 CFR 422.216(f).

"Network area" is defined in section 1852(d)(5)(B) of the Act, for a given plan year, as the area that the Secretary identifies (in the announcement of the risk and other factors to be used in adjusting MA capitation rates for each MA payment area for the previous plan year) as "having at least 2 network-based plans (as defined in section 1852(d)(5)(C) of the Act) with enrollment as of the first day of the year in which the announcement is made." The list of "network areas" for plan year 2012 will appear in the *Announcement of Calendar Year (CY) 2011 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies*. The list of "network areas" for plan year 2011 can be found on the CMS website at http://www.cms.hhs.gov/PrivateFeeforServicePlans/. We will use January 1, 2010 enrollment data to identify the location of "network areas" for plan year 2012.

[1] For this analysis, dual-eligibles are defined as those Medicare beneficiaries who are also eligible to receive care through the Department of Defense.

Attachment III. Changes in the Payment Methodology for Medicare Part D for CY 2011

Section A. Recalibration and Clinical Update of the RxHCC Risk Adjustment Model

The RxHCC risk adjustment model is used to adjust payments for Part D benefits offered by stand alone Prescription Drug Plans (PDPs), Medicare Advantage-Prescription Drug plans (MA-PDs), and PACE organizations. The RxHCC model includes both disease and demographic factors. The current RxHCC model was developed using 2000 and 2002 data from Medicaid programs and the Federal Employee Health Benefit Program and utilizes a base set of coefficients and applies multiplicative factors for beneficiaries with low income or long term institutional status. A separate set of coefficients, based on demographic factors alone, is used to calculate new enrollee risk scores. The RxHCC model was implemented for payment in 2006 and has not been recalibrated since then.

In 2011, CMS will implement an updated version of the RxHCC risk adjustment model. The 2011 model will encompass several key changes:

(1) the use of Part D program data, specifically, the use of Prescription Drug Event (PDE) data to calculate the Part D expenditures used in the recalibration of the model,
(2) updates to the data years used to recalibrate the model, and
(3) a clinical revision of the diagnoses included in each prescription drug hierarchical condition category (RxHCC).

The 2011 RxHCC model is estimated in the same manner as other HCC-based risk adjustment models, meaning that diagnoses from one year are used to predict costs (in the case of Part D, plan liability costs) in the following year.

CMS recalibrated the RxHCC risk adjustment model using diagnosis data from FFS claims and expenditure data from Prescription Drug Event (PDE) data for beneficiaries who are enrolled in Original Medicare in the base year (2006). We did not use data for beneficiaries enrolled in MA-PD plans because these plans have been submitting diagnostic data limited to the diagnoses included in the current RxHCC payment model. Without the additional diagnoses, these beneficiaries' data were not comprehensive enough for use in the clinical update. To recalibrate the model, data for 100% of FFS beneficiaries enrolled in a Part D plan were used, and 2007 diagnoses were used to predict 2008 expenditures. In addition to the data update in recalibrating the model, CMS also undertook a clinical update that involved reviewing the assignment of all ICD-9 diagnoses codes to diagnosis groupings that are used as the building blocks of the condition categories (CC). In consultation with a panel of outside clinicians, CMS reviewed the ICD-9 codes grouped with other clinically-similar ICD-9 codes. These diagnosis groupings were then mapped to condition categories based on similar clinical characteristics and severity, and cost implications. Both the panel of clinicians and analyses of cost data informed the creation of condition categories.

Coefficients for condition categories were estimated by regressing the plan liability for the Part D basic benefit for each beneficiary onto their demographic factors and condition categories, as indicated by their diagnoses. Resulting dollar coefficients represent the marginal (additional) cost of the condition or demographic factor (e.g., age/sex group, low income status, disability status).

Changes to the condition categories – additions, deletions, and revisions – are based on each category's ability to predict costs for Medicare Part D benefits. Condition categories that don't predict costs well –because the coefficient is small, the t-value is low, the number of beneficiaries with a certain condition is small so the coefficient is unstable, or the condition doesn't have well specified diagnostic coding – are not included in the model. Diagnoses mapped to condition categories that have been in the risk adjustment model are sometimes mapped to multiple condition categories, or are otherwise revised, when the costs associated with diagnoses codes with these RxHCCs differentially predict costs.

In a final step, hierarchies were imposed on the condition categories, ensuring that more advanced and costly forms of a condition are reflected in a higher coefficient.

There were no changes in the demographic factors used in the RxHCC model.

In order to use the risk adjustment model to calculate risk scores for payment, we create relative factors for each demographic factor and RxHCC in the model. The relative factors are used to calculate risk scores for individual beneficiaries, which will average 1.0 in the denominator year.

We create relative factors by dividing all the dollar coefficients by the average per capita predicted expenditure for a specific year. The denominator for the revised RxHCC risk adjustment model is developed using data for Medicare beneficiaries enrolled in both MAPDs and PDPs. We do this in order to set the average RxHCC risk score to 1.0 for the enrolled population. We used a denominator of average per capita costs for 2008 to create the relative factors for the model. The denominator, which is used to create relatives for all segments of the model, is $1,086.61.

Recalibration of the RxHCC model can result in changes in risk scores for individual beneficiaries and for average plan risk scores, depending on each individual beneficiary's combination of diagnoses.

Changes to model

The final revised RxHCC risk adjustment model is the result of clinical input regarding the composition of each RxHCC and of contribution to total medical costs. There are several key changes in the RxHCC model:

- As a result of the clinical revision of the model and changing cost patterns, the 2011 model has 78 RxHCCs, compared with the 84 RxHCCs for the model used for payment years 2006-

2010. The decrease in RxHCCs is a net result of the addition of new RxHCCs, the splitting of several existing RxHCCs, and the removal of a number of RxHCCs.

- Instead of a base model with multipliers for low income and long term institutional status, the 2011 RxHCC model will have 5 sets of coefficients: long term institutional, aged low income, aged non-low income, disabled low income, and disabled non-low income. In using PDE data, we were able to observe that these five groups of beneficiaries have distinct differences in costs, making the use of interaction terms for the disabled population unwieldy. In addition, there are variations in costs across RxHCCs in each set of coefficients that uniform multipliers could not accurately accommodate.

Differences between the current model and the revised model will occur for several reasons. In the new RxHCC model, each set of coefficients reflects the relative marginal costs of a different subset of beneficiaries. Further, changes in the marginal cost attributable to an RxHCC relative to changes in the average cost can alter the relative factor associated with that RxHCC. Similarly, changes in the marginal cost attributable to an RxHCC relative to changes in the marginal costs attributable to all other RxHCCs can also result in changes in the relative factor associated with that RxHCC. In addition, changes in the relative factors will result from changes in the assignment of ICD-9 codes to RxHCCs, as well as the addition or deletion of RxHCCs to the model.

Below we discuss the major changes in RxHCCs.

<u>New RxHCCs added to the model</u>:

Four of the newly added RxHCCs are related to developmental disabilities, including three levels of severity of mental retardation/development disability, and one RxHCC for autism.

In addition, other new RxHCCs include narcolepsy and cataplexy, morbid obesity, and gram-negative/Staphylococcus Pneumonia and Other Lung Infections.

<u>Changes to existing RxHCCs:</u>

A number of conditions were split out from RxHCCs in which they were grouped with other related conditions; newer data indicated that these conditions have distinct cost patterns that warrant the creation of separate RxHCCs. These newly separated RxHCCs are:

- Alzheimer's
- "Chronic pancreatic disease" split into "chronic pancreatitis" and other pancreatic disorders
- Sickle Cell anemia
- Pulmonary hypertension and other pulmonary heart disease, and coronary artery disease.
- Lung transplant, pancreas transplant

RxHCCs that are no longer included in the RxHCC risk adjustment model:

The following RxHCCs have been removed from the model:

- 3 RxHCCs related to Ear, Nose, Throat diseases
- 6 RxHCCs related to Urinary, Genital diseases
- 2 RxHCCs related to Injury
- Muscular Dystrophy
- Huntington's
- "Empyema, Lung Abscess, and Fungal and Parasitic Lung Infections"
- "Acute Bronchitis and Congenital Lung/Respiratory Anomaly"
- Macular Degeneration, and Glaucoma and Keratoconus (Open-Angle Glaucoma is a newly-defined RxHCC)

In Attachment V of this Notice, we provide draft coefficients for each RxHCC for each segment of the aged-disabled model.

Section B. LIS Benchmarks

The intent of the low-income benchmark is to provide fully-subsidized drug coverage options for beneficiaries with limited means, while providing strong incentives for sponsors to bid competitively. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) directs CMS to use a weighted average of plans' premiums for basic prescription drug coverage to calculate the regional low-income benchmark premium amount used in the determination of the low-income premium subsidy amount. The low-income benchmarks are released in August on the CMS website at http://www.cms.hhs.gov/MedicareAdvtgSpecRateStats/.

Under the statutorily-required weighting methodology, the low-income benchmark premium amount in certain regions is significantly lower than most plans' premiums. This is because MA-PD sponsors typically lower their Part D premiums through the application of Part C rebates. As a result, the Part D premiums for MA-PD plans tend to be lower than PDP premiums, which results in significantly lower benchmark amounts in regions with higher MA-PD penetration. The relatively low benchmarks result in many PDPs having a basic Part D premium that is not fully covered by the low-income premium subsidy. This reduces the PDP options for low-income beneficiaries in those regions and increases the number of low-income beneficiaries who need to be reassigned each year to different, fully-subsidized plans. CMS plans to continue to look into solutions to this issue for 2011.

Section C. Reinsurance Payment Demonstration

In 2006, CMS implemented the Part D Reinsurance Payment Demonstration in response to concerns noted in the Conference Report for the Medicare Prescription Drug, Improvement, and

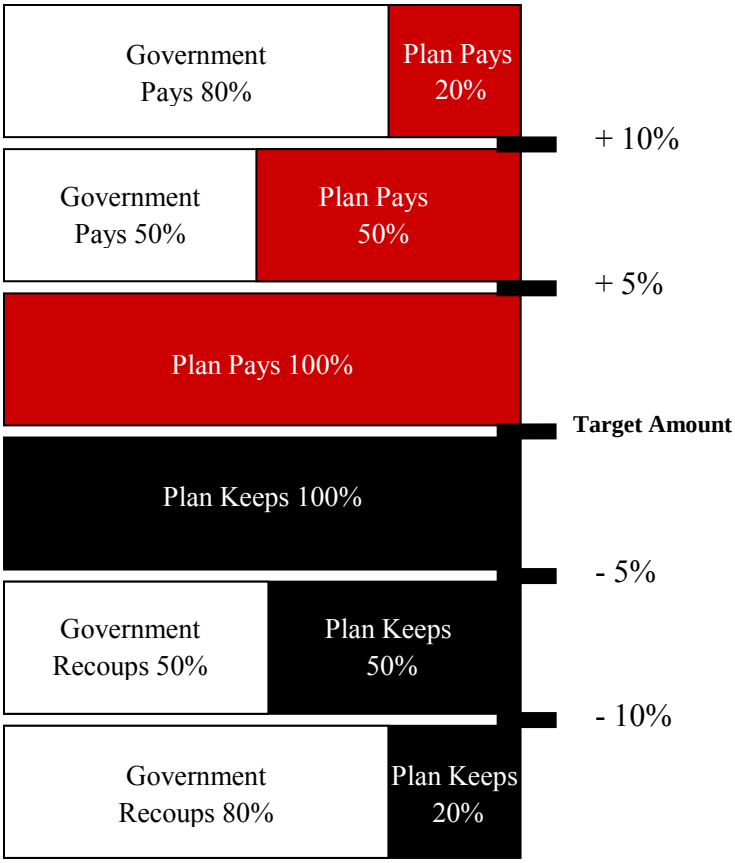
Modernization Act of 2003 regarding the reinsurance provisions of the Part D benefit. Specifically, conferees were concerned that the reinsurance provisions as they relate to the True Out-Of-Pocket (TrOOP) threshold established in section 1860D-2(b)(4)(B) of the Act, could create a disincentive for Part D sponsors to provide enhanced alternative prescription drug coverage. As an incentive for Part D sponsors to offer supplemental drug coverage to Medicare beneficiaries, under the Part D Reinsurance Payment Demonstration Medicare pays participating Part D plans a capitated reinsurance payment that is actuarially equivalent to the federal reinsurance payments they would otherwise receive when a beneficiary reaches the catastrophic phase of the Part D benefit ($4,550 in TrOOP costs for 2010).

The Part D Reinsurance Payment Demonstration was implemented as a five-year payment demonstration under which CMS applies an alternative payment methodology for Part D reinsurance. As stated in the 2010 Advance Notice, 2010 is the last year for the Part D Reinsurance Payment Demonstration. Therefore, Part D sponsors with Reinsurance Demonstration plans will not be allowed to offer such plans in 2011.

Section D. Payment Reconciliation

Pursuant to section 1860D-15(e) of the Act and the regulations at 42 CFR 423.336, the risk percentages and payment adjustments for Part D risk sharing are unchanged from contract year 2010. The risk percentages for the first and second thresholds remain at 5% and 10% of the target amount respectively for 2011. The payment adjustments for the first and second corridors are 50% and 80% respectively. Please see Figure 1 below which illustrates the risk corridors for 2008-2011.

Figure 1. Part D Risk Corridors for 2008-2011



Risk sharing when a plan's adjusted allowable risk corridor costs (AARCC) exceed the target amount:

For the portion of a plan's adjusted allowable risk corridor costs (AARCC) that is between the target amount and the first threshold upper limit (105% of the target amount), the Part D sponsor pays 100% of this amount. For the portion of the plan's AARCC that is between the first threshold upper limit and the second threshold upper limit (110% of the target amount), the government pays 50% and the plan pays 50%. For the portion of the plan's AARCC that exceeds the second threshold upper limit, the government pays 80% and the plan pays 20%.

Risk sharing when a plan's adjusted allowable risk corridor costs (AARCC) are below the target amount:

If a plan's AARCC is between the target amount and the first threshold lower limit (95% of the target amount), the plan keeps 100% of the difference between the target amount and the plan's AARCC. If a plan's AARCC is between the first threshold lower limit and the second threshold lower limit (90% of the target amount), the government recoups 50% of the difference between the first threshold lower limit and the plan's AARC. The plan would keep 50% of the difference

between the first threshold lower limit and the plan's AARC as well as 100% of the difference between the target amount and first threshold lower limit. If a plan's AARCC is less than the second threshold lower limit, the government recoups 80% of the difference between the plan's AARCC and the second threshold lower limit as well as 50% of the difference between the first and second threshold lower limits. In this case, the plan would keep 20% of the difference between the plan's AARCC and the second threshold lower limit, 50% of the difference between the first and second threshold lower limits, and 100% of the difference between the target amount and the first threshold lower limit.

Section E. Medicare Part D Benefit Parameters: Annual Adjustments for Defined Standard Benefit in 2011

In accordance with section 1860D-2(b) of the Social Security Act (the Act), CMS must update the statutory parameters for the defined standard Part D prescription drug benefit each year. These parameters include the annual deductible, initial coverage limit, annual out-of-pocket threshold, and minimum copayments for costs above the annual out-of-pocket threshold. As required by statute, the parameters for the defined standard benefit are indexed to the percentage increase in average per capita total Part D drug expenses for Medicare beneficiaries.

Accordingly, the actuarial value of the drug benefit increases along with any increase in Part D drug expenses, and the defined standard Part D benefit continues to cover a constant share of Part D drug expenses from year to year. The Part D benefit parameters are updated using two indexing methods specified by statute: (i) the annual percentage increase in average expenditures for Part D drugs per eligible beneficiary or the "annual percentage increase", and (ii) the annual percentage increase in the Consumer Price Index (CPI) (all items, U.S. city average).

As required by statute, the first indexing method, the "annual percentage increase," is used to update the following Part D benefit parameters:

(i) the deductible, initial coverage limit, and out-of-pocket threshold for the defined standard benefit;
(ii) minimum copayments for costs above the annual out-of-pocket threshold;
(iii) maximum copayments below the out-of-pocket threshold for certain low-income full subsidy eligible enrollees;
(iv) the deductible for partial low-income subsidy (LIS) eligible enrollees; and
(v) maximum copayments above the out-of-pocket threshold for partial LIS eligible enrollees.

The benefit parameters listed above will be increased by .31% for 2011 as summarized by Table III-1 below. This increase reflects the 2010 annual percentage trend of 4.63% as well as a multiplicative update of -4.13% for prior year revisions. Please see Attachment IV for additional information on the calculation of the annual percentage increase.

Per 42 CFR 423.886(b)(3), the cost threshold and cost limit for qualified retiree prescription drug plans are updated after 2006 in the same manner as the deductible and out-of-pocket threshold for the defined standard benefit. Thus, the "annual percentage increase" will be used to update these parameters as well. The cost threshold and cost limit for qualified retiree prescription drug plans will be increased by .31% from their 2010 values.

The statute requires CMS to use the second indexing method, the annual percentage increase in the CPI, to update the maximum copayments below the out-of-pocket threshold for full benefit dual eligible enrollees with incomes that do not exceed 100% of the Federal poverty line. These maximum copayments will be increased by 0% for 2011 as summarized in Table III-1 below.

This increase reflects the 2010 annual percentage trend in CPI of 1.58%, as well as a multiplicative update of -1.64% for prior year revisions. Please see Attachment IV for additional information on the calculation of the annual percentage increase in the CPI.

Table III-1. Updated Part D Benefit Parameters for Defined Standard Benefit, Low-Income Subsidy, and Retiree Drug Subsidy

Annual Percentage Increases

	Annual percentage trend for 2010	Prior year revisions	Annual percentage increase for 2010
Applied to all parameters but (1)	4.63%	-4.13%	.31%
CPI (all items, U.S. city average): Applied to (1)	1.58%	-1.64%	-.08%

Part D Benefit Parameters

	2010	2011
Standard Benefit		
Deductible	$310	$310
Initial Coverage Limit	$2,830	$2,840
Out-of-Pocket Threshold	$4,550	$4,550
Total Covered Part D Spend at Out-of-Pocket Threshold (2)	$6,440.00	$6,447.50
Minimum Cost-Sharing in Catastrophic Coverage Portion of the Benefit		
Generic/Preferred Multi-Source Drug	$2.50	$2.50
Other	$6.30	$6.30
Full Subsidy-Full Benefit Dual Eligible (FBDE) Individuals		
Deductible	$0.00	$0.00
Copayments for Institutionalized Beneficiaries		
Maximum Copayments for Non-Institutionalized Beneficiaries		
Up to or at 100% FPL		
Up to Out-of-Pocket Threshold (1)		
Generic/Preferred Multi-Source Drug (3)	$1.10	$1.10
Other (3)	$3.30	$3.30
Above Out-of-Pocket Threshold	$0.00	$0.00
Over 100% FPL		
Up to Out-of-Pocket Threshold		
Generic/Preferred Multi-Source Drug	$2.50	$2.50
Other	$6.30	$6.30
Above Out-of-Pocket Threshold	$0.00	$0.00
Full Subsidy-Non-FBDE Individuals		
Eligible for QMB/SLMB/QI, SSI or applied and income at or below 135% FPL and resources ≤ $6,600 (individuals) or ≤ $9,910 (couples) (4)		
Deductible	$0.00	$0.00
Maximum Copayments up to Out-of-Pocket Threshold		
Generic/Preferred Multi-Source Drug	$2.50	$2.50
Other	$6.30	$6.30
Maximum Copayments above Out-of-Pocket Threshold	$0.00	$0.00
Partial Subsidy		
Applied and income below 150% FPL and resources below $11,010 (individual) or $22,010 (couple)		
Deductible	$63.00	$63.00
Coinsurance up to Out-of-Pocket Threshold	15%	15%
Maximum Copayments above Out-of-Pocket Threshold		
Generic/Preferred Multi-Source Drug	$2.50	$2.50
Other	$6.30	$6.30
Retiree Drug Subsidy Amounts		
Cost Threshold	$310	$310
Cost Limit	$6,300	$6,300

(1) CPI adjustment applies to copayments for non-institutionalized beneficiaries up to or at 100% FPL.

(2) Amount of total drug spending required to attain out-of-pocket threshold in the defined standard benefit if beneficiary does not have prescription drug coverage through a group health plan, insurance, government-funded health program or similar third party arrangement.

(3) The increases to the LIS deductible, generic/preferred multi-source drugs and other drugs copayments are applied to the unrounded 2010 values of $62.93, $1.10, and $3.31, respectively.

(4) The actual amount of resources allowable will be updated for contract year 2011.

Attachment IV. Medicare Part D Benefit Parameters for the Defined Standard Benefit: Annual Adjustments for 2011

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) directs CMS to update the statutory parameters for the defined standard Part D drug benefit each year. These parameters include the standard deductible, initial coverage limit, and catastrophic coverage threshold, and minimum copayments for costs above the annual out-of-pocket threshold. In addition, CMS is statutorily required to update the parameters for the low income subsidy benefit and the cost threshold and cost limit for qualified retiree prescription drug plans eligible for the Retiree Drug Subsidy. Included in this notice are (i) the methodologies for updating these parameters, (ii) the updated parameter amounts for the Part D defined standard benefit and low-income subsidy benefit for 2011, and (iii) the updated cost threshold and cost limit for qualified retiree prescription drug plans.

As required by statute, the parameters for the defined standard benefit formula are indexed to the percentage increase in average per capita total Part D drug expenses for Medicare beneficiaries. Accordingly, the actuarial value of the drug benefit increases along with any increase in drug expenses, and the defined standard Part D benefit continues to cover a constant share of drug expenses from year to year.

All of the Part D benefit parameters are updated using one of two indexing methods specified by statute: (i) the annual percentage increase in average expenditures for Part D drugs per eligible beneficiary, and (ii) the annual percentage increase in the Consumer Price Index (CPI) (all items, U.S. city average).

I. Annual Percentage Increase in Average Expenditures for Part D Drugs Per Eligible Beneficiary

Section 1860D-2(b)(6) of the Social Security Act defines the "annual percentage increase" as "the annual percentage increase in average per capita aggregate expenditures for covered Part D drugs in the United States for Part D eligible individuals, as determined by the Secretary for the 12-month period ending in July of the previous year using such methods as the Secretary shall specify." The following parameters are updated using the "annual percentage increase":

Deductible: From $310 in 2010 and rounded to the nearest multiple of $5.

Initial Coverage Limit: From $2,830 in 2010 and rounded to the nearest multiple of $10.

Out-of-Pocket Threshold: From $4,550 in 2010 and rounded to the nearest multiple of $50.

Minimum Cost-Sharing in the Catastrophic Coverage Portion of the Benefit: From $2.50 per generic or preferred drug that is a multi-source drug, and $6.30 for all other drugs in 2010, and rounded to the nearest multiple of $0.05.

Maximum Copayments below the Out-of-Pocket Threshold for certain Low Income Full Subsidy Eligible Enrollees: From $2.50 per generic or preferred drug that is a multi-source drug, and $6.30 for all other drugs in 2010, and rounded to the nearest multiple of $0.05.

Deductible for Low Income (Partial) Subsidy Eligible Enrollees: From $63[2] in 2010 and rounded to the nearest $1.

Maximum Copayments above the Out-of-Pocket Threshold for Low Income (Partial) Subsidy Eligible Enrollees: From $2.50 per generic or preferred drug that is a multi-source drug, and $6.30 for all other drugs in 2010, and rounded to the nearest multiple of $0.05.

II. Annual Percentage Increase in Consumer Price Index, All Urban Consumers (all items, U.S. city average)

Section 1860D-14(a)(4) of the Social Security Act specifies that the annual percentage increase in the CPI, All Urban Consumers (all items, U.S. city average) as of September of the previous year is used to update the maximum copayments below the out-of-pocket threshold for full benefit dual eligible enrollees with incomes that do not exceed 100% of the Federal poverty line. These copayments are increased from $1.10 per generic or preferred drug that is a multi-source drug, and $3.30 for all other drugs in 2010[3], and rounded to the nearest multiple of $0.05 and $0.10, respectively.

III. Calculation Methodology

Annual Percentage Increase

For the 2007 and 2008 contract years, the annual percentage increases, as defined in section 1860D-2(b)(6) of the Social Security Act, were based on the National Health Expenditure (NHE) prescription drug per capita estimates because sufficient Part D program data was not available. Beginning with the 2009 contract year, the annual percentage increases are based on Part D program data. For the 2011 contract year benefit parameters, Part D program data is used to calculate the annual percentage trend as follows:

$$\frac{August\,2009 - July\,2010}{August\,2008 - July\,2009} = \frac{\$2{,}842.77}{\$2{,}716.87} = 1.0463$$

[2] Consistent with the statutory requirements of 1860D-14(a)(4)(B) of the Social Security Act, the update for the deductible for low income (partial) subsidy eligible enrollees is applied to the unrounded 2010 value of $62.93.

[3] Consistent with the statutory requirements of 1860D-14(a)(4)(A) of the Social Security Act, the copayments are increased from the unrounded 2010 values of $1.10 per generic or preferred drug that is a multi-source drug, and $3.31 for all other drugs.

In the formula, the average per capita cost for August 2008 – July 2009 ($2,716.87) is calculated from actual Part D prescription drug event (PDE) data and the average per capita cost for August 2009 – July 2010 ($2,842.77) is calculated based on actual Part D PDE data incurred from August – December, 2009 and projected through July, 2010.

The 2011 benefit parameters reflect the 2010 annual percentage trend as well as a revision to the prior estimates for prior years' annual percentage increases. Based on updated NHE prescription drug per capita costs and PDE data, the 2007, 2008, 2009 and 2010 increases are now estimated to be 6.48%, 5.12%, 4.42% and 3.22%, respectively. Accordingly, the 2011 benefit parameters reflect a multiplicative update of -4.13% for prior year revisions. In summary, the 2010 parameters outlined in section I are updated by 0.31% for 2011 as summarized by Table III-1.

Table III-1. Annual Percentage Increase

Annual percentage trend for July 2010	4.63%
Prior year revisions	-4.13%
Annual percentage increase for 2011	0.31%

Note: Percentages are multiplicative, not additive. Values are carried to additional decimal places and may not agree to the rounded values presented above.

Annual Percentage Increase in Consumer Price Index, All Urban Consumers (all items, U.S. city average)

The annual percentage increase in the CPI as of September of the previous year referenced in section 1860D-14(a)(4)(A)(ii) is interpreted to mean that, for contract year 2011, the September 2010 CPI should be used in the calculation of the index. To ensure that plan sponsors and CMS have sufficient time to incorporate the cost-sharing requirements into benefit, marketing material and systems development, the methodology to calculate this update includes an estimate of the September 2010 CPI based on the projected amount included in the President's FY2011 Budget. The September 2009 value is from the Bureau of Labor Statistics. The annual percentage trend in CPI for contract year 2011 is calculated as follows:

$$\frac{\text{Projected September 2010 CPI}}{\text{Actual September 2009 CPI}} \textit{ or } \frac{219.4}{216.0} = 1.0158$$

(Source: President's FY2011 Budget and Bureau of Labor Statistics, Department of Labor)

The 2011 benefit parameters reflect the 2010 annual percentage trend in the CPI, as well as a revision to the prior estimate for the 2009 annual percentage increase. The 2010 parameter update reflected an annual percentage trend in CPI of 0.36%. Based on the actual reported CPI for September 2009, the September 2009 CPI increase is now estimated to be -1.29%. Thus, the 2011 update reflects a multiplicative -1.64% correction for prior year revisions. In summary, the

cost sharing items outlined in section II are updated by 0% for 2011 as summarized by Table III-2.

Table III-2. Cumulative Annual Percentage Increase in CPI

Annual percentage trend for September 2010	1.58%
Prior year revisions	-1.64%
Annual percentage increase for 2010	-0.08%

Note: Percentages are multiplicative, not additive. Values are carried to additional decimal places and may not agree to the rounded values presented above.

IV. Retiree Drug Subsidy Amounts

As outlined in §423.886(b)(3) of the regulations implementing the Part D benefit, the cost threshold and cost limit for qualified retiree prescription drug plans that end in years after 2006 are adjusted in the same manner as the annual Part D deductible and out-of-pocket threshold are adjusted under §423.104(d)(1)(ii) and (d)(5)(iii)(B), respectively. Specifically, they are adjusted by the "annual percentage increase" as defined previously in this document and the cost threshold is rounded the nearest multiple of $5 and the cost limit is rounded to the nearest multiple of $50. The cost threshold and cost limit are defined as $295 and $6,000, respectively, for plans that end in 2009, and, as $310 and $6,300, respectively, for plans that end in 2010. For 2011, the cost threshold is unchanged at $310, and the cost limit is unchanged at $6,300.

Attachment V. Preliminary CMS-HCC, ESRD, and Rx-HCC Risk Adjustment Factors

Tables

Table 1. Preliminary Community and Institutional Relative Factors for the CMS-HCC Risk Adjustment Model

Variable	Disease Group	Community Factor	Institutional Factor
Female	-		-
0-34 Years		0.198	0.783
35-44 Years		0.212	0.723
45-54 Years		0.274	0.700
55-59 Years		0.359	0.805
60-64 Years		0.416	0.773
65-69 Years		0.283	1.004
70-74 Years		0.346	0.947
75-79 Years		0.428	0.874
80-84 Years		0.517	0.792
85-89 Years		0.632	0.699
90-94 Years		0.755	0.594
95 Years or Over		0.775	0.465
Male			
0-34 Years		0.079	0.994
35-44 Years		0.119	0.658
45-54 Years		0.165	0.687
55-59 Years		0.292	0.814
60-64 Years		0.332	0.877
65-69 Years		0.309	1.148
70-74 Years		0.378	1.195
75-79 Years		0.464	1.168
80-84 Years		0.565	1.104
85-89 Years		0.647	1.046
90-94 Years		0.776	0.928
95 Years or Over		0.963	0.842
Medicaid and Originally Disabled Interactions with Age and Sex			
Medicaid_Female_Aged		0.213	
Medicaid_Female_Disabled		0.104	
Medicaid_Male_Aged		0.210	
Medicaid_Male_Disabled		0.113	
Originally Disabled_Female		0.244	
Originally Disabled_Male		0.171	
Medicaid and Originally Disabled			
Medicaid			0.126
Originally Disabled			0.026

Disease Coefficients	Description Label	Community Factor	Institutional Factor
HCC1	HIV/AIDS	0.492	1.374
HCC2	Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock	0.520	0.471
HCC6	Opportunistic Infections	0.557	0.541
HCC8	Metastatic Cancer and Acute Leukemia	2.425	0.928
HCC9	Lung and Other Severe Cancers	1.006	0.610
HCC10	Lymphoma and Other Cancers	0.695	0.363

Disease Coefficients	Description Label	Community Factor	Institutional Factor
HCC11	Colorectal, Bladder, and Other Cancers	0.330	0.255
HCC12	Breast, Prostate, and Other Cancers and Tumors	0.180	0.165
HCC17	Diabetes with Acute Complications	0.344	0.434
HCC18	Diabetes with Chronic Complications	0.344	0.434
HCC19	Diabetes without Complication	0.124	0.187
HCC21	Protein-Calorie Malnutrition	0.653	0.343
HCC22	Morbid Obesity	0.342	0.353
HCC23	Other Significant Endocrine and Metabolic Disorders	0.240	0.248
HCC27	End-Stage Liver Disease	1.003	0.637
HCC28	Cirrhosis of Liver	0.425	0.343
HCC29	Chronic Hepatitis	0.313	0.343
HCC33	Intestinal Obstruction/Perforation	0.337	0.302
HCC34	Chronic Pancreatitis	0.257	0.175
HCC35	Inflammatory Bowel Disease	0.279	0.250
HCC39	Bone/Joint/Muscle Infections/Necrosis	0.423	0.386
HCC40	Rheumatoid Arthritis and Inflammatory Connective Tissue Disease	0.376	0.222
HCC46	Severe Hematological Disorders	1.078	0.638
HCC47	Disorders of Immunity	0.306	0.436
HCC48	Coagulation Defects and Other Specified Hematological Disorders	0.258	0.197
HCC51	Dementia With Complications	0.616	–
HCC52	Dementia Without Complication	0.343	–
HCC54	Drug/Alcohol Psychosis	0.358	0.051
HCC55	Drug/Alcohol Dependence	0.358	0.051
HCC57	Schizophrenia	0.471	0.274
HCC58	Major Depressive, Bipolar, and Paranoid Disorders	0.318	0.274
HCC70	Quadriplegia	1.075	0.497
HCC71	Paraplegia	0.868	0.497
HCC72	Spinal Cord Disorders/Injuries	0.441	0.191
HCC73	Amyotrophic Lateral Sclerosis and Other Motor Neuron Disease	1.016	0.294
HCC74	Cerebral Palsy	0.036	–
HCC75	Polyneuropathy	0.281	0.256
HCC76	Muscular Dystrophy	0.460	0.247
HCC77	Multiple Sclerosis	0.482	–
HCC78	Parkinson's and Huntington's Diseases	0.555	0.110
HCC79	Seizure Disorders and Convulsions	0.252	0.173
HCC80	Coma, Brain Compression/Anoxic Damage	0.533	0.103
HCC82	Respirator Dependence/Tracheostomy Status	1.732	1.567
HCC83	Respiratory Arrest	0.769	0.611
HCC84	Cardio-Respiratory Failure and Shock	0.326	0.346
HCC85	Congestive Heart Failure	0.361	0.226
HCC86	Acute Myocardial Infarction	0.283	0.394
HCC87	Unstable Angina and Other Acute Ischemic Heart Disease	0.283	0.394
HCC88	Angina Pectoris	0.210	0.366

Disease Coefficients	Description Label	Community Factor	Institutional Factor
HCC96	Specified Heart Arrhythmias	0.276	0.227
HCC99	Cerebral Hemorrhage	0.371	0.175
HCC100	Ischemic or Unspecified Stroke	0.333	0.175
HCC103	Hemiplegia/Hemiparesis	0.481	0.063
HCC104	Monoplegia, Other Paralytic Syndromes	0.212	0.063
HCC106	Atherosclerosis of the Extremities with Ulceration or Gangrene	1.313	0.773
HCC107	Vascular Disease with Complications	0.417	0.257
HCC108	Vascular Disease	0.288	0.146
HCC110	Cystic Fibrosis	0.388	0.323
HCC111	Chronic Obstructive Pulmonary Disease	0.388	0.323
HCC112	Fibrosis of Lung and Other Chronic Lung Disorders	0.294	0.252
HCC114	Aspiration and Specified Bacterial Pneumonias	0.691	0.239
HCC115	Pneumococcal Pneumonia, Empyema, Lung Abscess	0.212	0.194
HCC122	Proliferative Diabetic Retinopathy and Vitreous Hemorrhage	0.223	0.366
HCC124	Exudative Macular Degeneration	0.248	0.178
HCC134	Dialysis Status	0.617	0.538
HCC135	Acute Renal Failure	0.617	0.538
HCC136	Chronic Kidney Disease, Stage 5	0.227	0.304
HCC137	Chronic Kidney Disease, Severe (Stage 4)	0.227	0.304
HCC138	Chronic Kidney Disease, Moderate (Stage 3)	0.227	0.304
HCC139	Chronic Kidney Disease, Mild or Unspecified (Stages 1-2 or Unspecified)	0.227	0.304
HCC140	Unspecified Renal Failure	0.227	0.304
HCC141	Nephritis	0.075	0.235
HCC157	Pressure Ulcer of Skin with Necrosis Through to Muscle, Tendon, or Bone	1.071	0.284
HCC158	Pressure Ulcer of Skin with Full Thickness Skin Loss	1.071	0.284
HCC159	Pressure Ulcer of Skin with Partial Thickness Skin Loss	1.071	0.284
HCC160	Pressure Pre-Ulcer Skin Changes or Unspecified Stage	1.071	0.284
HCC161	Chronic Ulcer of Skin, Except Pressure	0.473	0.226
HCC162	Severe Skin Burn or Condition	0.458	–
HCC166	Severe Head Injury	0.533	0.103
HCC167	Major Head Injury	0.141	–
HCC169	Vertebral Fractures without Spinal Cord Injury	0.441	0.179
HCC170	Hip Fracture/Dislocation	0.363	–
HCC173	Traumatic Amputations and Complications	0.379	0.067
HCC176	Complications of Specified Implanted Device or Graft	0.555	0.369
HCC186	Major Organ Transplant or Replacement Status	1.032	1.120
HCC188	Artificial Openings for Feeding or Elimination	0.609	0.658

Disease Coefficients	Description Label	Community Factor	Institutional Factor
HCC189	Amputation Status, Lower Limb/Amputation Complications	0.804	0.384
Disease Interactions			
SEPSIS_CARD_RESP_FAIL	Sepsis*Cardiorespiratory Failure	0.634	
CANCER_IMMUNE	Cancer*Immune Disorders	1.101	
DIABETES_CHF	Diabetes*Congestive Heart Failure	0.237	0.143
CHF_COPD	Congestive Heart Failure*Chronic Obstructive Pulmonary Disease	0.255	0.159
CHF_RENAL	Congestive Heart Failure*Renal Disease	0.201	
COPD_CARD_RESP_FAIL	Chronic Obstructive Pulmonary Disease*Cardiorespiratory Failure	0.420	
CRFAIL_COPD	Cardiorespiratory Failure*Chronic Obstructive Pulmonary Disease		0.524
SEPSIS_PRESSURE_ULCER	Sepsis*Pressure Ulcer		0.538
SEPSIS_ARTIF_OPENINGS	Sepsis*Artificial Openings for Feeding or Elimination		0.453
ARTIF_OPENINGS_ PRESSURE_ULCER	Artificial Openings for Feeding or Elimination*Pressure Ulcer		0.361
COPD_ASP_SPEC_ BACT_PNEUM	Chronic Obstructive Pulmonary Disease*Aspiration and Specified Bacterial Pneumonias		0.249
ASP_SPEC_BACT_PNEUM_ PRES_ULCER	Aspiration and Specified Bacterial Pneumonias*Pressure Ulcer		0.325
SEPSIS_ASP_SPEC_ BACT_PNEUM	Sepsis*Aspiration and Specified Bacterial Pneumonias		0.387
SCHIZOPHRENIA_COPD	Schizophrenia*Chronic Obstructive Pulmonary Disease		0.187
SCHIZOPHRENIA_CHF	Schizophrenia*Congestive Heart Failure		0.220
SCHIZOPHRENIA_SEIZURES	Schizophrenia*Seizure Disorders and Convulsions		0.303
Disabled/Disease Interactions			
DISABLED_HCC6	Disabled, Opportunistic Infections	0.564	
DISABLED_HCC34	Disabled, Chronic Pancreatitis	0.757	
DISABLED_HCC46	Disabled, Severe Hematological Disorders	0.818	
DISABLED_HCC54	Disabled, Drug/Alcohol Psychosis	0.432	
DISABLED_HCC55	Disabled, Drug/Alcohol Dependence	0.147	
DISABLED_HCC110	Disabled, Cystic Fibrosis	2.397	
DISABLED_HCC176	Disabled, Complications of Specified Implanted Device or Graft	0.495	
DISABLED_HCC85	Disabled, Congestive Heart Failure		0.320
DISABLED_PRESSURE_ULCER	Disabled, Pressure Ulcer		0.421
DISABLED_HCC161	Disabled, Chronic Ulcer of the Skin, Except Pressure Ulcer		0.337
DISABLED_HCC39	Disabled, Bone/Joint Muscle Infections/Necrosis		0.624
DISABLED_HCC77	Disabled, Multiple Sclerosis		0.344
DISABLED_HCC6	Disabled, Opportunistic Infections		0.914

NOTES

1. The relative risk scores in this table were calculated by dividing the parameter estimates by the Part C national average predicted expenditures (CMS Part C Denominator). The Part C Denominator value used is $8,034.71.

2. The relative factor for HCC 160 is based on pressure ulcer, any stage, for all anatomical sites codes. The relative factor for HCC 160 is also assigned to HCCs 157, 158, and 159 in the constrained regression because the ICD9 codes for the stages of pressure ulcers are not implemented until FY09.

In the "disease interactions," the variables are defined as follows:

Artificial Openings for Feeding or Elimination = HCC 188.
Aspiration and Specified Bacterial Pneumonias = HCC 114.
Bone/Joint/Muscle Infections/Necrosis = HCC 39.
Cancer = HCCs 8-12.
Cardiorespiratory Failure = HCCs 82-84.
Chronic Obstructive Pulmonary Disease = HCCs 110-111.
Chronic Ulcer of Skin, except Pressure = HCC 161.
Congestive Heart Failure = HCC 85.
Diabetes = HCCs 17, 18, 19.
Immune Disorders = HCC 47.
Multiple Sclerosis = HCC 77.
Opportunistic Infections = HCC 6.
Pressure Ulcer = HCCs 157-160.
Renal Disease = HCCs 134-141.
Schizophrenia = HCC 57.
Seizure Disorders and Convulsions = HCC 79.
Sepsis = HCC 2.

SOURCE: RTI International analysis of 2006/2007 Medicare 5% sample.
SOURCE: RTI International analysis of 2006/2007 Medicare 100% institutional sample.

Table 2. Preliminary CMS-HCC Model Relative Factors for Aged and Disabled New Enrollees

	Non-Medicaid & Non-Originally Disabled	Medicaid & Non-Originally Disabled	Non-Medicaid & Originally Disabled	Medicaid & Originally Disabled
Female				
0-34 Years	0.453	0.784	-	-
35-44 Years	0.601	0.932	-	-
45-54 Years	0.810	1.141	-	-
55-59 Years	0.977	1.308	-	-
60-64 Years	1.082	1.414	-	-
65 Years	0.501	1.014	1.124	1.637
66 Years	0.543	1.016	1.192	1.665
67 Years	0.579	1.052	1.228	1.702
68 Years	0.598	1.071	1.247	1.721
69 Years	0.624	1.098	1.274	1.747
70-74 Years	0.737	1.233	1.327	1.823
75-79 Years	0.941	1.366	1.503	1.928
80-84 Years	1.116	1.542	1.678	2.104
85-89 Years	1.280	1.706	1.842	2.268
90-94 Years	1.372	1.797	1.934	2.359
95 Years or Over	1.247	1.672	1.809	2.234
Male				
0-34 Years	0.243	0.662	-	-
35-44 Years	0.450	0.869	-	-
45-54 Years	0.633	1.052	-	-
55-59 Years	0.825	1.244	-	-
60-64 Years	0.956	1.375	-	-
65 Years	0.542	1.096	1.109	1.663
66 Years	0.601	1.155	1.122	1.676
67 Years	0.631	1.185	1.152	1.706
68 Years	0.659	1.213	1.181	1.735
69 Years	0.680	1.234	1.202	1.756
70-74 Years	0.818	1.372	1.337	1.890
75-79 Years	1.056	1.569	1.497	2.010
80-84 Years	1.275	1.788	1.717	2.230
85-89 Years	1.446	1.960	1.888	2.401
90-94 Years	1.622	2.135	2.063	2.577
95 Years or Over	1.689	2.202	2.130	2.644

NOTES:

1. For payment purposes, a new enrollee is a beneficiary who did not have 12 months of Part B eligibility in the data collection year. The CMS-HCC new enrollee model is not based on diagnosis, but includes factors for different age and gender combinations by Medicaid and the original reason for Medicare entitlement.
2. The relative risk scores in this table were calculated by dividing the parameter estimates by the Part C national average predicted expenditures (CMS Part C Denominator). The Part C Denominator value used is $8,034.71.

SOURCE: RTI International analysis of 2006/2007 Medicare 5% sample.

Table 3. Preliminary list of Disease Hierarchies for the Revised CMS-HCC Model

DISEASE HIERARCHIES

Hierarchical Condition Category (HCC)	If the Disease Group is Listed in this column…	…Then drop the HCC(s) listed in this column
	Hierarchical Condition Category (HCC) LABEL	
8	Metastatic Cancer and Acute Leukemia	9,10,11,12
9	Lung and Other Severe Cancers	10,11,12
10	Lymphoma and Other Cancers	11,12
11	Colorectal, Bladder, and Other Cancers	12
17	Diabetes with Acute Complications	18,19
18	Diabetes with Chronic Complications	19
27	End-Stage Liver Disease	28,29,80
28	Cirrhosis of Liver	29
46	Severe Hematological Disorders	48
51	Dementia With Complications	52
54	Drug/Alcohol Psychosis	55
57	Schizophrenia	58
70	Quadriplegia	71,72,103,104,169
71	Paraplegia	72,104,169
72	Spinal Cord Disorders/Injuries	169
82	Respirator Dependence/Tracheostomy Status	83,84
83	Respiratory Arrest	84
86	Acute Myocardial Infarction	87,88
87	Unstable Angina and Other Acute Ischemic Heart Disease	88
99	Cerebral Hemorrhage	100
103	Hemiplegia/Hemiparesis	104
106	Atherosclerosis of the Extremities with Ulceration or Gangrene	107,108,161,189
107	Vascular Disease with Complications	108
110	Cystic Fibrosis	111,112
111	Chronic Obstructive Pulmonary Disease	112
114	Aspiration and Specified Bacterial Pneumonias	115
134	Dialysis Status	135,136,137,138,139,140,141
135	Acute Renal Failure	136,137,138,139,140,141
136	Chronic Kidney Disease, Stage 5	137,138,139,140,141
137	Chronic Kidney Disease, Severe (Stage 4)	138,139,140,141
138	Chronic Kidney Disease, Moderate (Stage 3)	139,140,141
139	Chronic Kidney Disease, Mild or Unspecified (Stages 1-2 or Unspecified)	140,141
140	Unspecified Renal Failure	141
157	Pressure Ulcer of Skin with Necrosis Through to Muscle, Tendon, or Bone	158,159,160,161
158	Pressure Ulcer of Skin with Full Thickness Skin Loss	159,160,161
159	Pressure Ulcer of Skin with Partial Thickness Skin Loss	160,161
160	Pressure Pre-Ulcer Skin Changes or Unspecified Stage	161
166	Severe Head Injury	80,167

How Payments are Made with a Disease Hierarchy EXAMPLE: If a beneficiary triggers HCCs 140 (Unspecified Renal Failure) and 141 (Nephritis), then HCC 141 will be dropped. In other words, payment will always be associated with the HCC in column 1, if a HCC in column 3 also occurs during the same collection period. Therefore, the organization's payment will be based on HCC 140 rather than HCC 141.

Table 4. Comparison of Current and Revised CMS-HCC Risk Adjustment Model HCCs

Current Model			Revised Model	
HCC	**Description**	**Category Short Name**	**HCC**	**Description**
HCC1	HIV/AIDS	Infection	HCC1	HIV/AIDS
HCC2	Septicemia/Shock		*HCC2*	*Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock*
HCC5	Opportunistic Infections		HCC6	Opportunistic Infections
HCC7	Metastatic Cancer and Acute Leukemia	Neoplasm	HCC8	Metastatic Cancer and Acute Leukemia
HCC8	Lung, Upper Digestive Tract, and Other Severe Cancers		HCC9	Lung and Other Severe Cancers
HCC9	Lymphatic, Head and Neck, Brain, and Other Major Cancers		HCC10	Lymphoma and Other Cancers
HCC10	Breast, Prostate, Colorectal and Other Cancers and Tumors		**HCC11**	**Colorectal, Bladder, and Other Cancers**
			HCC12	Breast, Prostate, and Other Cancers and Tumors
HCC15	Diabetes with Renal or Peripheral Circulatory Manifestation	Diabetes	HCC17	Diabetes with Acute Complications
HCC16	Diabetes with Neurologic or Other Specified Manifestation		*HCC18*	*Diabetes with Chronic Complications*
HCC17	Diabetes with Acute Complications		HCC19	Diabetes without Complication
HCC18	Diabetes with Ophthalmologic or Unspecified Manifestation			
HCC19	Diabetes without Complication			
HCC21	Protein-Calorie Malnutrition	Metabolic	HCC21	Protein-Calorie Malnutrition
			HCC22	**Morbid Obesity**
			HCC23	**Other Significant Endocrine and Metabolic Disorders**
HCC25	End-Stage Liver Disease	Liver	HCC27	End-Stage Liver Disease
HCC26	Cirrhosis of Liver		HCC28	Cirrhosis of Liver
HCC27	Chronic Hepatitis		HCC29	Chronic Hepatitis
HCC31	Intestinal Obstruction/Perforation	Gastrointestinal	HCC33	Intestinal Obstruction/Perforation
HCC32	Pancreatic Disease		*HCC34*	*Chronic Pancreatitis*
HCC33	Inflammatory Bowel Disease		HCC35	Inflammatory Bowel Disease
HCC37	Bone/Joint/Muscle Infections/Necrosis	Musculoskeletal	HCC39	Bone/Joint/Muscle Infections/Necrosis

Current Model			Revised Model	
HCC	**Description**	**Category Short Name**	**HCC**	**Description**
HCC38	Rheumatoid Arthritis and Inflammatory Connective Tissue Disease		HCC40	Rheumatoid Arthritis and Inflammatory Connective Tissue Disease
HCC44	Severe Hematological Disorders	Blood	HCC46	Severe Hematological Disorders
HCC45	Disorders of Immunity		HCC47	Disorders of Immunity
			HCC48	**Coagulation Defects and Other Specified Hematological Disorders**
		Cognitive	**HCC51**	**Dementia With Complications**
			HCC52	**Dementia Without Complication**
HCC51	Drug/Alcohol Psychosis	Substance Abuse	HCC54	Drug/Alcohol Psychosis
HCC52	Drug/Alcohol Dependence		HCC55	Drug/Alcohol Dependence
HCC54	Schizophrenia	Psychiatric	HCC57	Schizophrenia
HCC55	Major Depressive, Bipolar, and Paranoid Disorders		HCC58	Major Depressive, Bipolar, and Paranoid Disorders
HCC67	Quadriplegia, Other Extensive Paralysis	Spinal	*HCC70*	*Quadriplegia*
HCC68	Paraplegia		HCC71	Paraplegia
HCC69	Spinal Cord Disorders/Injuries		HCC72	Spinal Cord Disorders/Injuries
HCC70	Muscular Dystrophy	Neurological	**HCC73**	**Amyotrophic Lateral Sclerosis and Other Motor Neuron Disease**
HCC71	Polyneuropathy		**HCC74**	**Cerebral Palsy**
HCC72	Multiple Sclerosis		HCC75	Polyneuropathy
HCC73	Parkinson's and Huntington's Diseases		HCC76	Muscular Dystrophy
HCC74	Seizure Disorders and Convulsions		HCC77	Multiple Sclerosis
HCC75	Coma, Brain Compression/Anoxic Damage		HCC78	Parkinson's and Huntington's Diseases
			HCC79	Seizure Disorders and Convulsions
			HCC80	Coma, Brain Compression/Anoxic Damage
HCC77	Respirator Dependence/Tracheostomy Status	Arrest	HCC82	Respirator Dependence/Tracheostomy Status
HCC78	Respiratory Arrest		HCC83	Respiratory Arrest
HCC79	Cardio-Respiratory Failure and Shock		HCC84	Cardio-Respiratory Failure and Shock
HCC80	Congestive Heart Failure	Heart	HCC85	Congestive Heart Failure
HCC81	Acute Myocardial Infarction		HCC86	Acute Myocardial Infarction
HCC82	Unstable Angina and Other Acute Ischemic Heart Disease		HCC87	Unstable Angina and Other Acute Ischemic Heart Disease

Current Model			Revised Model	
HCC	**Description**	**Category Short Name**	**HCC**	**Description**
HCC83	Angina Pectoris/Old Myocardial Infraction		*HCC88*	*Angina Pectoris*
HCC92	Specified Heart Arrhythmias		HCC96	Specified Heart Arrhythmias
HCC95	Cerebral Hemorrhage	Cerebrovascular Disease	HCC99	Cerebral Hemorrhage
HCC96	Ischemic or Unspecified Stroke		HCC100	Ischemic or Unspecified Stroke
HCC100	Hemiplegia/Hemiparesis		HCC103	Hemiplegia/Hemiparesis
HCC101	Cerebral Palsy and Other Paralytic Syndromes		*HCC104*	*Monoplegia, Other Paralytic Syndromes*
HCC104	Vascular Disease with Complications	Vascular	**HCC106**	**Atherosclerosis of the Extremities with Ulceration or Gangrene**
HCC105	Vascular Disease		HCC107	Vascular Disease with Complications
			HCC108	Vascular Disease
HCC107	Cystic Fibrosis	Lung	HCC110	Cystic Fibrosis
HCC108	Chronic Obstructive Pulmonary Disease		HCC111	Chronic Obstructive Pulmonary Disease
HCC111	Aspiration and Specified Bacterial Pneumonias		**HCC112**	**Fibrosis of Lung and Other Chronic Lung Disorders**
HCC112	Pneumococcal Pneumonia, Empyema, Lung Abscess		HCC114	Aspiration and Specified Bacterial Pneumonias
			HCC115	Pneumococcal Pneumonia, Empyema, Lung Abscess
HCC119	Proliferative Diabetic Retinopathy and Vitreous Hemorrhage	Eye	HCC122	Proliferative Diabetic Retinopathy and Vitreous Hemorrhage
			HCC124	**Exudative Macular Degeneration**
HCC130	Dialysis Status	Kidney	HCC134	Dialysis Status
HCC131	Renal Failure		*HCC135*	*Acute Renal Failure*
HCC132	Nephritis		*HCC136*	*Chronic Kidney Disease, Stage 5*
			HCC137	*Chronic Kidney Disease, Severe (Stage 4)*
			HCC138	*Chronic Kidney Disease, Moderate (Stage 3)*
			HCC139	*Chronic Kidney Disease, Mild or Unspecified (Stages 1-2 or Unspecified)*
			HCC140	*Unspecified Renal Failure*
			HCC141	Nephritis

Current Model			Revised Model	
HCC	**Description**	**Category Short Name**	**HCC**	**Description**
HCC148	Decubitus Ulcer of Skin	Skin	**HCC157**	**Pressure Ulcer of Skin with Necrosis Through to Muscle, Tendon, or Bone**
HCC149	Chronic Ulcer of Skin, Except Decubitus		**HCC158**	**Pressure Ulcer of Skin with Full Thickness Skin Loss**
HCC150	Extensive Third-Degree Burns		**HCC159**	**Pressure Ulcer of Skin with Partial Thickness Skin Loss**
			HCC160	Pressure Pre-Ulcer Skin Changes or Unspecified Stage
			HCC161	Chronic Ulcer of Skin, Except Pressure
			HCC162	*Severe Skin Burn or Condition*
HCC154	Severe Head Injury	Injury	HCC166	Severe Head Injury
HCC155	Major Head Injury		HCC167	Major Head Injury
HCC157	Vertebral Fractures w/o Spinal Cord Injury		HCC169	Vertebral Fractures without Spinal Cord Injury
HCC158	Hip Fracture/Dislocation		HCC170	Hip Fracture/Dislocation
HCC161	Traumatic Amputation		*HCC173*	*Traumatic Amputations and Complications*
HCC164	Major Complications of Medical Care and Trauma	Complications	*HCC176*	*Complications of Specified Implanted Device or Graft*
HCC174	Major Organ Transplant Status	Transplant	HCC186	Major Organ Transplant or Replacement Status
HCC176	Artificial Openings for Feeding or Elimination	Openings	HCC188	Artificial Openings for Feeding or Elimination
HCC177	Amputation Status, Lower Limb/Amputation Complications	Amputation	HCC189	Amputation Status, Lower Limb/Amputation Complications
		Disabled/Disease Interactions		
D-HCC5	Disabled_Opportunistic Infections		D_HCC6	Disabled, Opportunistic Infections
D-HCC44	Disabled_Severe Hematological Disorders		**D_HCC34**	**Disabled, Chronic Pancreatitis**
			D_HCC46	Disabled, Severe Hematological Disorders
D-HCC51	Disabled_Drug/Alcohol Psychosis		D_HCC54	Disabled, Drug/Alcohol Psychosis
D-HCC52	Disabled_Drug/Alcohol Dependence		D_HCC55	Disabled, Drug/Alcohol Dependence
D-HCC107	Disabled_Cystic Fibrosis		D_HCC110	Disabled, Cystic Fibrosis

Current Model			Revised Model	
HCC	**Description**	**Category Short Name**	**HCC**	**Description**
			D_HCC176	**Disabled, Complications of Specified Implanted Device or Graft**
		DiseaseInteractions		
INT1	DM_CHF		**SEPSIS_CARD_RESP_FAIL**	**Sepsis*Cardiorespiratory Failure**
INT2	DM_CVD		**CANCER_IMMUNE**	**Cancer*Immune Disorders**
INT3	CHF_COPD		DIABETES_CHF	Diabetes*Congestive Heart Failure
INT4	COPD_CVD_CAD		CHF_COPD	Congestive Heart Failure*Chronic Obstructive Pulmonary Disease
INT5	RF_CHF		CHF_RENAL	Congestive Heart Failure*Renal Disease
INT6	RF_CHF_DM		**COPD_CARD_RESP_FAIL**	**Chronic Obstructive Pulmonary Disease*Cardiorespiratory Failure**

Current Model NOTES:

Beneficiaries with three-way interaction RF_CHF_DM are excluded from the two-way interactions DM_CHF and RF_CHF.
DM is diabetes mellitus (HCCs 15-19).
CHF is congestive heart failure (HCC 80).
COPD is chronic obstructive pulmonary disease (HCC 108).
CVD is cerebrovascular disease (HCCs 95-96, 100-101).
CAD is coronary artery disease (HCCs 81-83).
RF is renal failure (HCC 131).

Revised Model NOTES:

New HCCs, demographic factors, or interactions (compared to the current model HCCs) are bolded.
Substantially revised HCCs, demographic factors, or interactions (compared to the current model HCCs) are in italics.
In the "disease interactions", the variables are defined as follows:
Sepsis = HCC 2.
Cardiorespiratory Failure = HCCs 82-84.
Cancer = HCCs 8-12.
Immune Disorders = HCC 47.
Diabetes = HCCs 17, 18, 19.
Congestive Heart Failure = HCC 85.
Chronic Obstructive Pulmonary Disease = HCCs 110-111.
Renal Disease = HCCs 134-141.

Table 5. Preliminary ESRD Continuing Enrollee Dialysis CMS-HCC Model Relative Factors

Variable	Relative Factors
Female	
0-34 Years	0.622
35-44 Years	0.622
45-54 Years	0.622
55-59 Years	0.629
60-64 Years	0.643
65-69 Years	0.712
70-74 Years	0.729
75-79 Years	0.745
80-84 Years	0.768
85-89 Years	0.774
90-94 Years	0.774
95 Years or Over	0.774
Male	
0-34 Years	0.612
35-44 Years	0.612
45-54 Years	0.612
55-59 Years	0.622
60-64 Years	0.633
65-69 Years	0.686
70-74 Years	0.712
75-79 Years	0.722
80-84 Years	0.764
85-89 Years	0.781
90-94 Years	0.781
95 Years or Over	0.781
Medicaid, Originally Disabled, and Originally ESRD Interactions with Age and Sex	
Medicaid_Female_Aged	0.054
Medicaid_Female_NonAged (Age <65)	0.059
Medicaid_Male_Aged	0.068
Medicaid_Male_NonAged (Age <65)	0.035
Originally Disabled_Female[2]	0.051
Originally Disabled_Male[2]	0.047
Originally ESRD_Female[3]	-0.065
Originally ESRD_Male[3]	-0.047

Disease Coefficients	Description Label	Relative Factors
HCC1	HIV/AIDS	0.178
HCC2	Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock	0.080
HCC6	Opportunistic Infections	0.083
HCC8	Metastatic Cancer and Acute Leukemia	0.261
HCC9	Lung and Other Severe Cancers	0.179
HCC10	Lymphoma and Other Cancers	0.110

Disease Coefficients	Description Label	Relative Factors
HCC11	Colorectal, Bladder, and Other Cancers	0.061
HCC12	Breast, Prostate, and Other Cancers and Tumors	0.032
HCC17	Diabetes with Acute Complications	0.210
HCC18	Diabetes with Chronic Complications	0.090
HCC19	Diabetes without Complication	0.078
HCC21	Protein-Calorie Malnutrition	0.038
HCC22	Morbid Obesity	0.137
HCC23	Other Significant Endocrine and Metabolic Disorders	0.004
HCC27	End-Stage Liver Disease	0.209
HCC28	Cirrhosis of Liver	0.089
HCC29	Chronic Hepatitis	0.055
HCC33	Intestinal Obstruction/Perforation	0.060
HCC34	Chronic Pancreatitis	0.040
HCC35	Inflammatory Bowel Disease	0.058
HCC39	Bone/Joint/Muscle Infections/Necrosis	0.070
HCC40	Rheumatoid Arthritis and Inflammatory Connective Tissue Disease	0.078
HCC46	Severe Hematological Disorders	0.154
HCC47	Disorders of Immunity	0.033
HCC48	Coagulation Defects and Other Specified Hematological Disorders	0.079
HCC51	Dementia With Complications	0.132
HCC52	Dementia Without Complication	0.062
HCC54	Drug/Alcohol Psychosis	0.000
HCC55	Drug/Alcohol Dependence	0.000
HCC57	Schizophrenia	0.142
HCC58	Major Depressive, Bipolar, and Paranoid Disorders	0.088
HCC70	Quadriplegia	0.214
HCC71	Paraplegia	0.214
HCC72	Spinal Cord Disorders/Injuries	0.109
HCC73	Amyotrophic Lateral Sclerosis and Other Motor Neuron Disease	0.000
HCC74	Cerebral Palsy	0.071
HCC75	Polyneuropathy	0.058
HCC76	Muscular Dystrophy	0.000
HCC77	Multiple Sclerosis	0.071
HCC78	Parkinson's and Huntington's Diseases	0.057
HCC79	Seizure Disorders and Convulsions	0.072
HCC80	Coma, Brain Compression/Anoxic Damage	0.123
HCC82	Respirator Dependence/Tracheostomy Status	0.307
HCC83	Respiratory Arrest	0.118
HCC84	Cardio-Respiratory Failure and Shock	0.064
HCC85	Congestive Heart Failure	0.075
HCC86	Acute Myocardial Infarction	0.095
HCC87	Unstable Angina and Other Acute Ischemic Heart Disease	0.095
HCC88	Angina Pectoris	0.045
HCC96	Specified Heart Arrhythmias	0.073
HCC99	Cerebral Hemorrhage	0.080
HCC100	Ischemic or Unspecified Stroke	0.080
HCC103	Hemiplegia/Hemiparesis	0.079
HCC104	Monoplegia, Other Paralytic Syndromes	0.079
HCC106	Atherosclerosis of the Extremities with Ulceration or Gangrene	0.290
HCC107	Vascular Disease with Complications	0.087

Disease Coefficients	Description Label	Relative Factors
HCC108	Vascular Disease	0.053
HCC110	Cystic Fibrosis	0.068
HCC111	Chronic Obstructive Pulmonary Disease	0.068
HCC112	Fibrosis of Lung and Other Chronic Lung Disorders	0.056
HCC114	Aspiration and Specified Bacterial Pneumonias	0.084
HCC115	Pneumococcal Pneumonia, Empyema, Lung Abscess	0.015
HCC122	Proliferative Diabetic Retinopathy and Vitreous Hemorrhage	0.000
HCC124	Exudative Macular Degeneration	0.000
HCC157	Pressure Ulcer of Skin with Necrosis Through to Muscle, Tendon, or Bone	0.177
HCC158	Pressure Ulcer of Skin with Full Thickness Skin Loss	0.177
HCC159	Pressure Ulcer of Skin with Partial Thickness Skin Loss	0.177
HCC160	Pressure Pre-Ulcer Skin Changes or Unspecified Stage	0.177
HCC161	Chronic Ulcer of Skin, Except Pressure	0.123
HCC162	Severe Skin Burn or Condition	0.049
HCC166	Severe Head Injury	0.123
HCC167	Major Head Injury	0.020
HCC169	Vertebral Fractures without Spinal Cord Injury	0.052
HCC170	Hip Fracture/Dislocation	0.042
HCC173	Traumatic Amputations and Complications	0.042
HCC176	Complications of Specified Implanted Device or Graft	0.000
HCC186	Major Organ Transplant or Replacement Status	0.165
HCC188	Artificial Openings for Feeding or Elimination	0.049
HCC189	Amputation Status, Lower Limb/Amputation Complications	0.119
Disease Interactions		0.000
SEPSIS_CARD_RESP_FAIL	Sepsis*Cardiorespiratory Failure	0.104
CANCER_IMMUNE	Cancer*Immune Disorders	0.097
DIABETES_CHF	Diabetes*Congestive Heart Failure	0.021
CHF_COPD	Congestive Heart Failure*Chronic Obstructive Pulmonary Disease	0.018
COPD_CARD_RESP_FAIL	Chronic Obstructive Pulmonary Disease*Cardiorespiratory Failure	0.013
NonAged (Age <65)/Disease Interactions		0.000
NONAGED_HCC6	NonAged, Opportunistic Infections	0.076
NONAGED_HCC34	NonAged, Chronic Pancreatitis	0.120
NONAGED_HCC46	NonAged, Severe Hematological Disorders	0.039
NONAGED_HCC54	NonAged, Drug/Alcohol Psychosis	0.172
NONAGED_HCC55	NonAged, Drug/Alcohol Dependence	0.172
NONAGED_HCC110	NonAged, Cystic Fibrosis	0.384
NONAGED_HCC176	NonAged, Complications of Specified Implanted Device or Graft	0.048

NOTES:

[1] The relative risk factors in this table were calculated by dividing the parameter estimates by the national average predicted expenditures (CMS Dialysis Denominator). The Dialysis Denominator value used was $72,735.37 based on July 2009 continuing enrollee and new enrollee dialysis status beneficiaries with dialysis MSP adjustments included.

[2] Originally Disabled indicates beneficiary originally entered Medicare due to a condition other than ESRD.

[3] Originally ESRD indicates beneficiary originally entered Medicare due to ESRD. Beneficiaries that are Originally ESRD cannot be Originally Disabled.

The estimate for HCC 160 is based on pressure ulcer, any stage, for all anatomical sites codes. The estimated coefficient for HCC 160 is also assigned to HCCs 157, 158, and 159 in the constrained regression because the ICD9 codes for the stages of pressure ulcers are not implemented until FY09.

In the "disease interactions," the variables are defined as follows:
Sepsis = HCC 2.
Cardiorespiratory Failure = HCCs 82-84.
Cancer = HCCs 8-12.
Immune Disorders = HCC 47.
Diabetes = HCCs 17, 18, 19.
Congestive Heart Failure = HCC 85.
Chronic Obstructive Pulmonary Disease = HCCs 110-111.

SOURCE: RTI International analysis of 2006/2007 Medicare 100% ESRD sample claims and enrollment data.

Table 6. Preliminary ESRD Demographic CMS-HCC Model Relative Factors for New Enrollees in Dialysis Status

	Non-Medicaid & Non-Originally Disabled	Medicaid & Non-Originally Disabled	Non-Medicaid & Originally Disabled	Medicaid & Originally Disabled
Female				
0-34 Years	0.881	1.004	1.117	1.240
35-44 Years	0.881	1.004	1.117	1.240
45-54 Years	0.881	1.004	1.117	1.240
55-59 Years	0.917	1.040	1.153	1.275
60-64 Years	0.937	1.059	1.172	1.295
65-69 Years	1.060	1.164	1.296	1.399
70-74 Years	1.107	1.210	1.342	1.446
75-79 Years	1.167	1.270	1.402	1.506
80-84 Years	1.172	1.275	1.407	1.510
85 Years or Over	1.186	1.290	1.422	1.525
Male				
0-34 Years	0.764	0.875	0.995	1.106
35-44 Years	0.805	0.917	1.036	1.148
45-54 Years	0.843	0.954	1.074	1.186
55-59 Years	0.876	0.988	1.107	1.219
60-64 Years	0.901	1.013	1.132	1.244
65-69 Years	1.012	1.131	1.243	1.362
70-74 Years	1.071	1.189	1.302	1.420
75-79 Years	1.114	1.232	1.345	1.464
80-84 Years	1.148	1.266	1.379	1.497
85 Years or Over	1.163	1.282	1.394	1.513

NOTES:
1. The relative risk factors in this table were calculated by dividing the parameter estimates by the national average predicted expenditures (CMS Dialysis Denominator). The Dialysis Denominator value used was $72,735.37 based on July 2009 continuing enrollee and new enrollee dialysis status beneficiaries with dialysis MSP adjustments included.
2. Originally disabled terms refer to people originally entitled to Medicare for reasons of disability other than ESRD.

SOURCE: RTI International analysis of 2006/2007 Medicare 100% ESRD sample claims and enrollment data.

Table 7. Preliminary ESRD Kidney Transplant CMS-HCC Model Relative Factors for Transplant Beneficiaries

	Beneficiaries	**Kidney Transplant** *Actual Dollars*	**Kidney Transplant Relative Risk Factor**
Month 1	8,412	36,618.30	6.041
Months 2 and 3		5,540.51	0.914
Total (Actual Months 1-3)		**47,569.19**	

NOTES:
1. Kidney transplant is identified by DRG 302 for discharge dates through September 30, 2007 and by MS-DRG 652 for discharge dates from October 1, 2007 on.
2. The transplant month payments were computed by aggregating the costs for each of the three monthly payments.
3. The transplant factor is calculated in this manner: (kidney transplant month's dollars/Dialysis Denominator)*12. The Dialysis Denominator value used was $72,735.37 based on July 2009 continuing enrollee and new enrollee dialysis status beneficiaries with dialysis MSP adjustments included.

SOURCE: RTI International analysis of 2006/2007 Medicare 100% ESRD sample claims and enrollment data.

Table 8. Preliminary ESRD Functioning Graft CMS-HCC Model Relative Factors for Community Population

Variable	**Relative Factor**
Functioning Graft Factors	
Aged 65+, with duration since transplant of 4-9 months	2.596
Aged <65, with duration since transplant of 4-9 months	2.435
Aged 65+, with duration since transplant of 10 months or more	1.284
Aged <65, with duration since transplant of 10 months or more	1.169
Female	
0-34 Years	0.198
35-44 Years	0.212
45-54 Years	0.274
55-59 Years	0.359
60-64 Years	0.416
65-69 Years	0.283
70-74 Years	0.346
75-79 Years	0.428
80-84 Years	0.517
85-89 Years	0.632
90-94 Years	0.755
95 Years or Over	0.775
Male	
0-34 Years	0.079
35-44 Years	0.119
45-54 Years	0.165
55-59 Years	0.292
60-64 Years	0.332
65-69 Years	0.309
70-74 Years	0.378

Variable	Relative Factor
75-79 Years	0.464
80-84 Years	0.565
85-89 Years	0.647
90-94 Years	0.776
95 Years or Over	0.963
Medicaid and Originally Disabled Interactions with Age and Sex	
Medicaid_Female_Aged	0.213
Medicaid_Female_NonAged (Age <65)	0.104
Medicaid_Male_Aged	0.210
Medicaid_Male_NonAged (Age <65)	0.113
Originally Disabled_Female_Age ≥65	0.244
Originally Disabled_Male_Age ≥65	0.171

Disease Coefficients	Description Label	Relative Factor
HCC1	HIV/AIDS	0.492
HCC2	Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock	0.520
HCC6	Opportunistic Infections	0.557
HCC8	Metastatic Cancer and Acute Leukemia	2.425
HCC9	Lung and Other Severe Cancers	1.006
HCC10	Lymphoma and Other Cancers	0.695
HCC11	Colorectal, Bladder, and Other Cancers	0.330
HCC12	Breast, Prostate, and Other Cancers and Tumors	0.180
HCC17	Diabetes with Acute Complications	0.344
HCC18	Diabetes with Chronic Complications	0.344
HCC19	Diabetes without Complication	0.124
HCC21	Protein-Calorie Malnutrition	0.653
HCC22	Morbid Obesity	0.342
HCC23	Other Significant Endocrine and Metabolic Disorders	0.240
HCC27	End-Stage Liver Disease	1.003
HCC28	Cirrhosis of Liver	0.425
HCC29	Chronic Hepatitis	0.313
HCC33	Intestinal Obstruction/Perforation	0.337
HCC34	Chronic Pancreatitis	0.257
HCC35	Inflammatory Bowel Disease	0.279
HCC39	Bone/Joint/Muscle Infections/Necrosis	0.423
HCC40	Rheumatoid Arthritis and Inflammatory Connective Tissue Disease	0.376
HCC46	Severe Hematological Disorders	1.078
HCC47	Disorders of Immunity	0.306
HCC48	Coagulation Defects and Other Specified Hematological Disorders	0.258
HCC51	Dementia With Complications	0.616
HCC52	Dementia Without Complication	0.343
HCC54	Drug/Alcohol Psychosis	0.358
HCC55	Drug/Alcohol Dependence	0.358
HCC57	Schizophrenia	0.471
HCC58	Major Depressive, Bipolar, and Paranoid Disorders	0.318
HCC70	Quadriplegia	1.075
HCC71	Paraplegia	0.868
HCC72	Spinal Cord Disorders/Injuries	0.441

Disease Coefficients	Description Label	Relative Factor
HCC73	Amyotrophic Lateral Sclerosis and Other Motor Neuron Disease	1.016
HCC74	Cerebral Palsy	0.036
HCC75	Polyneuropathy	0.281
HCC76	Muscular Dystrophy	0.460
HCC77	Multiple Sclerosis	0.482
HCC78	Parkinson's and Huntington's Diseases	0.555
HCC79	Seizure Disorders and Convulsions	0.252
HCC80	Coma, Brain Compression/Anoxic Damage	0.533
HCC82	Respirator Dependence/Tracheostomy Status	1.732
HCC83	Respiratory Arrest	0.769
HCC84	Cardio-Respiratory Failure and Shock	0.326
HCC85	Congestive Heart Failure	0.361
HCC86	Acute Myocardial Infarction	0.283
HCC87	Unstable Angina and Other Acute Ischemic Heart Disease	0.283
HCC88	Angina Pectoris	0.210
HCC96	Specified Heart Arrhythmias	0.276
HCC99	Cerebral Hemorrhage	0.371
HCC100	Ischemic or Unspecified Stroke	0.333
HCC103	Hemiplegia/Hemiparesis	0.481
HCC104	Monoplegia, Other Paralytic Syndromes	0.212
HCC106	Atherosclerosis of the Extremities with Ulceration or Gangrene	1.313
HCC107	Vascular Disease with Complications	0.417
HCC108	Vascular Disease	0.288
HCC110	Cystic Fibrosis	0.388
HCC111	Chronic Obstructive Pulmonary Disease	0.388
HCC112	Fibrosis of Lung and Other Chronic Lung Disorders	0.294
HCC114	Aspiration and Specified Bacterial Pneumonias	0.691
HCC115	Pneumococcal Pneumonia, Empyema, Lung Abscess	0.212
HCC122	Proliferative Diabetic Retinopathy and Vitreous Hemorrhage	0.223
HCC124	Exudative Macular Degeneration	0.248
HCC134	Dialysis Status	0.000
HCC135	Acute Renal Failure	0.617
HCC136	Chronic Kidney Disease, Stage 5	0.227
HCC137	Chronic Kidney Disease, Severe (Stage 4)	0.227
HCC138	Chronic Kidney Disease, Moderate (Stage 3)	0.227
HCC139	Chronic Kidney Disease, Mild or Unspecified (Stages 1-2 or Unspecified)	0.227
HCC140	Unspecified Renal Failure	0.227
HCC141	Nephritis	0.075
HCC157	Pressure Ulcer of Skin with Necrosis Through to Muscle, Tendon, or Bone	1.071
HCC158	Pressure Ulcer of Skin with Full Thickness Skin Loss	1.071
HCC159	Pressure Ulcer of Skin with Partial Thickness Skin Loss	1.071
HCC160	Pressure Pre-Ulcer Skin Changes or Unspecified Stage	1.071
HCC161	Chronic Ulcer of Skin, Except Pressure	0.473
HCC162	Severe Skin Burn or Condition	0.458
HCC166	Severe Head Injury	0.533
HCC167	Major Head Injury	0.141
HCC169	Vertebral Fractures without Spinal Cord Injury	0.441
HCC170	Hip Fracture/Dislocation	0.363
HCC173	Traumatic Amputations and Complications	0.379
HCC176	Complications of Specified Implanted Device or Graft	0.555

Disease Coefficients	Description Label	Relative Factor
HCC186	Major Organ Transplant or Replacement Status	0.000
HCC188	Artificial Openings for Feeding or Elimination	0.609
HCC189	Amputation Status, Lower Limb/Amputation Complications	0.804
Disease Interactions		
SEPSIS_CARD_RESP_FAIL	Sepsis*Cardiorespiratory Failure	0.634
CANCER_IMMUNE	Cancer*Immune Disorders	1.101
DIABETES_CHF	Diabetes*Congestive Heart Failure	0.237
CHF_COPD	Congestive Heart Failure*Chronic Obstructive Pulmonary Disease	0.255
CHF_RENAL	Congestive Heart Failure*Renal Disease	0.201
COPD_CARD_RESP_FAIL	Chronic Obstructive Pulmonary Disease*Cardiorespiratory Failure	0.420
NonAged (Age <65)/Disease Interactions		
NONAGED_HCC6	NonAged, Opportunistic Infections	0.564
NONAGED_HCC34	NonAged, Chronic Pancreatitis	0.757
NONAGED_HCC46	NonAged, Severe Hematological Disorders	0.818
NONAGED_HCC54	NonAged, Drug/Alcohol Psychosis	0.432
NONAGED_HCC55	NonAged, Drug/Alcohol Dependence	0.147
NONAGED_HCC110	NonAged, Cystic Fibrosis	2.397
NONAGED_HCC176	NonAged, Complications of Specified Implanted Device or Graft	0.495

NOTES:
1. All coefficients for demographic factors and HCCs were constrained to their values in the 2006-2007 Aged-Disabled Community model except for the coefficients for HCC134 and HCC186. These coefficients are constrained to 0 because this is a population defined by having had a major organ transplant and not being in dialysis status.
2. The coefficients estimated for this model are the Functioning Graft add-on factors for being in a month after the 3 months accounted for in the Transplant segment of the ESRD system. Early months post-transplant incur higher Medicare spending than later months. The model differentiates the six months, months 4-9, from months further from the transplant period.
3. Originally disabled terms refer to people originally entitled to Medicare for reasons of disability other than ESRD.
4. The relative risk scores in this table were calculated by dividing the parameter estimates by the national average predicted expenditures (CMS Part C Denominator). The Part C Denominator value used was $8,034.71.

The estimate for HCC 160 is based on *pressure ulcer, any stage, for all anatomical sites* codes. The estimated coefficient for HCC 160 is also assigned to HCCs 157, 158, and 159 in the constrained regression because the ICD9 codes for the stages of pressure ulcers are not implemented until FY09.

In the "disease interactions," the variables are defined as follows:
Sepsis = HCC 2.
Cardiorespiratory Failure = HCCs 82-84.
Cancer = HCCs 8-12.
Immune Disorders = HCC 47.
Diabetes = HCCs 17, 18, 19.
Congestive Heart Failure = HCC 85.
Chronic Obstructive Pulmonary Disease = HCCs 110-111.
Renal Disease = HCCs 134-141.

SOURCE: RTI International analysis of 2006/2007 100% ESRD sample claims and enrollment data and 2006/2007 Medicare 5% sample.

Table 9. Preliminary ESRD Functioning Graft CMS-HCC Model Relative Factors for Institutionalized Population

Variable	Relative Factor
Functioning Graft Factors	
Aged 65+, with duration since transplant of 4-9 months	2.596
Aged <65, with duration since transplant of 4-9 months	2.435
Aged 65+, with duration since transplant of 10 months or more	1.284
Aged <65, with duration since transplant of 10 months or more	1.169
Female	
0-34 Years	0.783
35-44 Years	0.723
45-54 Years	0.700
55-59 Years	0.805
60-64 Years	0.773
65-69 Years	1.004
70-74 Years	0.947
75-79 Years	0.874
80-84 Years	0.792
85-89 Years	0.699
90-94 Years	0.594
95 Years or Over	0.465
Male	
0-34 Years	0.994
35-44 Years	0.658
45-54 Years	0.687
55-59 Years	0.814
60-64 Years	0.877
65-69 Years	1.148
70-74 Years	1.195
75-79 Years	1.168
80-84 Years	1.104
85-89 Years	1.046
90-94 Years	0.928
95 Years or Over	0.842
Medicaid and Originally Disabled	
Medicaid	0.126
Originally Disabled_Age ≥65	0.026

Disease Coefficients	Description Label	
HCC1	HIV/AIDS	1.374
HCC2	Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock	0.471
HCC6	Opportunistic Infections	0.541
HCC8	Metastatic Cancer and Acute Leukemia	0.928
HCC9	Lung and Other Severe Cancers	0.610
HCC10	Lymphoma and Other Cancers	0.363
HCC11	Colorectal, Bladder, and Other Cancers	0.255

Disease Coefficients	Description Label	
HCC12	Breast, Prostate, and Other Cancers and Tumors	0.165
HCC17	Diabetes with Acute Complications	0.434
HCC18	Diabetes with Chronic Complications	0.434
HCC19	Diabetes without Complication	0.187
HCC21	Protein-Calorie Malnutrition	0.343
HCC22	Morbid Obesity	0.353
HCC23	Other Significant Endocrine and Metabolic Disorders	0.248
HCC27	End-Stage Liver Disease	0.637
HCC28	Cirrhosis of Liver	0.343
HCC29	Chronic Hepatitis	0.343
HCC33	Intestinal Obstruction/Perforation	0.302
HCC34	Chronic Pancreatitis	0.175
HCC35	Inflammatory Bowel Disease	0.250
HCC39	Bone/Joint/Muscle Infections/Necrosis	0.386
HCC40	Rheumatoid Arthritis and Inflammatory Connective Tissue Disease	0.222
HCC46	Severe Hematological Disorders	0.638
HCC47	Disorders of Immunity	0.436
HCC48	Coagulation Defects and Other Specified Hematological Disorders	0.197
HCC51	Dementia With Complications	0.000
HCC52	Dementia Without Complication	0.000
HCC54	Drug/Alcohol Psychosis	0.051
HCC55	Drug/Alcohol Dependence	0.051
HCC57	Schizophrenia	0.274
HCC58	Major Depressive, Bipolar, and Paranoid Disorders	0.274
HCC70	Quadriplegia	0.497
HCC71	Paraplegia	0.497
HCC72	Spinal Cord Disorders/Injuries	0.191
HCC73	Amyotrophic Lateral Sclerosis and Other Motor Neuron Disease	0.294
HCC74	Cerebral Palsy	0.000
HCC75	Polyneuropathy	0.256
HCC76	Muscular Dystrophy	0.247
HCC77	Multiple Sclerosis	0.000
HCC78	Parkinson's and Huntington's Diseases	0.110
HCC79	Seizure Disorders and Convulsions	0.173
HCC80	Coma, Brain Compression/Anoxic Damage	0.103
HCC82	Respirator Dependence/Tracheostomy Status	1.567
HCC83	Respiratory Arrest	0.611
HCC84	Cardio-Respiratory Failure and Shock	0.346
HCC85	Congestive Heart Failure	0.226
HCC86	Acute Myocardial Infarction	0.394
HCC87	Unstable Angina and Other Acute Ischemic Heart Disease	0.394
HCC88	Angina Pectoris	0.366
HCC96	Specified Heart Arrhythmias	0.227
HCC99	Cerebral Hemorrhage	0.175
HCC100	Ischemic or Unspecified Stroke	0.175
HCC103	Hemiplegia/Hemiparesis	0.063
HCC104	Monoplegia, Other Paralytic Syndromes	0.063
HCC106	Atherosclerosis of the Extremities with Ulceration or Gangrene	0.773
HCC107	Vascular Disease with Complications	0.257
HCC108	Vascular Disease	0.146
HCC110	Cystic Fibrosis	0.323

Disease Coefficients	Description Label	
HCC111	Chronic Obstructive Pulmonary Disease	0.323
HCC112	Fibrosis of Lung and Other Chronic Lung Disorders	0.252
HCC114	Aspiration and Specified Bacterial Pneumonias	0.239
HCC115	Pneumococcal Pneumonia, Empyema, Lung Abscess	0.194
HCC122	Proliferative Diabetic Retinopathy and Vitreous Hemorrhage	0.366
HCC124	Exudative Macular Degeneration	0.178
HCC134	Dialysis Status	0.000
HCC135	Acute Renal Failure	0.538
HCC136	Chronic Kidney Disease, Stage 5	0.304
HCC137	Chronic Kidney Disease, Severe (Stage 4)	0.304
HCC138	Chronic Kidney Disease, Moderate (Stage 3)	0.304
HCC139	Chronic Kidney Disease, Mild or Unspecified (Stages 1-2 or Unspecified)	0.304
HCC140	Unspecified Renal Failure	0.304
HCC141	Nephritis	0.235
HCC157	Pressure Ulcer of Skin with Necrosis Through to Muscle, Tendon, or Bone	0.284
HCC158	Pressure Ulcer of Skin with Full Thickness Skin Loss	0.284
HCC159	Pressure Ulcer of Skin with Partial Thickness Skin Loss	0.284
HCC160	Pressure Pre-Ulcer Skin Changes or Unspecified Stage	0.284
HCC161	Chronic Ulcer of Skin, Except Pressure	0.226
HCC162	Severe Skin Burn or Condition	0.000
HCC166	Severe Head Injury	0.103
HCC167	Major Head Injury	0.000
HCC169	Vertebral Fractures without Spinal Cord Injury	0.179
HCC170	Hip Fracture/Dislocation	0.000
HCC173	Traumatic Amputations and Complications	0.067
HCC176	Complications of Specified Implanted Device or Graft	0.369
HCC186	Major Organ Transplant or Replacement Status	0.000
HCC188	Artificial Openings for Feeding or Elimination	0.658
HCC189	Amputation Status, Lower Limb/Amputation Complications	0.384
Disease Interactions		
CHF_COPD	Congestive Heart Failure*Chronic Obstructive Pulmonary Disease	0.159
CRFAIL_COPD	Cardiorespiratory Failure*Chronic Obstructive Pulmonary Disease	0.524
SEPSIS_PRESSURE_ULCER	Sepsis*Pressure Ulcer	0.538
SEPSIS_ARTIF_OPENINGS	Sepsis*Artificial Openings for Feeding or Elimination	0.453
ARTIF_OPENINGS_ PRESSURE_ULCER	Artificial Openings for Feeding or Elimination*Pressure Ulcer	0.361
DIABETES_CHF	Diabetes*Congestive Heart Failure	0.143
COPD_ASP_SPEC_ BACT_PNEUM	Chronic Obstructive Pulmonary Disease*Aspiration and Specified Bacterial Pneumonias	0.249
ASP_SPEC_BACT_PNEUM_ PRES_ULCER	Aspiration and Specified Bacterial Pneumonias*Pressure Ulcer	0.325
SEPSIS_ASP_SPEC_ BACT_PNEUM	Sepsis*Aspiration and Specified Bacterial Pneumonias	0.387
SCHIZOPHRENIA_COPD	Schizophrenia*Chronic Obstructive Pulmonary Disease	0.187
SCHIZOPHRENIA_CHF	Schizophrenia*Congestive Heart Failure	0.220
SCHIZOPHRENIA_SEIZURES	Schizophrenia*Seizure Disorders and Convulsions	0.303
NonAged (Age <65)/Disease Interactions		

Disease Coefficients	Description Label	
NONAGED_HCC85	NonAged, Congestive Heart Failure	0.320
NONAGED_PRESSURE_ULCER	NonAged, Pressure Ulcer	0.421
NONAGED_HCC161	NonAged, Chronic Ulcer of the Skin, Except Pressure Ulcer	0.337
NONAGED_HCC39	NonAged, Bone/Joint Muscle Infections/Necrosis	0.624
NONAGED_HCC77	NonAged, Multiple Sclerosis	0.344
NONAGED_HCC6	NonAged, Opportunistic Infections	0.914

NOTES:
1. All coefficients for demographic factors and HCCs were constrained to their values in the 2006-2007 Aged-Disabled Institutional model except for the coefficients for HCC134 and HCC186. These coefficients are constrained to 0 because this is a population defined by having had a major organ transplant and not being in dialysis status.
2. The coefficients estimated for this model are the Functioning Graft add-on factors for being in a month after the 3 months accounted for in the Transplant segment of the ESRD system. Early months post-transplant incur higher Medicare spending than later months. The model differentiates the six months, months 4-9, from months further from the transplant period.
3. Originally disabled term refers to people originally entitled to Medicare for reasons of disability other than ESRD.
4. The relative risk scores in this table were calculated by dividing the parameter estimates by the national average predicted expenditures (CMS Part C Denominator). The Part C Denominator value used was $8,034.71.

The estimate for HCC 160 is based on *pressure ulcer, any stage, for all anatomical sites* codes. The estimated coefficient for HCC 160 is also assigned to HCCs 157, 158, and 159 in the constrained regression because the ICD9 codes for the stages of pressure ulcers are not implemented until FY09.

In the "Disease interactions" and "NonAged interactions," the variables are defined as follows:
Sepsis = HCC 2.
Cardiorespiratory Failure = HCCs 82-84.
Diabetes = HCCs 17, 18, 19.
Congestive Heart Failure = HCC 85.
Chronic Obstructive Pulmonary Disease = HCCs 110-111.
Pressure Ulcer = HCCs 157-160.
Artificial Openings for Feeding or Elimination = HCC 188.
Aspiration and Specified Bacterial Pneumonias = HCC 114.
Schizophrenia = HCC 57.
Seizure Disorders and Convulsions = HCC 79.
Chronic Ulcer of Skin, except Pressure = HCC 161.
Bone/Joint/Muscle Infections/Necrosis = HCC 39.
Multiple Sclerosis = HCC 77.
Opportunistic Infections = HCC 6.

SOURCE: RTI International analysis of 2006/2007 100% ESRD sample claims and enrollment data and 2006/2007 Medicare 100% institutional sample.

Table 10. Preliminary ESRD Demographic CMS-HCC Model Relative Factors for Functioning Graft New Enrollees Duration Since Transplant of 4-9 Months

(Table entries are annualized expenditures.)

	Non-Medicaid & Non-Originally Disabled	Medicaid & Non-Originally Disabled	Non-Medicaid & Originally Disabled	Medicaid & Originally Disabled
Female				
0-34 Years	2.886	3.216	–	–
35-44 Years	3.033	3.362	–	–
45-54 Years	3.241	3.570	–	–
55-59 Years	3.407	3.736	–	–
60-64 Years	3.512	3.841	–	–
65 Years	3.095	3.606	3.714	4.225
66 Years	3.136	3.607	3.782	4.253
67 Years	3.172	3.643	3.818	4.289
68 Years	3.191	3.662	3.837	4.308
69 Years	3.218	3.689	3.864	4.335
70-74 Years	3.330	3.824	3.916	4.410
75-79 Years	3.533	3.956	4.092	4.515
80-84 Years	3.707	4.130	4.266	4.690
85-89 Years	3.870	4.293	4.429	4.853
90-94 Years	3.961	4.385	4.521	4.944
95 Years or Over	3.837	4.260	4.396	4.819
Male				
0-34 Years	2.677	3.094	–	–
35-44 Years	2.883	3.299	–	–
45-54 Years	3.065	3.481	–	–
55-59 Years	3.256	3.673	–	–
60-64 Years	3.386	3.803	–	–
65 Years	3.136	3.687	3.700	4.251
66 Years	3.194	3.745	3.713	4.264
67 Years	3.224	3.775	3.743	4.294
68 Years	3.252	3.804	3.771	4.322
69 Years	3.273	3.824	3.792	4.343
70-74 Years	3.411	3.961	3.927	4.477
75-79 Years	3.647	4.157	4.086	4.596
80-84 Years	3.865	4.376	4.304	4.815
85-89 Years	4.035	4.546	4.475	4.985
90-94 Years	4.210	4.721	4.649	5.160
95 Years or Over	4.277	4.788	4.716	5.227

NOTES:

1. The table entries are derived from the Graft New Enrollee model. In that model, the functioning graft add-ons are carried forward from the Community Graft model and all demographic variables are carried forward from the CMS-HCC New Enrollee model.
2. Originally Disabled terms refer to people originally entitled to Medicare for reasons of disability other than ESRD. In this model, Originally Disabled is defined only for beneficiaries age 65 and greater.

SOURCE: RTI International analysis of 2006/2007 100% ESRD sample claims and enrollment data and 2006/2007 Medicare 5% sample.

Table 11. Preliminary ESRD Demographic CMS-HCC Model Relative Factors for Functioning Graft New Enrollees Duration Since Transplant of 10 Months or More

(Table entries are annualized expenditures.)

	Non-Medicaid & Non-Originally Disabled	Medicaid & Non-Originally Disabled	Non-Medicaid & Originally Disabled	Medicaid & Originally Disabled
Female				
0-34 Years	1.620	1.950	–	–
35-44 Years	1.767	2.097	–	–
45-54 Years	1.975	2.305	–	–
55-59 Years	2.141	2.471	–	–
60-64 Years	2.246	2.576	–	–
65 Years	1.782	2.293	2.402	2.912
66 Years	1.824	2.295	2.470	2.941
67 Years	1.860	2.331	2.506	2.977
68 Years	1.879	2.350	2.525	2.996
69 Years	1.905	2.376	2.551	3.022
70-74 Years	2.017	2.511	2.604	3.098
75-79 Years	2.220	2.643	2.779	3.202
80-84 Years	2.394	2.818	2.954	3.377
85-89 Years	2.557	2.981	3.117	3.540
90-94 Years	2.649	3.072	3.208	3.631
95 Years or Over	2.524	2.947	3.083	3.507
Male				
0-34 Years	1.411	1.828	–	–
35-44 Years	1.617	2.034	–	–
45-54 Years	1.799	2.216	–	–
55-59 Years	1.990	2.407	–	–
60-64 Years	2.121	2.537	–	–
65 Years	1.823	2.375	2.387	2.938
66 Years	1.881	2.432	2.400	2.951
67 Years	1.911	2.463	2.430	2.981
68 Years	1.940	2.491	2.458	3.010
69 Years	1.961	2.512	2.479	3.031
70-74 Years	2.098	2.649	2.614	3.165
75-79 Years	2.334	2.845	2.773	3.284
80-84 Years	2.553	3.063	2.992	3.502
85-89 Years	2.723	3.233	3.162	3.673
90-94 Years	2.898	3.408	3.337	3.847
95 Years or Over	2.964	3.475	3.403	3.914

NOTES:

1. The table entries are derived from the Graft New Enrollee model. In that model, the functioning graft add-ons are carried forward from the Community Graft model and all demographic variables are carried forward from the CMS-HCC New Enrollee model.
2. Originally Disabled terms refer to people originally entitled to Medicare for reasons of disability other than ESRD. In this model, Originally Disabled is defined only for beneficiaries age 65 and greater.

SOURCE: RTI International analysis of 2006/2007 100% ESRD sample claims and enrollment data and 2006/2007 Medicare 5% sample.

Table 12. Preliminary CMS RxHCC Model Relative Factors for Continuing Enrollees

		Continuing Enrollee (CE) RxHCC Model Segments				
Variable	**Disease Group**	Community, Non-Low Income, Age>=65	Community, Non-Low Income, Age<65	Community, Low Income, Age>=65	Community, Low Income, Age<65	Institutional
Female						
0-34 Years		-	0.266	-	0.405	1.555
35-44 Years		-	0.472	-	0.599	1.576
45-54 Years		-	0.578	-	0.672	1.490
55-59 Years		-	0.571	-	0.643	1.411
60-64 Years		-	0.577	-	0.617	1.357
65 Years		0.418	-	0.449	-	1.447
66 Years		0.418	-	0.449	-	1.447
67 Years		0.418	-	0.449	-	1.447
68 Years		0.418	-	0.449	-	1.447
69 Years		0.418	-	0.449	-	1.447
70-74 Years		0.415	-	0.439	-	1.367
75-79 Years		0.421	-	0.436	-	1.309
80-84 Years		0.431	-	0.432	-	1.254
85-89 Years		0.440	-	0.422	-	1.199
90-94 Years		0.438	-	0.399	-	1.127
95 Years or Over		0.414	-	0.328	-	0.981
Male						
0-34 Years		-	0.244	-	0.435	1.582
35-44 Years		-	0.396	-	0.562	1.542
45-54 Years		-	0.521	-	0.604	1.471
55-59 Years		-	0.519	-	0.571	1.377
60-64 Years		-	0.536	-	0.541	1.325
65 Years		0.425	-	0.367	-	1.384
66 Years		0.425	-	0.367	-	1.384
67 Years		0.425	-	0.367	-	1.384
68 Years		0.425	-	0.367	-	1.384
69 Years		0.425	-	0.367	-	1.384
70-74 Years		0.416	-	0.359	-	1.339
75-79 Years		0.407	-	0.354	-	1.295

		Continuing Enrollee (CE) RxHCC Model Segments				
Variable	**Disease Group**	Community, Non-Low Income, Age>=65	Community, Non-Low Income, Age<65	Community, Low Income, Age>=65	Community, Low Income, Age<65	Institutional
80-84 Years		0.402	-	0.342	-	1.265
85-89 Years		0.404	-	0.343	-	1.242
90-94 Years		0.429	-	0.364	-	1.197
95 Years or Over		0.433	-	0.357	-	1.094
Originally Disabled Interactions with Sex						
Originally Disabled		-	-	-	-	0.031
Originally Disabled_Female		0.066	-	0.102	-	-
Originally Disabled_Female_Age 65		-	-	-	-	-
Originally Disabled_Female_Age 66-69		-	-	-	-	-
Originally Disabled_Female_Age 70-74		-	-	-	-	-
Originally Disabled_Female_Age 75+		-	-	-	-	-
Originally Disabled_Male		0.018	-	0.091	-	-
Originally Disabled_Male_Age 65		-	-	-	-	-
Originally Disabled_Male_Age 66-69		-	-	-	-	-
Originally Disabled_Male_Age 70-74		-	-	-	-	-
Originally Disabled_Male_Age 75+		-	-	-	-	-

		Continuing Enrollee (CE) RxHCC Model Segments				
Disease Coefficients	**Description Label**	Community, Non-Low Income, Age>=65	Community, Non-Low Income, Age<65	Community, Low Income, Age>=65	Community, Low Income, Age<65	Institutional
RXHCC1	HIV/AIDS	1.625	2.381	2.123	2.545	1.082
RXHCC5	Opportunistic Infections	0.111	0.124	0.083	0.180	0.083
RXHCC8	Chronic Myeloid Leukemia	1.684	2.124	2.099	2.374	1.056
RXHCC9	Multiple Myeloma and Other Neoplastic Disorders	1.116	1.304	1.017	1.215	0.557
RXHCC10	Breast, Lung, and Other Cancers and Tumors	0.207	0.206	0.237	0.254	0.102
RXHCC11	Prostate and Other Cancers and Tumors	0.040	0.051	0.116	0.063	0.081
RXHCC14	Diabetes with Complications	0.246	0.186	0.275	0.271	0.158
RXHCC15	Diabetes without Complication	0.173	0.151	0.213	0.222	0.113

		Continuing Enrollee (CE) RxHCC Model Segments				
Disease Coefficients	**Description Label**	Community, Non-Low Income, Age>=65	Community, Non-Low Income, Age<65	Community, Low Income, Age>=65	Community, Low Income, Age<65	Institutional
RXHCC18	Diabetes Insipidus and Other Endocrine and Metabolic Disorders	0.242	0.564	0.187	0.624	0.126
RXHCC19	Pituitary, Adrenal Gland, and Other Endocrine and Metabolic Disorders	0.043	0.060	0.030	0.060	0.060
RXHCC20	Thyroid Disorders	0.037	0.091	0.046	0.104	0.037
RXHCC21	Morbid Obesity	0.038	0.013	0.037	0.049	0.069
RXHCC23	Disorders of Lipoid Metabolism	0.120	0.134	0.142	0.182	0.062
RXHCC25	Chronic Viral Hepatitis	0.078	0.042	0.220	0.111	–
RXHCC30	Chronic Pancreatitis	0.085	0.154	0.046	0.075	0.021
RXHCC31	Pancreatic Disorders and Intestinal Malabsorption, Except Pancreatitis	0.032	0.066	0.034	0.075	0.021
RXHCC32	Inflammatory Bowel Disease	0.264	0.245	0.190	0.315	0.075
RXHCC33	Esophageal Reflux and Other Disorders of Esophagus	0.135	0.111	0.161	0.175	0.075
RXHCC38	Aseptic Necrosis of Bone	0.053	0.153	0.044	0.233	0.068
RXHCC40	Psoriatic Arthropathy	0.321	0.447	0.571	1.011	0.377
RXHCC41	Rheumatoid Arthritis and Other Inflammatory Polyarthropathy	0.169	0.258	0.197	0.390	0.095
RXHCC42	Systemic Lupus Erythematosus, Other Connective Tissue Disorders, and Inflammatory Spondylopathies	0.122	0.236	0.161	0.266	0.084
RXHCC45	Osteoporosis, Vertebral and Pathological Fractures	0.093	0.157	0.125	0.181	0.027
RXHCC47	Sickle Cell Anemia	0.144	0.093	0.133	0.433	0.036
RXHCC48	Myelodysplastic Syndromes, Except High-Grade	0.211	0.370	0.299	0.231	0.426
RXHCC49	Immune Disorders	0.149	0.244	0.130	0.276	0.141
RXHCC50	Aplastic Anemia and Other Significant Blood Disorders	0.044	0.087	0.059	0.073	0.036
RXHCC54	Alzheimer`s Disease	0.468	0.265	0.310	0.184	0.016
RXHCC55	Dementia, Except Alzheimer`s Disease	0.250	0.097	0.143	0.049	–
RXHCC58	Schizophrenia	0.422	0.569	0.645	0.959	0.343
RXHCC59	Bipolar Disorders	0.353	0.435	0.427	0.677	0.293

		Continuing Enrollee (CE) RxHCC Model Segments				
Disease Coefficients	**Description Label**	Community, Non-Low Income, Age>=65	Community, Non-Low Income, Age<65	Community, Low Income, Age>=65	Community, Low Income, Age<65	Institutional
RXHCC60	Major Depression	0.265	0.337	0.308	0.439	0.205
RXHCC61	Specified Anxiety, Personality, and Behavior Disorders	0.159	0.216	0.220	0.439	0.175
RXHCC62	Depression	0.134	0.169	0.146	0.230	0.116
RXHCC63	Anxiety Disorders	0.056	0.122	0.088	0.182	0.116
RXHCC65	Autism	0.171	0.326	0.495	0.661	0.175
RXHCC66	Profound or Severe Mental Retardation/Developmental Disability	0.027	0.326	0.495	0.400	–
RXHCC67	Moderate Mental Retardation/Developmental Disability	0.023	0.178	0.404	0.294	–
RXHCC68	Mild or Unspecified Mental Retardation/Developmental Disability	0.010	0.054	0.239	0.144	–
RXHCC71	Myasthenia Gravis, Amyotrophic Lateral Sclerosis and Other Motor Neuron Disease	0.181	0.303	0.159	0.314	0.057
RXHCC72	Spinal Cord Disorders	0.061	0.156	0.072	0.095	–
RXHCC74	Polyneuropathy	0.085	0.203	0.082	0.182	0.058
RXHCC75	Multiple Sclerosis	0.451	0.811	0.494	1.338	0.123
RXHCC76	Parkinson`s Disease	0.406	0.485	0.295	0.292	0.154
RXHCC78	Intractable Epilepsy	0.355	0.636	0.354	0.915	0.124
RXHCC79	Epilepsy and Other Seizure Disorders, Except Intractable Epilepsy	0.214	0.267	0.170	0.370	0.079
RXHCC80	Convulsions	0.106	0.125	0.099	0.230	0.041
RXHCC81	Migraine Headaches	0.113	0.216	0.111	0.201	0.146
RXHCC83	Trigeminal and Postherpetic Neuralgia	0.093	0.170	0.107	0.154	0.079
RXHCC86	Pulmonary Hypertension and Other Pulmonary Heart Disease	0.253	0.397	0.292	0.345	0.121
RXHCC87	Congestive Heart Failure	0.175	0.089	0.247	0.108	0.099
RXHCC88	Hypertension	0.170	0.078	0.219	0.096	0.064

		Continuing Enrollee (CE) RxHCC Model Segments				
Disease Coefficients	**Description Label**	Community, Non-Low Income, Age>=65	Community, Non-Low Income, Age<65	Community, Low Income, Age>=65	Community, Low Income, Age<65	Institutional
RXHCC89	Coronary Artery Disease	0.145	0.082	0.133	0.046	0.017
RXHCC93	Atrial Arrhythmias	0.060	0.045	0.023	–	0.011
RXHCC97	Cerebrovascular Disease, Except Hemorrhage or Aneurysm	0.065	–	0.050	–	–
RXHCC98	Spastic Hemiplegia	0.142	0.239	0.056	0.149	0.011
RXHCC100	Venous Thromboembolism	0.013	0.043	–	0.085	–
RXHCC101	Peripheral Vascular Disease	0.056	0.030	0.093	0.064	–
RXHCC103	Cystic Fibrosis	0.198	0.665	0.223	1.346	0.117
RXHCC104	Chronic Obstructive Pulmonary Disease and Asthma	0.198	0.123	0.221	0.204	0.117
RXHCC105	Pulmonary Fibrosis and Other Chronic Lung Disorders	0.113	0.123	0.098	0.202	0.037
RXHCC106	Gram-Negative/Staphylococcus Pneumonia and Other Lung Infections	–	0.070	–	0.042	0.028
RXHCC111	Diabetic Retinopathy	0.094	0.085	0.079	0.039	0.035
RXHCC113	Open-Angle Glaucoma	0.142	0.103	0.154	0.124	0.101
RXHCC120	Kidney Transplant Status	0.266	0.170	0.386	0.407	0.338
RXHCC121	Dialysis Status	0.216	0.303	0.283	0.536	0.217
RXHCC122	Chronic Kidney Disease Stage 5	0.114	0.136	0.130	0.167	0.111
RXHCC123	Chronic Kidney Disease Stage 4	0.114	0.136	0.130	0.167	0.111
RXHCC124	Chronic Kidney Disease Stage 3	0.097	0.136	0.115	0.167	0.081
RXHCC125	Chronic Kidney Disease Stage 1, 2, or Unspecified	0.038	0.056	0.035	0.071	0.042
RXHCC126	Nephritis	0.038	0.036	0.035	0.070	0.013
RXHCC142	Chronic Ulcer of Skin, Except Pressure	0.040	0.055	0.028	0.061	–
RXHCC145	Pemphigus	0.110	0.151	0.123	0.258	–
RXHCC147	Psoriasis, Except with Arthropathy	0.106	0.188	0.206	0.289	0.126
RXHCC156	Narcolepsy and Cataplexy	0.267	0.328	0.164	0.440	0.104
RXHCC166	Lung Transplant Status	0.919	0.905	0.968	1.114	0.688
RXHCC167	Major Organ Transplant Status, Except Lung, Kidney, and Pancreas	0.411	0.372	0.417	0.480	0.338
RXHCC168	Pancreas Transplant Status	0.266	0.170	0.386	0.351	0.338

		Continuing Enrollee (CE) RxHCC Model Segments				
Disease Coefficients	**Description Label**	Community, Non-Low Income, Age>=65	Community, Non-Low Income, Age<65	Community, Low Income, Age>=65	Community, Low Income, Age<65	Institutional
Non-Aged Disease Interactions						
NonAged_RXHCC1	HIV/AIDS	-	-	-	-	1.093
NonAged_RXHCC58	Schizophrenia	-	-	-	-	0.388
NonAged_RXHCC59	Bipolar Disorders	-	-	-	-	0.243
NonAged_RXHCC60	Major Depression	-	-	-	-	0.115
NonAged_RXHCC61	Specified Anxiety, Personality, and Behavior Disorders	-	-	-	-	0.115
NonAged_RXHCC62	Depression	-	-	-	-	0.058
NonAged_RXHCC63	Anxiety Disorders	-	-	-	-	0.032
NonAged_RXHCC65	Autism	-	-	-	-	0.115
NonAged_RXHCC75	Multiple Sclerosis	-	-	-	-	0.477
NonAged_RXHCC78	Intractable Epilepsy	-	-	-	-	0.204
NonAged_RXHCC79	Epilepsy and Other Seizure Disorders, Except Intractable Epilepsy	-	-	-	-	0.040
NonAged_RXHCC80	Convulsions	-	-	-	-	0.034

Notes:

1. The relative risk scores in this table were calculated by dividing the parameter estimates by the Part D national average predicted expenditures (CMS Part D Denominator). The Part D Denominator value used was $1,086.61. This Part D Denominator is based on the combined PDP and MA-PD populations.
2. Because Part D drugs post-transplant are less costly for younger Medicare beneficiaries, RxHCC120, which takes precedence over RxHCC121, has a lower coefficient than RxHCC121 for those under age 65.

Source: RTI Analysis of 100% 2008 PDE, 2007 NCH, 2008 HPMS, 2008 CME, and 2007-2008 Denominator.

Table 13. Preliminary RxHCC Model Relative Factors for New Enrollees, Non-Low Income

Variable	Baseline – Not Concurrently ESRD, Not Originally Disabled	Concurrently ESRD, Not Originally Disabled	Originally Disabled, Not Concurrently ESRD	Originally Disabled, Concurrently ESRD
Female				
0-34 Years	0.473	0.908	-	-
35-44 Years	0.789	1.224	-	-
45-54 Years	1.056	1.491	-	-
55-59 Years	1.124	1.559	-	-
60-64 Years	1.173	1.608	-	-
65 Years	0.764	1.199	1.148	1.583
66 Years	0.760	1.195	0.899	1.334
67 Years	0.760	1.195	0.899	1.334
68 Years	0.760	1.195	0.899	1.334
69 Years	0.760	1.195	0.899	1.334
70-74 Years	0.744	1.179	0.744	1.179
75-79 Years	0.681	1.116	0.681	1.116
80-84 Years	0.652	1.087	0.652	1.087
85-89 Years	0.570	1.005	0.570	1.005
90-94 Years	0.570	1.005	0.570	1.005
95 Years or Over	0.570	1.005	0.570	1.005
Male				
0-34 Years	0.323	0.758	-	-
35-44 Years	0.607	1.042	-	-
45-54 Years	0.870	1.304	-	-
55-59 Years	0.927	1.361	-	-
60-64 Years	1.017	1.452	-	-
65 Years	0.781	1.216	1.022	1.457
66 Years	0.765	1.200	0.765	1.200
67 Years	0.765	1.200	0.765	1.200
68 Years	0.765	1.200	0.765	1.200
69 Years	0.765	1.200	0.765	1.200
70-74 Years	0.727	1.162	0.727	1.162
75-79 Years	0.645	1.079	0.645	1.079
80-84 Years	0.544	0.979	0.544	0.979
85-89 Years	0.465	0.900	0.465	0.900
90-94 Years	0.465	0.900	0.465	0.900
95 Years or Over	0.465	0.900	0.465	0.900

NOTES:

1. The Part D Denominator used to calculate relative factors is $1,086.61. This Part D Denominator is based on the combined PDP and MA-PD populations.
2. Originally Disabled is defined as originally entitled to Medicare by disability only.
3. Concurrently ESRD is defined as at least one month in 2008 of ESRD status—dialysis, transplant, or post-graft.

Source: RTI Analysis of 100% 2008 PDE SAF, 2007-2008 HPMS, 2008 CME, and 2007-2008 Denominator.

Table 14. Preliminary RxHCC Model Relative Factors for New Enrollees, Low Income

Variable	Baseline – Not Concurrently ESRD and Not Originally Disabled	Concurrently ESRD, Not Originally Disabled	Originally Disabled, Not Concurrently ESRD	Originally Disabled, Concurrently ESRD
Female				
0-34 Years	0.892	1.441	-	-
35-44 Years	1.241	1.790	-	-
45-54 Years	1.278	1.827	-	-
55-59 Years	1.165	1.713	-	-
60-64 Years	1.137	1.686	-	-
65 Years	0.868	1.417	1.061	1.610
66 Years	0.599	1.148	0.756	1.305
67 Years	0.599	1.148	0.756	1.305
68 Years	0.599	1.148	0.756	1.305
69 Years	0.599	1.148	0.756	1.305
70-74 Years	0.610	1.159	0.767	1.316
75-79 Years	0.665	1.214	0.823	1.372
80-84 Years	0.697	1.246	0.855	1.404
85-89 Years	0.696	1.245	0.854	1.402
90-94 Years	0.696	1.245	0.854	1.402
95 Years or Over	0.696	1.245	0.854	1.402
Male				
0-34 Years	0.836	1.385	-	-
35-44 Years	1.115	1.664	-	-
45-54 Years	1.075	1.623	-	-
55-59 Years	0.931	1.480	-	-
60-64 Years	0.882	1.431	-	-
65 Years	0.687	1.236	0.787	1.336
66 Years	0.445	0.994	0.549	1.098
67 Years	0.445	0.994	0.549	1.098
68 Years	0.445	0.994	0.549	1.098
69 Years	0.445	0.994	0.549	1.098
70-74 Years	0.457	1.006	0.561	1.110
75-79 Years	0.487	1.036	0.487	1.036
80-84 Years	0.480	1.029	0.480	1.029
85-89 Years	0.517	1.065	0.517	1.065
90-94 Years	0.517	1.065	0.517	1.065
95 Years or Over	0.517	1.065	0.517	1.065

NOTES:

1. The Part D Denominator used to calculate relative factors is $1,086.61. This Part D Denominator is based on the combined PDP and MA-PD populations.
2. Originally Disabled is defined as originally entitled to Medicare by disability only.
3. Concurrently ESRD is defined as at least one month in 2008 of ESRD status—dialysis, transplant, or post-graft.

Source: RTI Analysis of 100% 2008 PDE SAF, 2007-2008 HPMS, 2008 CME, and 2007-2008 Denominator.

Table 15. Preliminary RxHCC Model Relative Factors for New Enrollees, Institutional

Variable	Baseline – Not Concurrently ESRD	Concurrently ESRD
Female		
0-34 Years	2.136	2.371
35-44 Years	2.136	2.371
45-54 Years	2.050	2.285
55-59 Years	2.013	2.248
60-64 Years	1.952	2.187
65 Years	2.024	2.259
66 Years	1.816	2.051
67 Years	1.816	2.051
68 Years	1.816	2.051
69 Years	1.816	2.051
70-74 Years	1.646	1.881
75-79 Years	1.578	1.813
80-84 Years	1.403	1.638
85-89 Years	1.235	1.470
90-94 Years	1.235	1.470
95 Years or Over	1.235	1.470
Male		
0-34 Years	2.159	2.394
35-44 Years	2.159	2.394
45-54 Years	2.098	2.333
55-59 Years	1.975	2.210
60-64 Years	1.826	2.061
65 Years	1.823	2.058
66 Years	1.715	1.950
67 Years	1.715	1.950
68 Years	1.715	1.950
69 Years	1.715	1.950
70-74 Years	1.603	1.838
75-79 Years	1.567	1.802
80-84 Years	1.533	1.768
85-89 Years	1.317	1.552
90-94 Years	1.317	1.552
95 Years or Over	1.317	1.552

NOTES:

1. The Part D Denominator used to calculate relative factors is $1,086.61. This Part D Denominator is based on the combined PDP and MA-PD populations.
2. Concurrently ESRD is defined as at least one month in 2008 of ESRD status—dialysis, transplant, or post-graft.
3. The Part D New Enrollee Institutional sample does not have an Originally Disabled add-on (set to $0 because of regression results).

Source: RTI Analysis of 100% 2008 PDE SAF, 2007-2008 HPMS, 2008 CME, and 2007-2008 Denominator.

Table 16. Preliminary list of Disease Hierarchies for the Revised RxHCC Model

DISEASE HIERARCHIES

Rx Hierarchical Condition Category (RxHCC)	If the Disease Group is Listed in this column…	…Then drop the RxHCC(s) listed in this column
	Rx Hierarchical Condition Category (RxHCC) LABEL	
8	Chronic Myeloid Leukemia	9,10,11,48,50
9	Multiple Myeloma and Other Neoplastic Disorders	10,11,48,50
10	Breast, Lung, and Other Cancers and Tumors	11
14	Diabetes with Complications	15
18	Diabetes Insipidus and Other Endocrine and Metabolic Disorders	19
30	Chronic Pancreatitis	31
40	Psoriatic Arthropathy	41,42,147
41	Rheumatoid Arthritis and Other Inflammatory Polyarthropathy	42
47	Sickle Cell Anemia	50
48	Myelodysplastic Syndromes, Except High-Grade	50
54	Alzheimer's Disease	55
58	Schizophrenia	59,60,61,62,63,65,66,67,68
59	Bipolar Disorders	60,61,62,63
60	Major Depression	61,62,63
61	Specified Anxiety, Personality, and Behavior Disorders	62,63
62	Depression	63
65	Autism	61,62,63,66,67,68
66	Profound or Severe Mental Retardation/Developmental Disability	67,68
67	Moderate Mental Retardation/Developmental Disability	68
78	Intractable Epilepsy	79,80
79	Epilepsy and Other Seizure Disorders, Except Intractable Epilepsy	80
86	Pulmonary Hypertension and Other Pulmonary Heart Disease	87,88
87	Congestive Heart Failure	88
103	Cystic Fibrosis	104,105
104	Chronic Obstructive Pulmonary Disease and Asthma	105
120	Kidney Transplant Status	121,122,123,124,125,126,168
121	Dialysis Status	122,123,124,125,126
122	Chronic Kidney Disease Stage 5	123,124,125,126
123	Chronic Kidney Disease Stage 4	124,125,126
124	Chronic Kidney Disease Stage 3	125,126
125	Chronic Kidney Disease Stage 1, 2, or Unspecified	126
166	Lung Transplant Status	167,168
167	Major Organ Transplant Status, Except Lung, Kidney, and Pancreas	168

SOURCE: RTI International.

Table 17. Comparison of Current and Revised RxHCC Risk Adjustment Model RxHCCs

Version 01 RxHCCs			Version 03 RxHCCs	
RxHCC	**Description**	**Category Short Name**	**RxHCC**	**Description**
RXHCC1	HIV/AIDS	Infection	RXHCC1	HIV/AIDS
RXHCC2	Opportunistic Infections		RXHCC5	Opportunistic Infections
RXHCC3	Infectious Diseases			
RXHCC8	Acute Myeloid Leukemia	Neoplasm	RXHCC8	Chronic Myeloid Leukemia
RXHCC9	Metastatic Cancer, Acute Leukemia, and Severe Cancers		RXHCC9	Multiple Myeloma and Other Neoplastic Disorders
RXHCC10	Lung, Upper Digestive Tract, and Other Severe Cancers		RXHCC10	Breast, Lung, and Other Cancers and Tumors
			RXHCC11	Prostate and Other Cancers and Tumors
RXHCC17	Diabetes with Complications	Diabetes	RXHCC14	Diabetes with Complications
RXHCC18	Diabetes without Complication		RXHCC15	Diabetes without Complication
RXHCC19	Disorders of Lipoid Metabolism	Metabolic	RXHCC18	Diabetes Insipidus and Other Endocrine and Metabolic Disorders
RXHCC20	Other Significant Endocrine and Metabolic Disorders		RXHCC19	Pituitary, Adrenal Gland, and Other Endocrine and Metabolic Disorders
RXHCC21	Other Specified Endocrine/Metabolic/Nutritional Disorders		RXHCC20	Thyroid Disorders
			RXHCC21	Morbid Obesity
			RXHCC23	Disorders of Lipoid Metabolism
RXHCC24	Chronic Viral Hepatitis	Liver	RXHCC25	Chronic Viral Hepatitis
RXHCC31	Chronic Pancreatic Disease	Gastrointestinal	RXHCC30	Chronic Pancreatitis
			RXHCC31	Pancreatic Disorders and Intestinal Malabsorption, Except Pancreatitis
RXHCC33	Inflammatory Bowel Disease		RXHCC32	Inflammatory Bowel Disease
RXHCC34	Peptic Ulcer and Gastrointestinal Hemorrhage		RXHCC33	Esophageal Reflux and Other Disorders of Esophagus
RXHCC37	Esophageal Disease			
RXHCC39	Bone/Joint/Muscle Infections/Necrosis	Musculoskeletal	RXHCC38	Aseptic Necrosis of Bone
RXHCC40	Behçet's Syndrome and Other Connective Tissue Disease		RXHCC40	Psoriatic Arthropathy
RXHCC41	Rheumatoid Arthritis and Other Inflammatory Polyarthropathy		RXHCC41	Rheumatoid Arthritis and Other Inflammatory Polyarthropathy

Version 01 RxHCCs			Version 03 RxHCCs	
RxHCC	**Description**	**Category Short Name**	**RxHCC**	**Description**
RXHCC42	Inflammatory Spondylopathies		RXHCC42	Systemic Lupus Erythematosus, Other Connective Tissue Disorders, and Inflammatory Spondylopathies
RXHCC43	Polymyalgia Rheumatica		RXHCC45	Osteoporosis, Vertebral and Pathological Fractures
RXHCC44	Psoriatic Arthropathy			
RXHCC45	Disorders of the Vertebrae and Spinal Discs			
RXHCC47	Osteoporosis and Vertebral Fractures			
RXHCC48	Other Musculoskeletal and Connective Tissue Disorders			
RXHCC51	Severe Hematological Disorders	Blood	RXHCC47	Sickle Cell Anemia
RXHCC52	Disorders of Immunity		RXHCC48	Myelodysplastic Syndromes, Except High-Grade
RXHCC54	Polycythemia Vera		RXHCC49	Immune Disorders
RXHCC55	Coagulation Defects and Other Specified Blood Diseases		RXHCC50	Aplastic Anemia and Other Significant Blood Disorders
RXHCC57	Delirium and Encephalopathy	Cognitive	RXHCC54	Alzheimer's Disease
RXHCC59	Dementia with Depression or Behavioral Disturbance		RXHCC55	Dementia, Except Alzheimer's Disease
RXHCC60	Dementia/Cerebral Degeneration			
RXHCC65	Schizophrenia	Psychiatric	RXHCC58	Schizophrenia
RXHCC66	Other Major Psychiatric Disorders		RXHCC59	Bipolar Disorders
RXHCC67	Other Psychiatric Symptoms/Syndromes		RXHCC60	Major Depression
RXHCC75	Attention Deficit Disorder		RXHCC61	Specified Anxiety, Personality, and Behavior Disorders
			RXHCC62	Depression
			RXHCC63	Anxiety Disorders
		Developmental Disability	RXHCC65	Autism
			RXHCC66	Profound or Severe Mental Retardation/Developmental Disability
			RXHCC67	Moderate Mental Retardation/Developmental Disability

Version 01 RxHCCs			Version 03 RxHCCs	
RxHCC	**Description**	**Category Short Name**	**RxHCC**	**Description**
			RXHCC68	Mild or Unspecified Mental Retardation/Developmental Disability
RXHCC76	Motor Neuron Disease and Spinal Muscular Atrophy	Neurological	RXHCC71	Myasthenia Gravis, Amyotrophic Lateral Sclerosis and Other Motor Neuron Disease
RXHCC77	Quadriplegia, Other Extensive Paralysis, and Spinal Cord Injuries		RXHCC72	Spinal Cord Disorders
RXHCC78	Muscular Dystrophy		RXHCC74	Polyneuropathy
RXHCC79	Polyneuropathy, except Diabetic		RXHCC75	Multiple Sclerosis
RXHCC80	Multiple Sclerosis		RXHCC76	Parkinson`s Disease
RXHCC81	Parkinson's Disease		RXHCC78	Intractable Epilepsy
RXHCC82	Huntington's Disease		RXHCC79	Epilepsy and Other Seizure Disorders, Except Intractable Epilepsy
RXHCC83	Seizure Disorders and Convulsions		RXHCC80	Convulsions
RXHCC85	Migraine Headaches		RXHCC81	Migraine Headaches
RXHCC86	Mononeuropathy, Other Abnormal Movement Disorders		RXHCC83	Trigeminal and Postherpetic Neuralgia
RXHCC87	Other Neurological Conditions/Injuries			
RXHCC91	Congestive Heart Failure	Heart	RXHCC86	Pulmonary Hypertension and Other Pulmonary Heart Disease
RXHCC92	Acute Myocardial Infarction and Unstable Angina		RXHCC87	Congestive Heart Failure
RXHCC98	Hypertensive Heart Disease or Hypertension		RXHCC88	Hypertension
RXHCC99	Specified Heart Arrhythmias		RXHCC89	Coronary Artery Disease
			RXHCC93	Atrial Arrhythmias
RXHCC102	Cerebral Hemorrhage and Effects of Stroke	Cerebrovascular Disease	RXHCC97	Cerebrovascular Disease, Except Hemorrhage or Aneurysm
			RXHCC98	Spastic Hemiplegia
RXHCC105	Pulmonary Embolism and Deep Vein Thrombosis	Vascular	RXHCC100	Venous Thromboembolism
RXHCC106	Vascular Disease		RXHCC101	Peripheral Vascular Disease
RXHCC108	Cystic Fibrosis	Lung	RXHCC103	Cystic Fibrosis
RXHCC109	Asthma and COPD		RXHCC104	Chronic Obstructive Pulmonary Disease and Asthma

Version 01 RxHCCs			Version 03 RxHCCs	
RxHCC	**Description**	**Category Short Name**	**RxHCC**	**Description**
RXHCC110	Fibrosis of Lung and Other Chronic Lung Disorders		RXHCC105	Pulmonary Fibrosis and Other Chronic Lung Disorders
RXHCC111	Aspiration and Specified Bacterial Pneumonias		RXHCC106	Gram-Negative/Staphylococcus Pneumonia and Other Lung Infections
RXHCC112	Empyema, Lung Abscess, and Fungal and Parasitic Lung Infections			
RXHCC113	Acute Bronchitis and Congenital Lung/Respiratory Anomaly			
RXHCC120	Vitreous/Retinal Hemorrhage and Vascular Retinopathy except Diabetic	Eye	RXHCC111	Diabetic Retinopathy
RXHCC121	Macular Degeneration and Retinal Disorders, Except Detachment and Vascular Retinopathies		RXHCC113	Open-Angle Glaucoma
RXHCC122	Open-angle Glaucoma			
RXHCC123	Glaucoma and Keratoconus			
RXHCC126	Larynx/Vocal Cord Diseases	Ear, Nose, Throat		
RXHCC129	Other Diseases of Upper Respiratory System			
RXHCC130	Salivary Gland Diseases			
RXHCC132	Kidney Transplant Status	Kidney	RXHCC120	Kidney Transplant Status
RXHCC134	Chronic Renal Failure		RXHCC121	Dialysis Status
			RXHCC122	Chronic Kidney Disease Stage 5
			RXHCC123	Chronic Kidney Disease Stage 4
			RXHCC124	Chronic Kidney Disease Stage 3
			RXHCC125	Chronic Kidney Disease Stage 1, 2, or Unspecified
RXHCC135	Nephritis		RXHCC126	Nephritis
RXHCC137	Urinary Obstruction and Retention	Urinary, Genital		
RXHCC138	Fecal Incontinence			
RXHCC139	Incontinence			
RXHCC140	Impaired Renal Function and Other Urinary Disorders			
RXHCC144	Vaginal and Cervical Diseases			
RXHCC145	Female Stress Incontinence			
RXHCC157	Chronic Ulcer of Skin, Except Decubitus	Skin	RXHCC142	Chronic Ulcer of Skin, Except Pressure

Version 01 RxHCCs			Version 03 RxHCCs	
RxHCC	**Description**	**Category Short Name**	**RxHCC**	**Description**
RXHCC158	Psoriasis		RXHCC145	Pemphigus
RXHCC159	Cellulitis and Local Skin Infection		RXHCC147	Psoriasis, Except with Arthropathy
RXHCC160	Bullous Dermatoses and Other Specified Erythematous Conditions			
RXHCC165	Vertebral Fractures without Spinal Cord Injury	Injury		*(See Note 2.)*
RXHCC166	Pelvic Fracture			
		Sleep	RXHCC156	Narcolepsy and Cataplexy
RXHCC186	Major Organ Transplant Status	Transplant	RXHCC166	Lung Transplant Status
RXHCC187	Other Organ Transplant/Replacement		RXHCC167	Major Organ Transplant Status, Except Lung, Kidney, and Pancreas
			RXHCC168	Pancreas Transplant Status
		Disabled-Disease Interactions		
DRXHCC65	Age < 65 and RXHCC65 (Schizophrenia)			
DRXHCC66	Age < 65 and RXHCC66 (Other Major Psychiatric Disorders)			
DRXHCC108	Age < 65 and RXHCC108 (Cystic Fibrosis)			
		Interactions That Are in the V03 Institutional RxHCC Model *Only*		
			NonAged_RXHCC1	NonAged * HIV/AIDS
			NonAged_RXHCC58	NonAged * Schizophrenia
			NonAged_RXHCC59	NonAged * Bipolar Disorders
			NonAged_RXHCC60	NonAged * Major Depression
			NonAged_RXHCC61	NonAged * Specified Anxiety, Personality, and Behavior Disorders
			NonAged_RXHCC62	NonAged * Depression
			NonAged_RXHCC63	NonAged * Anxiety Disorders
			NonAged_RXHCC65	NonAged * Autism
			NonAged_RXHCC75	NonAged * Multiple Sclerosis
			NonAged_RXHCC78	NonAged * Intractable Epilepsy
			NonAged_RXHCC79	NonAged * Epilepsy and Other Seizure Disorders, Except Intractable Epilepsy
			NonAged_RXHCC80	NonAged * Convulsions

NOTES:
1. NonAged is defined as age < 65 as of February 1 of the payment year.

SOURCE: RTI International.

Table 18. Preliminary Recalibrated Frailty Factors for CY 2011

ADL	2009 Factors (Non-Medicaid)	2011 Recalibrated Factors (Non-Medicaid)	2009 Factors (Medicaid)	2011 Recalibrated Factors (Medicaid)
0	-0.093	-0.079	-0.180	-0.201
1-2	0.112	0.118	0.035	0.000
3-4	0.201	0.187	0.155	0.105
5-6	0.381	0.335	0.200	0.121

Attachment VI: 2011 Call Letter

How to Use This Call Letter

The 2011 Call Letter contains information on the Part C cost-based (Quality and Performance Measures section only), and Part D programs. Also, we indicate when certain sections apply to cost-reimbursed HMOs, PACE programs, and employer and union-sponsored group health plans (EGWPs).

This year's letter is structured differently from prior year call letters. Section 1 provides new policy for MA plans, MA-PD plans, and PDPs (and with respect to non-contracting physician payment, cost-reimbursed HMOs). Section 2 provides updated information for Parts C and D organizations/sponsors, including the updated calendar for CY 2011.

Over the past year, CMS has committed its resources to improving the quality of plan choices for beneficiaries who elect to enroll in Medicare Advantage and prescription drug plans. As part of this effort, CMS:

- Published a proposed regulation (4085-P) on October 22, 2009 that would make revisions to the Parts C and D regulations to ensure meaningful differences among plan offerings, strengthen beneficiary protections, and improve data for CMS oversight and quality assessment. CMS is currently reviewing comments submitted by the public and is in the process of developing the policies for the final rule.
- Released new or revised Medicare manual chapters.
- Non-renewed a number of plans for CY 2010 because they had little or no enrollment, thus reducing the beneficiary's confusion when choosing to enroll in a Medicare Advantage or prescription drug plan.
- Conducted listening sessions for industry and advocacy groups before the end of CY 2009, to give them the opportunity to communicate their concerns to CMS regarding any procedural or operational issues they would like CMS to address in the 45-day notice and call letter for CY 2011.

Since this year's final Call Letter will be released close to the expected final publication of the final rule (4085-F), the content is limited to clarification of current policy and operational guidance. However, requirements contained in the final rule may be included in this year's final Call Letter, even if they have not been included in this draft Call Letter. We remind sponsoring organizations to continue to remain responsible for familiarizing themselves with statutory requirements, regulations, and guidance governing the MA and Part D programs, including the Medicare Advantage and Prescription Drug Benefit Manuals. CMS will separately issue technical and procedural clarifications regarding bid and formulary submissions, benefits, HPMS

data, CMS marketing models, and other operational issues of interest to sponsoring organizations.

We hope this information helps you implement and comply with CMS policies and procedures as you prepare either to offer a plan for the first time or continue offering plans under the MA and/or Part D programs.

If you have questions concerning this Call Letter, please contact:
Christopher McClintick at Christopher.McClintick@cms.hhs.gov for Part C Call Letter items
Christine Hinds at Christine.Hinds@cms.hhs.gov for Part D Call Letter items

Table of Contents

Section 1 - New Policy

Part C

I. Special Needs Plans (SNP)

State Resource Center

Section 164 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) directed CMS to provide technical assistance to States to promote Medicare-Medicaid benefit integration for dual eligible populations. The Resource Center was CMS' response to equip States with helpful information as they engage in contract negotiations with MAOs seeking to offer new or expanded dual eligible special needs plans (SNP).

The goal of the State Resource Center is to support State Medicaid agencies' efforts to increase coordination with MAOs offering specialized plans for dually eligible individuals (dual eligible SNPs). Additionally, the State Resource Center provides a forum for States to make inquires and share knowledge about the coordination of State and Federal policies pertaining to SNPs. To these ends, since its establishment the resource center has--

- Developed best practices with respect to model contracts with States
- Led training sessions
- Established a website to provide information on coordination issues (http://www.cms.hhs.gov/SpecialNeedsPlans/05_StateResourceCenter.asp)

II. Quality and Performance Measures

CAHPS and HOS Reporting for Special Needs Plans

For plan year 2011, the Consumer Assessment of Health Plans Survey (CAHPS) and the Medicare Health Outcomes Survey (HOS) will continue to sample, collect, and report data at the contract level. However, oversampling of SNP plan benefit packages will occur within each eligible contract to allow for a more focused analysis of SNP results. CMS will release information about the expected increase in sample size for applicable organizations in future guidance.

CMS is currently analyzing limited aggregate SNP data available from prior HOS and CAHPS data sets and will publicly share findings in a report that will be released later in 2010.

Note: Continuing 1876 cost contracts should continue to report the same quality and performance measures as they have in the past.

HOS Survey Administration

The current year Health Employer Data Information Set (HEDIS) reporting category that reports the HOS results applies to the following managed care organization types with a minimum of 500 members that had a Medicare contract in effect on or before January 1, 2010: (1) all coordinated care contractors, including health maintenance organizations (HMOs), local preferred provider organizations (PPOs) and regional PPOs; (2) private fee-for-service (PFFS) contracts; (3) medical savings account (MSA) contracts; and (4) continuing 1876 cost contracts with open enrollment. Organizations eligible to report also include MA contracts with exclusively special needs plan benefit packages, regardless of institutional, chronically ill, or dual-eligible enrollment.

All Programs of All Inclusive Care for the Elderly (PACE) with contracts in effect on or before January 1, 2010 should administer the HOS-Modified (HOS-M) survey for current year HEDIS reporting. A minimum enrollment threshold does not apply to the HOS-M. Note that the Minnesota Senior Health Options, Minnesota Disability Health Options, Wisconsin Partnership Programs, and Massachusetts MassHealth Senior Care Options MA contracts are required to report HOS and no longer participate in HOS-M.

Part D

I. Part D Benefits

Potential New B versus D Coverage Determination for beneficiaries with End Stage Renal Disease

CMS published a notice of proposed rulemaking (NPRM) in the Federal Register on September 29, 2009 that would implement a case-mix adjusted bundled prospective payment system (PPS) for Medicare outpatient end-stage renal disease (ESRD) dialysis facilities beginning January 1, 2011, in compliance with the statutory requirement of the Medicare Improvements for Patients and Providers Act (MIPPA) of 2008. (74 FR 49922) The proposed ESRD PPS would replace the current basic case-mix adjusted composite payment system and the methodologies for the reimbursement of separately billable outpatient ESRD services. In accordance with MIPPA, the rule proposes to include erythropoiesis stimulating agents, and other drugs and biologicals and their oral equivalents, furnished to individuals for the treatment of ESRD in the new bundled payment as “renal dialysis services”. Any such drugs or biologicals that would be defined as “renal dialysis services” under the new ESRD PPS would not be eligible for coverage under Part D when furnished to individuals for the treatment of ESRD. Rather, these drugs or biologicals and all other renal dialysis services would be covered under the Medicare Part B benefit. CMS will explore the possibility of providing an indicator on transaction reply reports to identify ESRD beneficiaries in the dialysis stage that could assist Part D sponsors with making associated

Medicare Part B vs. Part D determinations. CMS plans to publish the ESRD PPS final rule in 2010.

Encouragement of Sponsor Practices to Curb Waste of Unused Drugs Dispensed in the Retail Setting

As part of CMS's effort to contain health care costs and reduce waste associated with the Medicare prescription drug benefit, we are requesting that Part D sponsors consider allowing beneficiaries in the community (versus institutional) setting the option to request a trial supply of no more than 7 to 14 days of a Part D covered medication when first prescribed. With this option, Part D sponsors would be expected to prorate cost-share amounts associated with that prescription. For 2011, we have included a field in the PBP to allow sponsors to indicate whether they will offer prorated copayments to support this practice.

Current physician prescribing patterns and pharmacy benefit management payment practices result in most prescriptions being dispensed in 30 or 90 day quantities. Whenever the full amount dispensed is not utilized by the patient due to death, adverse reactions, medication substitution, or other reason for discontinuation, the remaining unused medication becomes waste. It also becomes an environmental hazard when disposed of, and is sometimes a safety hazard in the home or diverted to illegal use.

CMS' review of 2007 Prescription Drug Event (PDE) data suggests that up to as many as 30% of first fills for chronic medications are not refilled. If the disincentive of paying the full cost sharing amount was eliminated, and copays were prorated for the amount actually dispensed, beneficiaries might appreciate the opportunity to request an initial trial fill for new medications. We believe that trial fills will be most appreciated by beneficiaries and their physicians when initiating new therapies and for more expensive medications. We also believe that the proration of prescriptions ("partial fills") is a practice consistent with state pharmacy law and accommodated by pharmacies and transaction systems today. Thus, only a change in payer practices including negotiation of appropriate dispensing or incentive fees for promotion of these trial fills may be needed to implement this waste reduction strategy at the pharmacy counter.

There are several benefits to the program in adopting the proration of cost-sharing for trial supplies:

- Discourages both environmental waste and diversion of unused drugs for illegal use.
- Motivates the beneficiary to request partial fills in order to gauge tolerance of the new drug. By allowing plan members to obtain a partial fill for new medications, the member may try the medication and return to the pharmacy for the full amount when the patient has demonstrated a tolerance for the new medication.
- May serve as a substitute for physicians' practice of giving patients samples of medications that may not be compatible with the patient's Part D plan formulary.
- Promotes savings to the beneficiary, Part D sponsor and Medicare program.

For 2011, we have included a field in the PBP to allow sponsors to indicate whether they offer prorated copayments to support this practice. We encourage Part D sponsors to discuss implementing this practice with network pharmacies and to support this effort. We also requests comments or concerns regarding implementation of the practice of trial fills in the community setting from all stakeholders, including from beneficiary advocates, physicians, pharmacies, and Part D sponsors.

II. Reassignment

In the fall of 2010, we will again conduct reassignment of certain low income subsidy (LIS) beneficiaries who were originally assigned to a Prescription Drug Plan (PDP) whose premium is below the LIS benchmark in 2010, but will go above the LIS benchmark in 2011. Details of the process may be found in section 30.1.5 of the PDP Eligibility, Enrollment, and Disenrollment Guidance, on our website at http://www.cms.hhs.gov/MedicarePresDrugEligEnrol/Downloads/PDPEnrollmentGuidanceUpdateFINAL2010.pdf

In the past, we have reassigned only individuals who have never chosen a plan on their own and, thus, remain in a plan into which they were auto-enrolled by CMS. We have not reassigned individuals who chose their PDP, although we have conducted outreach, including notifying them via tan-colored letters of the zero-premium plans available in their region.

For the fall of 2010, we are considering expanding reassignment to these "choosers" based on their 2011 premium liability, for example, if their 2011 premium will be $10 or greater. We are concerned that these beneficiaries – despite targeted outreach – may not fully understand they have less expensive alternatives. Particularly with premiums higher than $10, we believe there is increased risk that individuals will not be able to pay their premiums, which could result in disenrollment for nonpayment of premium.

As with the standard reassignment process, these beneficiaries would be informed that if they take no action, CMS would reassign them to a zero premium plan; but if they want to remain in their current PDP, they need only contact that PDP and indicate they want to stay enrolled. We are exploring the feasibility of considering past medication use as part of the reassignment process.

We solicit comments on this proposal, including whether we should "reassign" choosers and if so, the premium liability threshold that should trigger reassignment. We also solicit comments on what other criteria, if any, we might consider when reassigning beneficiaries in addition to premium liability and medication use.

The premium liabilities for 2010 LIS choosers array as follows:

LIS Plan Premium Range	Number of Plans	Number of Beneficiaries	Proportion of Choosers
Premium < $5	290	473,756	27.7%
Premium $5 - $9.99	201	654,359	38.3%
Premium $10 - $14.99	168	349,615	20.5%
Premium $15 - $19.99	132	80,241	4.7%
Premium $20 - $29.99	132	59,184	3.5%
Premium $30 +	416	91,498	5.4%
Total	1,339	1,708,653	

Section 2 - Updates to Parts C and D Policy/Calendar

2011 MA, MA-PD, Part D and Cost-Based Plan Calendar **(All dates, unless identified as statutory, are subject to change)**				
2010 ***Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D Sponsors also apply to MA and Cost-based plans offering a Part D benefit.**		***Part C**	***Part D Sponsors**	**Cost**
March 5, 2010	Initial Submission deadline for risk adjustment data with dates of service January 1, 2009 through December 31, 2009	✓		✓
March 29, 2010	Release Health Plan Management System (HPMS) formulary submissions module.	✓	✓	
March 2010	Release guidance regarding potentially duplicative and /or low enrollment plans for 2011 bid submission.	✓		
TBD	Conference call with industry to discuss the 2011 Call Letter.	✓	✓	✓
TBD	Medicare Advantage and Part D National Conference.	✓	✓	
Early April 2010	Information about renewal options for contract year 2011 (including HPMS crosswalk charts) will be provided to plans.	✓	✓	
April 2010	Release guidance regarding benefits review standards for 2011 bid submissions.	✓	✓	

2011 MA, MA-PD, Part D and Cost-Based Plan Calendar **(All dates, unless identified as statutory, are subject to change)**				
2010 ***Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D Sponsors also apply to MA and Cost-based plans offering a Part D benefit.**		***Part C**	***Part D Sponsors**	**Cost**
April 5, 2010	2011 Final Call Letter released. Announce CY 2011 MA Capitation Rates and MA and Part D Payment Policies. *(applies to Part C and Part D Sponsors only)*	✓	✓	✓
April 9, 2010	2011 Plan Creation Module, Plan Benefit Package (PBP), and Bid Pricing Tool (BPT) available on HPMS.	✓	✓	
April 19, 2010	2011 Formulary Submissions due from all sponsors offering Part D (11:59 p.m. EDT). Transition Attestations due to CMS *(Part D sponsors only)*	✓	✓	
May 2010	Final marketing model documents will be available for all organizations. (Models containing significant revisions will be released for public comment prior to this date).		✓	
May 3, 2010	Voluntary Non-Renewal. CMS strongly encourages MA and MA-PDs and cost-based organizations to notify CMS of an intention to non-renew a county or counties for individuals, but continue the county for "800 series" EGWP members, by May 3, 2010. Additionally, CMS strongly encourages MA and MA-PDs and cost-based organizations that intend to request a new partial county service area to submit that request by May 1, 2010. Requests must include documents for justification that meet the county integrity rule as outlined in Chapter 4 of the Medicare Managed Care Manual.	✓		✓
May 3, 2010	*Voluntary non-renewal*: Part D Sponsors are strongly encouraged to notify CMS by May 3, 2010 of any type of service area reduction, or conversion to offering employer-only contracts, so that CMS can make the required changes in HPMS to facilitate a sponsor's ability to correctly upload its bid in June.		✓	

2011 MA, MA-PD, Part D and Cost-Based Plan Calendar **(All dates, unless identified as statutory, are subject to change)**				
2010 ***Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D Sponsors also apply to MA and Cost-based plans offering a Part D benefit.**		***Part C**	***Part D Sponsors**	**Cost**
May 14, 2010	CMS begins accepting CY 2011 bids via HPMS. *(applies to Part C and Part D Sponsors only)* CMS begins accepting CY2011 broker/agent compensation structures.	✓	✓	✓
May 21, 2010	PBP/BPT upload available		✓	
Mid-May/June 2010	CMS sends contract eligibility determinations to applicants based on review of the 2011 applications for new contracts or service area expansions.	✓	✓	✓
Late Spring/Early Summer 2010	Update of the MA/PDP Enrollment, Eligibility, and Disenrollment, Marketing Guidelines.	✓	✓	✓
Tentative date - June 4, 2010	CMS begins accepting CY 2011 marketing material for review.	✓	✓	✓
June 7, 2010	Deadline for submission of CY 2011 bids for all MA, MA-PD, PDP, cost-based plan offering a Part D benefit, "800 series" EGWP and direct contract EGWP applicants and renewing organizations; deadline for cost-based plans wishing to appear in the 2010 Medicare Options Compare to submit PBPs (11:59 p.m. PDT). Submission deadline for agent/broker compensation structures due to CMS. Voluntary Non-Renewal. Deadline for MA, MA-PDs and PDPs to submit a contract non-renewal, service area reduction notice to CMS for CY 2011. Deadline also applies to an MAO that intends to terminate a current MA and/or MA-PDs plan benefit package (i.e., Plan 01, Plan 02) for CY 2011. Medicare cost-based contractors and cost-based sponsors strongly encouraged to submit a non-renewal or service area reduction notice to CMS.	✓	✓	✓

2011 MA, MA-PD, Part D and Cost-Based Plan Calendar **(All dates, unless identified as statutory, are subject to change)**				
2010 ***Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D Sponsors also apply to MA and Cost-based plans offering a Part D benefit.**		***Part C**	***Part D Sponsors**	**Cost**
June 14, 2010	CMS begins accepting Supplemental Formulary files, Free First Fill file, Partial Gap file, Excluded Drug file, Over the Counter (OTC) drug file, and Home Infusion file through HPMS. CMS begins accepting CY 2011 Actuarial Certifications in HPMS.	✓	✓	
June 30, 2010	Final date to submit CY 2010 marketing materials for assured CMS' review and approval. NOTE: This date does not apply to CY 2010 file and use materials since these may be filed with the regional office five calendar days prior to their use.	✓	✓	✓
Late June 2010	Non-Renewal. CMS to issue an acknowledgement letter to all MA, MA-PD and Medicare cost-based plans that have notified CMS they are non-renewing or reducing their service area.	✓		✓
Late June or July, 2010	Industry training on Annual Notice of Change (ANOC)/Evidence of Coverage (EOC) and other marketing models.	✓	✓	✓
August, 2010	Non-Renewal. CMS to release a special election period (SEP) letter to plans remaining in the service areas of plans that have non-renewed. Additionally, CMS to post the model final non-renewal notification letter, and State-specific final notification letter. Release of the 2011 Part D national average monthly bid amount, the Medicare Part D base beneficiary premium, the Part D regional low-income premium subsidy amounts, and the Medicare Advantage regional PPO benchmarks. Rebate reallocation period begins after release of the above amounts.	✓	✓	✓

2011 MA, MA-PD, Part D and Cost-Based Plan Calendar **(All dates, unless identified as statutory, are subject to change)**				
2010 ***Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D Sponsors also apply to MA and Cost-based plans offering a Part D benefit.**		***Part C**	***Part D Sponsors**	**Cost**
Early August, 2010	Cost-based plans are encouraged to submit their summary of benefits (SBs) by this date so that materials can be reviewed and approved prior to the publishing of "Medicare Options Compare" and the *Medicare & You* handbook. SBs must be submitted by this date to be assured of being included.			✓
August 2, 2010	Deadline for CMS to inform currently contracted organizations of CMS' decision not to authorize a renewal of a contract for 2011.	✓	✓	
August 3, 2010	Plans are expected to submit non-model Low Income Subsidy (LIS) riders to the regional office for review.		✓	
August 13, 2010	Dual eligible SNPs that are fully integrated with the State are expected to submit the Annual Notice of Change and Summary of Benefits to the regional office for review.	✓		
Late August, 2010	***Non-Renewal***: Final date for CMS to approve final beneficiary notification letter of non-renewal.	✓	✓	
Late August/Early September, 2010	CMS completes review and approval of 2011 bid data. Submit attestations, contracts, and final actuarial certifications.	✓	✓	
September 1, 2010	Last date for contracting MAOs to provide CMS with evidence of contracting with the State in order to operate a Medicaid dual eligible SNP for CY 2011.	✓		
September 1, 2010	Plans are expected to submit model Low Income Subsidy (LIS) riders to the regional office for review.		✓	
September 3, 2010	Initial Submission deadline for risk adjustment data with dates of service from July 1, 2009 through June 30, 2010.	✓		✓
September, 2010	If applicable, plans preview the 2011 *Medicare & You* plan data in HPMS prior to printing of the CMS publication (not applicable to EGWPs). CMS will begin accepting plan correction requests upon contract approval.	✓	✓	✓

2011 MA, MA-PD, Part D and Cost-Based Plan Calendar **(All dates, unless identified as statutory, are subject to change)**				
2010 ***Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D Sponsors also apply to MA and Cost-based plans offering a Part D benefit.**		***Part C**	***Part D Sponsors**	**Cost**
October 1, 2010	Plans may begin CY 2011 marketing activities. Once an organization begins marketing CY 2011 plans, the organization must cease marketing CY 2010 plans through mass media or direct mail marketing (except for age-in mailings). Organizations may still provide CY 2010 materials upon request, conduct one-on-one sales appointments and process enrollment applications. Plans are required to include information in CY 2010 marketing and enrollment materials to inform potential enrollees about the possibility of plan (benefit) changes beginning January 1, 2011. Last day for Part D sponsors to request plan benefit package (PBP) plan corrections via HPMS.	✓	✓	✓

2011 MA, MA-PD, Part D and Cost-Based Plan Calendar **(All dates, unless identified as statutory, are subject to change)**				
2010 ***Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D Sponsors also apply to MA and Cost-based plans offering a Part D benefit.**		***Part C**	***Part D Sponsors**	**Cost**
October 1, 2010	MA, MA-PD and Medicare cost-based organizations may not market to beneficiaries of non-renewing plans until after October 1, 2010. Deadline for cost-based, MA, and MA-PD organizations to request a plan correction to the plan benefit package (PBP). Deadline for cost-based, MA and MA-PD organizations to request of a SB hard copy change. Requests for administrative changes may begin on June 14, 2010 and for changes to benefits, in early August 2010. Dual eligible SNPs that are fully integrated with the State that plan to use a non-standardized, non-combined EOC are expected to submit these for regional office review. Non-Renewal. The final beneficiary non-renewal notification letter must be a personalized letter and received by MA, MA-PD enrollees by October 1, 2010. Non-Renewal. Cost-based plans must publish a CMS-approved public notice of non-renewal in one or more newspapers of general circulation covering each community or county in their contract areas.	✓		✓
October 1, 2010	Last date for Medicare cost-based contractors and cost-based sponsors to submit a non-renewal or service area reduction notice to CMS NOTE: We strongly encourage submission by June 7, 2010.			✓

2011 MA, MA-PD, Part D and Cost-Based Plan Calendar **(All dates, unless identified as statutory, are subject to change)**				
2010 ***Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D Sponsors also apply to MA and Cost-based plans offering a Part D benefit.**		***Part C**	***Part D Sponsors**	**Cost**
October 8, 2010	Tentative date for 2011 plan benefit data to be displayed on Medicare Options Compare and for 2011 plan drug benefit information to be displayed on the Medicare Prescription Drug Plan Finder on Medicare.gov (not applicable to EGWPs).	✓	✓	✓
Mid-October, 2010	Non-Renewal. CMS to issue an acknowledgement letter to all Medicare cost-based plans that are non-renewing or reducing their service areas.			✓
October 15-29, 2010	CMS mails the 2011 *Medicare & You* handbook to Medicare beneficiaries.	✓	✓	✓
October 30, 2010	CY 2011 standardized, combined Annual Notice of Change (ANOC)/Evidence of Coverage (EOC) is due to all MA, MA-PD, PDP members, and members of cost-based plans offering Part D. MA and MA-PD organizations must mail the combined ANOC/EOC before this date to ensure receipt by members by October 31. Organizations are not required to mail the Summary of Benefits (SB) to existing members when using the combined, standardized ANOC/EOC; however the SB must be available upon request. Exception: Dual eligible SNPs that are fully integrated with the State are not required to use the standardized, combined ANOC/EOC. Dual eligible SNPs that are fully integrated with the State must mail an Annual Notice of Change and Summary of Benefits before this date to ensure receipt by members by October 31. All plans offering Part D must mail their LIS riders and abridged or comprehensive formularies before this date to ensure receipt by members by October 31.	✓	✓	

2011 MA, MA-PD, Part D and Cost-Based Plan Calendar **(All dates, unless identified as statutory, are subject to change)**				
2010 ***Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D Sponsors also apply to MA and Cost-based plans offering a Part D benefit.**		***Part C**	***Part D Sponsors**	**Cost**
November 2, 2010	Non-renewal. Enrollees in cost-based plans and PDPs that are non-renewing must receive the final beneficiary non-renewal notification letter.		✓	✓
November 15, 2010	2011 Annual Coordinated Election Period begins. All organizations must hold open enrollment (for EGWPs, see Chapter 2 of the Medicare Managed Care Manual, Section 30.4.4). Marketing guidelines require that all plans mail a CY 2010 EOC to each new member no later than when they notify the new member of acceptance of enrollment. Organizations offering Part D must mail their Low Income Subsidy Rider (LIS) and abridged or comprehensive formularies with the EOC for new members. New members with an effective date of 1/1/2011 or later do not need to (but may) receive the ANOC portion of the standardized/combined ANOC/EOC.	✓	✓	✓
Mid November 2010	Notices of Intent (NOI) for CY 2012 due for MA, MA-PD, PDP cost-based, "800 series" EGWPs and Direct Contract EGWPs.	✓	✓	✓
Mid November 2010	CMS issues pending HPMS contract numbers for CY 2012 to MA, MA-PD, cost, PDP and EGWP NOIs.	✓	✓	✓
November – December, 2010	Non-Renewal. CMS to issue "close out" information and instructions to MA, MA-PDs, PDPs, and cost-based plans that are non-renewing or reducing service areas.	✓	✓	✓
December 1, 2010	Medicare cost-based plans not offering Part D must send the combined ANOC/EOC for receipt by members by December 1, 2010.			✓
December 1, 2010	Non-Renewal. Cost-based plans must publish notice of non-renewal.			✓
December 31, 2010	2011 Annual Coordinated Election Period ends.	✓	✓	

2011 MA, MA-PD, Part D and Cost-Based Plan Calendar **(All dates, unless identified as statutory, are subject to change)**				
2010 ***Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D Sponsors also apply to MA and Cost-based plans offering a Part D benefit.**		***Part C**	***Part D Sponsors**	**Cost**
December 31, 2010	Dual eligible SNPs that are fully integrated with the State must mail an Evidence of Coverage, LIS riders and abridged or comprehensive formularies before this date to ensure receipt by members by December 31. SNPs that were disproportionate percentage SNPs in 2009 must disenroll all non-special needs members who were enrolled prior to 1/1/2010. Chronic care SNPs must disenroll all members of chronic care SNPs who no longer qualify for the special needs requirement after the redesignation of chronic conditions for 2010 and were enrolled prior to 1/1/2010.	✓		
2011				
January 1, 2011	Plan Benefit Period Begins.	✓	✓	✓
January 1 – March 31, 2011	MA open enrollment period (OEP).	✓		
Early January, 2011	Automated CY 2012 applications released.	✓	✓	✓
Early January, 2011	Industry training on CY 2012 applications.	✓	✓	✓
January 31, 2011	Final Submission deadline for risk adjustment data with dates of service January 1, 2009 through December 31, 2009	✓		✓
Late February, 2011	Applications due for CY 2012.	✓	✓	✓
March 4, 2011	Initial Submission deadline for risk adjustment data with dates of service January 1, 2010 through December 31, 2010	✓		✓

2011 MA, MA-PD, Part D and Cost-Based Plan Calendar **(All dates, unless identified as statutory, are subject to change)**				
2010 ***Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D Sponsors also apply to MA and Cost-based plans offering a Part D benefit.**		***Part C**	***Part D Sponsors**	**Cost**
September 2, 2011	Initial Submission deadline for risk adjustment data with dates of service from July 1, 2010 through June 30, 2011	✓		✓

I. Recommended Deadlines for Cost-Based Plan Non-Renewals

Beginning with the application cycle for 2011 contracts, CMS is strongly encouraging all cost-based plans to follow the schedule established for MA, MA-PD for both submitting service area expansion applications as well as requesting non-renewal/service area reductions. Use of concurrent time frames will allow for a more efficient allocation of CMS resources and consistency across managed care programs.

II. Coordination of Benefits (COB) User Fees

CMS is authorized to impose user fees on Part D sponsors for the transmittal of information necessary for benefit coordination between sponsors and other entities providing prescription drug coverage. CMS may review and update this user fee annually to reflect the costs associated with COB activities. For contract year 2010, the Part D COB user fee was decreased to $1.89 per enrollee per year. While we continue to work on the de-linking of the enrollment and payment modules in MARx as well as other projects to improve the quality reliability and timeliness of the COB-related data, a review of the incremental on-going costs of COB activities in 2011 indicates the Part D COB user fee can be decreased further to $1.17 per enrollee per year for contract year 2011. This COB user fee will be collected at a monthly rate of $0.13 for the first 9 months of the coverage year (for an annual rate of $0.10 per enrollee per month) for a total user fee of $1.17 per enrollee per year. Part D sponsors should account for this COB user fee when developing their 2011 bids.

III. Specialty Tier Threshold

For contract year 2011, we will maintain the $600 threshold for drugs on the specialty tier. Thus, only Part D drugs with negotiated prices that exceed $600 per month may be placed in the specialty tier, and the specialty tiers will be evaluated and approved in accordance with section 30.2.4 of Chapter 6 of the Medicare Prescription Drug Benefit Manual. In addition to cost calculations, CMS considers claims history in reviewing the placement of drugs on Part D sponsors' specialty tiers. Except for newly approved drugs for which Part D sponsors would have little or no claims data, CMS will approve specialty tiers that only include drugs on specialty tiers when their claims data demonstrates that the majority of fills exceed the specialty tier cost criteria. Part D sponsors should be prepared to provide CMS the applicable claims data during the formulary review process.

IV. Medicare Enrollment Assistance Demonstration

In late 2009, CMS announced that it was considering the implementation of a Medicare Enrollment Assistance Demonstration Project. Under the proposed demonstration, CMS envisioned hiring a contractor to reach out to a targeted group of Medicare beneficiaries with comprehensive information and assistance services to help them in understanding and choosing

among their Medicare coverage options. CMS sought stakeholder input on the development of the project and received input from a diverse group of stakeholders during an Open Door Forum and written comment period.

Stakeholders were generally supportive of enhancing the information available to inform coverage decision-making and exploring efforts to develop more effective outreach to specific beneficiary populations. However, stakeholders did not offer strong support of the Medicare Enrollment Assistance Demonstration Project as a method for developing and testing those strategies. Therefore, CMS is reevaluating its intended approach to the enrollment demonstration project based on the comments we received, and we do not anticipate implementing the project for plan year 2011.

V. Risk Adjustment Data Validation (RADV)

This is to remind contracting MA organizations of their obligations under 42 CFR 422.504(e)(2). MAOs are required to provide CMS access to facilities and records used in the determination of amounts payable under an MA contract. This obligates MAOs to provide CMS access to facilities and records (including medical records) that are to be used for risk-adjustment data validation (RADV) purposes, since such records are used for the determination of amounts payable under the MA contract. We would also like to stress the importance of including specific language in contracts with providers that reminds them of their obligation to cooperate in the provision of such records, in accordance with 42 CFR 422.310(e).

VI. Release of Part C and Part D Payment Data

In keeping with the President's January 21st, 2009 Memorandum on Transparency and Open Government (74 FR 26277), CMS is considering the routine release of Part C and Part D payment data. These data would be routinely released on an annual basis in the year after the year for which payments were made. The data release would occur after final risk adjustment reconciliation has been completed for the payment year in question and, for Part D, after final payment reconciliation of the various subsidies. For example, we would release data for payment year 2009 in the fall of 2010.

For Part C, we are considering the release of payment data summarized at the plan benefit package level. Specifically, we would release average per member per month (PMPM) payments for A/B benefits and average PMPM rebate payments. Given that CMS already makes Part C enrollment data publicly available, interested parties could readily calculate gross Part C payments to Medicare Advantages Organizations (MAOs) or to the specific plan benefit packages offered by these organizations. In addition, as part of the annual release, CMS is considering the release of the average Part C risk score for each plan benefit package for the payment year in question.

In addition, we are considering releasing aggregated Part C payment data by county. Specifically, we would release average PMPM amounts for A/B benefits and rebate payments at the MA plan type level (i.e., HMO, PPO, etc.) for each county in which such plan types are represented.

For Part D, we are also considering the release of payment data summarized at the plan benefit package level. Specifically, we would release average per member per month (PMPM) payments for the direct subsidy, the low-income cost sharing subsidy, and the Federal reinsurance subsidy. Given that CMS already makes Part D enrollment data publicly available, with this new data interested parties could readily calculate gross Part D payments to Part D sponsors or the specific plan benefit packages offered by these sponsors. In addition, as part of the annual release, CMS is considering the release of the average Part D risk score for each plan benefit package for the payment year in question.

CMS is not proposing to release data that have been provided to CMS by MAOs or Part D sponsors as part of their annual bids. It could be possible, however, to approximate the bid amount for a particular plan benefit package using the payment and risk score information that CMS is considering for release. Given that the data will not be released until a full two years after MAOs or sponsors have submitted such bids, we do not believe release would undermine the competitive aspects of the Part C or Part D program. Further, we do not believe that the availability of payment information of this sort poses a realistic threat to proprietary or confidential information.

We solicit comment on the public release of Part C and Part D payment data as outlined above. In particular, we solicit comment on whether release of payment data at the plan benefit package level would negatively affect the competitive nature of the bidding processes in either Part C or Part D. In addition, we solicit comment on whether the release of the proposed payment data would reveal information that MAOs or Part D sponsors have provided to CMS that is of a proprietary nature.

February 18, 2011

NOTE TO: Medicare Advantage Organizations, Prescription Drug Plan Sponsors, and Other Interested Parties

SUBJECT: Advance Notice of Methodological Changes for Calendar Year (CY) 2012 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2012 Call Letter

In accordance with Section 1853(b)(2) of the Social Security Act (the Act), we are notifying you of planned changes in the MA capitation rate methodology and risk adjustment methodology applied under Part C of the Act for CY 2012. Preliminary estimates of the national per capita MA growth percentage and other MA payment methodology changes for CY 2012 are also discussed. For 2012, CMS will announce the MA capitation rates on the first Monday in April 2011, in accordance with the timetable established in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA).

Attachment I shows the preliminary estimates of the national per capita MA growth percentage, which is a key factor in determining the MA capitation rates.

The Administration remains committed to a permanent, fiscally responsible, solution to the Medicare physician payment system. A permanent solution would improve payment rates for Medicare Advantage plans as well as physicians in the future. If such a solution – or even a temporary extension to prevent a payment cut in 2012 -- could be enacted early this year, it could affect MA rates for 2012.

Attachment II sets forth the changes in payment methodology for CY 2012 for original Medicare benefits and rebates. Attachment III set forth the changes in payment methodology for CY 2012 for Part D benefits. Attachment IV presents the annual adjustments for CY 2012 to the Medicare Part D benefit parameters for the defined standard benefit. Attachment V presents the preliminary ESRD and RxHCC risk adjustment factors.

Attachment VI provides the draft CY 2012 Call Letter for Medicare Advantage (MA) organizations (MAOs); section 1876 cost-based contractors; prescription drug plan (PDP) sponsors; demonstrations; Programs of All-Inclusive Care for the Elderly (PACE) organizations; and employer and union-sponsored group plans, including both employer/union-only group health plans (EGWPs) and direct contract plans. The Call Letter contains information these plan sponsor organizations will find useful as they prepare their bids for the new contract year.

Comments or questions may be submitted electronically to the following address: AdvanceNotice2012@cms.hhs.gov. Comments or questions also may be mailed to:

Deondra Moseley
Centers for Medicare
7500 Security Boulevard
C1-13-07
Baltimore, Maryland 21244

Comments may be made public, so submitters should not include any confidential or personal information. In order to receive consideration prior to the April 4, 2011 release of the Announcement of Calendar Year (CY) 2012 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies, comments must be received by 6:00 PM Eastern time on Friday, March 4, 2011.

/ s /
Jonathan Blum
Director
Center for Medicare
/ s /
Paul Spitalnic, A.S.A., M.A.A.A.
Director
Parts C & D Actuarial Group
Office of the Actuary

Attachments

2012 ADVANCE NOTICE
TABLE OF CONTENTS

Attachment I. Preliminary Estimate of the National Per Capita Growth Percentage for Calendar Year 2012

The Affordable Care Act establishes a new blended benchmark as the MA county rate, effective 2012. Beginning in 2012, county rates will be determined by blending two components: an applicable amount (pre-Affordable Care Act rate set under section 1853(k)(1) of the Act) and a specified amount (new Affordable Care Act rate set under section 1853(n)(2) of the Act).

The applicable amount is the pre-Affordable Care Act rate established under section 1853(k)(1). For 2012, this rate is the greater of: 1) the county's 2012 FFS rate or 2) the 2011 applicable amount increased by the CY 2012 national per capita MA growth percentage. For 2012, the specified amount will be based on a percentage of the 2012 FFS rate.

MA Growth Percentage.

The current estimate of the change in the national per capita MA growth percentage for aged and disabled enrollees combined in CY 2012 is 0.7 percent. This estimate reflects an underlying trend change for CY 2012 in per capita costs of -3.32 percent and, as required under section 1853(c)(6)(C) of the Act, adjustments to the estimates for prior years as indicated in the table below.

As required by Section 3201 of the Affordable Care Act of 2010[1], the capitation rates for 2011 were the same as the capitation rates for 2010; therefore, the CY 2011 Rate Announcement did not publish final estimates of the MA growth percentages or the associated key assumptions tables. We will be calculating the 2012 rates as if there was an update in 2011 and that update was 0%. We then follow the typical process of comparing the updated projection to the update used in the prior year. The table below reflects the current trend for 2011 as well as for 2012. Our new estimates are higher than those actually used in calculating the CY 2010 capitation rate book for CYs 2006, 2007, and 2010 and lower than the estimates for CYs 2004, 2005, 2008, and 2009 that were published on April 6, 2009. Section 1853(c)(1)(D)(i) of the Act, as added by sections 4101(e) and 4102(d) of the Health Information Technology for Economic and Clinical Health Act (HITECH Act), requires that electronic health record (EHR) incentive payments be excluded from the calculation of the adjusted average per capita cost.

The following tables summarize the estimates for the change in the national per capita MA growth percentage for aged/disabled rates (Table I-1) and ESRD rates (Table I-2).

[1] The original version of section 3201 was repealed and replaced with the current version in section 1102 of the Reconciliation Bill that amended the Senate-passed version of the Affordable Care Act.

Table I-1. National Per Capita MA Growth Percentage – Aged/disabled

	Aged+Disabled
2012 Trend Change	-3.32%
2011 Trend Change	2.75%
Revision to CY 2010 Estimate	3.56%
Revision to CY 2009 Estimate	-0.83%
Revision to CY 2008 Estimate	-0.75%
Revision to CY 2007 Estimate	0.18%
Revision to CY 2006 Estimate	0.02%
Revision to CY 2005 Estimate	-0.31%
Revision to CY 2004 Estimate	-0.44%
Total Change	0.70%

Notes: The total percentage change is multiplicative, not additive, and may not exactly match due to rounding.

For 2012, CMS will retabulate the ESRD state rates with fee-for-service costs based on 2008 data. The table below shows the dialysis-only national growth percentage for each year from 2010 to 2012. The final rate for 2012 will be the estimated 2012 fee-for-service amount.

Table I-2. National Per Capita MA Growth Percentage – ESRD

	ESRD
2012 Trend Change	0.94%
2011 Trend Change	2.11%
2010 Trend Change	3.36%
Total Trend	6.54%

Notes: The total percentage change is multiplicative, not additive, and may not exactly match due to rounding.

These estimates are preliminary and could change when the final rates are announced on April 4, 2011 in the final Announcement of Calendar Year (CY) 2012 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies. Further details on the derivation of the national per capita MA growth percentage will also be presented in the April 4, 2011 Announcement.

Attachment II. Changes in the Payment Methodology for Original Medicare Benefits for CY 2012

PART C

Section A. MA Benchmark, Quality Bonus Payments and Rebate

There are a number of changes being implemented in the MA payment methodology for CY 2012 as a result of payment changes enacted in the Affordable Care Act.

New Methodology for 2012 County Rates

The Affordable Care Act establishes a new blended benchmark as the MA county rate, effective 2012. Beginning in 2012, county rates will be determined by blending two components: an applicable amount (pre-Affordable Care Act rate set under section 1853(k)(1) of the Act) and a specified amount (new Affordable Care Act rate set under section 1853(n)(2) of the Act). As required under section 1853(n)(4) of the Act, the blended benchmark is capped at the level of the 1853(k)(1) applicable amount. For additional information about the Affordable Care Act changes to the rate calculation, please see proposed rule CMS-4144-P, which is available at http://edocket.access.gpo.gov/2010/pdf/2010-28774.pdf.

Applicable Amount

The applicable amount is the pre-Affordable Care Act rate established under section 1853(k)(1), which will be phased-out under the Affordable Care Act. For 2012, this rate is the greater of: 1) the county's 2012 FFS rate or 2) the 2011 applicable amount increased by the CY 2012 National Per Capita Medicare Advantage Growth Percentage.

For regional plans, CMS will determine the 2012 applicable amount using the same rules as established prior to the Affordable Care Act by first establishing the component of each MA region's benchmark that is based on the CY 2012 MA county rates (weighted by the number of MA eligible beneficiaries, and then by determining the average of regional plan bids for a region). These two components will then be weighted together by the percentage of Medicare beneficiaries enrolled in Fee-for-Service (FFS) vs. Medicare Advantage (MA) plans nationwide to determine the 2012 rate.

Specified Amount

The specified amount is based upon the following formula:

(2012 FFS rate minus IME phase-out amount) * (applicable percentage + applicable percentage quality increase)

We will rebase the 2012 county FFS rates in accordance with section 1853(c)(1)(D)(ii) of the Act, which requires CMS to rebase the FFS rates at least every three years. Section 1853(n)(2)(C) requires CMS to determine applicable percentages for a year based on county FFS rate rankings for the previous year that was a rebasing year. To determine the CY 2012 applicable percentages counties in the 50 States and the District of Columbia, CMS will rank counties from highest to lowest based upon their 2009 FFS costs, because 2009 is the most recent FFS rate rebasing year prior to 2012. CMS will then place the rates into four quartiles. For the territories, CMS will assign an applicable percentage to each county based on where the county rate falls in the quartiles established for the 50 States and the District of Columbia.

Each county's Applicable Percentage is assigned based upon its quartile ranking, as follows:

Table II-1 FFS Quartile Assignment Rules under the Affordable Care Act

Quartile	Applicable Percentage
4th (highest)	95%
3rd	100%
2nd	107.5%
1st (lowest)	115%

We have published each county's Applicable Percentage on the CMS website at: http://www.cms.gov/MedicareAdvtgSpecRateStats/.

Quality Bonus Payment Demonstration/Applicable Percentage Quality Increase

The Affordable Care Act provides for CMS to make quality bonus payments (QBPs) to MA organizations that achieve at least four stars in a five-star quality rating system. Under the Secretary's authority to conduct demonstration projects to test changes in methods of payment[2] CMS is conducting a nationwide three-year demonstration that will be in effect from 2012 to 2014 to test an alternative method for determining QBPs. The demonstration will test whether providing scaled bonuses to MA organizations with three or more stars will lead to more rapid and larger year-to-year quality improvements in their quality scores, compared to what would occur under the current law bonus structure. During this demonstration, for contracts at or above three stars, QBPs will be computed along a scale; the higher a contract's star rating, the greater the QBP percentage. For additional information please see: http://www.cms.gov/apps/docs/Fact-Sheet-2011-Landscape-for-MAe-and-Part-D-FINAL111010.pdf .

The QBP percentage for each star rating will be as follows:

[2] Section 402(a)(1)(A) of the 1967 Social Security Amendments, as amended.

Table II-2 Percentage Add-on to Applicable Percentage for Quality Bonus Payments

Stars Rating	QBP Percentage
Less than 3 stars	0%
3 stars	3%
3.5 stars	3.5%
4 stars	4%
4.5 stars	4%
5 stars	5%

Under the demonstration for 5 star plans, CMS will apply the QBP percentage to the entire 2012 blended county rate, and will not cap the blended rate at the level of the pre-Affordable Care Act rate. For plans with 3 to 4.5 stars, the QBP percentage will be applied as an add-on to the Applicable Percentage before multiplying the Applicable Percentage by the 2012 FFS rate to determine the Specified Amount.

CMS is considering modifying the foregoing demonstration design to further incent more rapid and larger year-to-year quality improvement. Specifically, we are considering applying the QBP percentages noted in the table above to the entire blended county rate for 3, 3.5, 4 and 4.5 star plans, in addition to the blended county rate for 5 star plans. In addition, we are considering to what extent the benchmarks for 3, 3.5, 4, and 4.5 star plans need to be capped under this revised demonstration design. We are also considering ways to transition plans from the demonstration to current law requirements as outlined under the ACA, between 2012 and 2014. We are soliciting comments on the above demonstration features, including the potential modifications to the demonstration that we are considering.

We are also interested in comments on how best to incent plans to achieve a 5 star rating. Plan star ratings for 2011 will be used in determining 2012 QBP percentages. Contracts that did not have an overall plan rating for 2011 fall into two categories: new MA contracts or low enrollment contracts. A new MA contract offered by a parent organization that has not had any MA contract(s) with CMS in the previous three years is treated as a qualifying contract, per statute, and is assigned three stars for QBP purposes for 2012 and 2013, and 3.5 stars in 2014. These contracts are treated as new MA contracts during the demonstration until the contract has enough data to calculate a star rating. For a parent organization that has had MA contract(s) with CMS in the previous three years, any new MA contract under that parent organization will receive an average of the star ratings earned by the parent organization's existing MA contracts, weighted by the December 2010 enrollment. A low enrollment contract is a contract that could not undertake Healthcare Effectiveness Data and Information Set (HEDIS) and Health Outcome Survey (HOS) data collections because of a lack of a sufficient number of enrollees to reliably measure the performance of the health plan. For 2012, low enrollment contracts receive 3 stars for QBP purposes under the demonstration.

Qualifying County Bonus Payment

Beginning with payment year 2012, the Affordable Care Act extends a double quality percentage point increase to a qualifying plan located in a "qualifying county." (An MA plan's star rating is the rating assigned to its contract.) Under the demonstration a qualifying plan is a plan that has a quality rating of three stars or higher. Section 1853(o)(3)(B) defines a qualifying county as a county that meets the following three criteria: 1) has an MA capitation rate that, in 2004, was based on the amount specified in subsection (c)(1)(B) for a Metropolitan Statistical Area with a population of more than 250,000; 2) as of December 2009, had at least 25 percent of beneficiaries residing in the county enrolled in a MA plan; and 3) has average FFS county spending for 2012 that is less than the national average FFS spending for 2012. For example, a plan with a rating of 3.5 stars will have 3.5 percentage points added to the applicable percentage of each county in its service area. For a qualifying county in that plan's service area, an additional 3.5 percentage points would be added to that county's applicable percentage for a total of 7 percentage points. If this qualifying county has an applicable percentage of 95 percent, this is increased to 102 percent.

The Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) established a schedule for the phase-in of risk-adjusted rates and the phase-out of the demographic-only rates. Payments in 2004 were calculated using a 70/30 blend of demographic rates and risk rates. Due to the payment blend in 2004, counties that meet criterion 1 are defined as those counties in the March-December 2004 aged, disabled, or risk ratebooks that were assigned urban floor rates. The 2004 aged, disabled, and risk rate books can be obtained at: http://www.cms.gov/MedicareAdvtgSpecRateStats/RSD/list.asp.

CMS will calculate the MA penetration rate of a county using data from our enrollment database systems. The numerator represents the total number of county residents enrolled in MA in a county in December 2009. The numerator will be calculated by using all MA plan types, including demonstration plans. The denominator represents the total number of MA eligible county residents in December 2009. Hospice and ESRD beneficiaries are included in both the numerator and denominator.

The 2012 FFS rates are not available at the time this Advance Notice is published. The FFS rates and the national average FFS spending amount will be published in the 2012 Rate Announcement.

CMS will publish a complete list of qualifying counties in the 2012 Rate Announcement. The listing will contain all counties that meet all three criteria as stated in Section 1853(o)(3)(B) of the Act. We have published two of the three elements for determining a qualifying county: 1) 2004 urban floors (Y/N for each county) and 2) 2009 Medicare Advantage penetration rates (%).

These elements can be found at the CMS website at http://www.cms.gov/MedicareAdvtgSpecRateStats/.

Affordable Care Act County Rates Transitional Phase-In

The blend of the Specified Amount and Applicable Amount used to create the county rates, as discussed above, will be phased-in on a transitional basis beginning in 2012 and ending in 2017. Each county will be assigned to one of three transition periods - two, four, or six years. A county's specific transition period is determined by the difference between the county's Projected 2010 Benchmark Amount and 2010 Applicable Amount. The Projected 2010 Benchmark Amount is a one-time only calculation, which has been employed solely for the purpose of assigning each county its appropriate transition period, in accordance with the Affordable Care Act.

In order to calculate the Projected 2010 Benchmark Amount, CMS took the following steps:

1. First, CMS modified each county's Applicable Percentage by adding 1.5 percentage points (3 percentage points in qualifying counties) to create each county's Modified Applicable Percentage. (The statute provides at section 1853(n)(3)(C)(ii)(II) that the 2012 applicable percentage increase of 1.5 percentage points (at section 1853(o)(1)(A)) should be applied to this 2010 calculation.)
2. Then CMS tabulated the 2010-only Modified Specified Amount by multiplying the 2010 county FFS rate by the 2010 Modified Applicable Percentage.
3. Next, CMS tabulated the Projected 2010 Benchmark Amount by adding 50 percent of the 2010 Applicable Amount to 50 percent of the 2010-only Modified Specified Amount.

Finally, each county's Projected 2010 Benchmark Amount was compared to each county's 2010 Applicable Amount to determine the applicable transition period. The county transition period will be based on the differentials in the table below.

Table II-3 County transition periods:

Two Year County Blend	**Four Year County Blend**	**Six Year County Blend**
Difference between 2010 Applicable Amount and Projected 2010 Benchmark is < $30	Difference between 2010 Applicable Amount and Projected 2010 Benchmark is at least $30 and less than $50	Difference between 2010 Applicable Amount and Projected 2010 Benchmark is at least $50

The transition periods for each county (2, 4, or 6 years) can be found at the CMS website at http://www.cms.gov/MedicareAdvtgSpecRateStats/.

Blended Benchmark Calculations.

Section 1853(n)(3) sets forth the rules for calculating the blended benchmark, depending on the assigned transition period.

Table II-4 Blended Benchmark Calculations

	Two Year County Blend		**Four Year County Blend**		**Six Year County Blend**	
Year	Pre-ACA	ACA	Pre-ACA	ACA	Pre-ACA	ACA
2012	1/2	1/2	3/4	1/4	5/6	1/6
2013	0	100%	1/2	1/2	2/3	1/3
2014	0	100%	1/4	3/4	1/2	1/2
2015	0	100%	0	100%	1/3	2/3
2016	0	100%	0	100%	1/6	5/6
2017	0	100%	0	100%	0	100%

Rebate and Quality Bonus.

Section 1854(b)(1)(C) of the Affordable Care Act changes the calculation of the amount of monthly rebate an MA plan must provide an enrollee, and mandates that the level of rebate is tied to the level of the plan's star rating. While the Pre-ACA rebate was equal to 75 percent of the difference between the plan benchmark and the plan bid, the Affordable Care Act stipulates that by 2014, new rebate percentages will apply and these new percentages will be phased-in during 2012 and 2013, as shown in Table II-5.

Table II-5. Determination of MA Plan Beneficiary Rebate Amounts

Star Rating	**2012**	**2013**	**2014**
4.5+ Stars	73.33%	71.67%	70%
3.5 to <4.5 stars	71.67%	68.33%	65%
< 3.5 stars	66.67%	58.33%	50%

The law mandates two exceptions for determining the level of rebate for 2012: a low enrollment plan will be treated as having a star rating of 4.5 stars and a new plan under a new parent organization will be treated as having a star rating of 3.5 stars. This specific provision for the determination of star levels for new and low enrollment plans is for purposes of determining the rebate level only, and not for other payment purposes.

The amount of rebate that plans must offer enrollees is phased-in over 3 years. In 2012 the rebate amount is the sum of 2/3 of the pre-ACA rebate amount and 1/3 ACA rebate amount; in 2013, the rebate amount is the sum of 1/3 of the pre-ACA rebate amount and 2/3 of the ACA rebate amount; and in 2014, the rebate amount equals the ACA rebate amount.

Uses of Rebate Dollars

The unamended version of the Affordable Care Act (the Senate bill) would have imposed new restrictions beginning in 2012 on the use of the rebate dollars, which MA organizations are required under section 1854(b)(1)(C)(i) to provide to beneficiaries if their bid is below the benchmark. Under the Senate bill, the existing provisions in section 1854(b)(1)(C)(ii) specifying how rebate dollars could be used were to continue to apply "for plan years before 2012," and thus applied for 2011.

The reconciliation act amending the Senate version of the Affordable Care Act, deleted the statutory language containing the new restrictions on the use of rebates for year 2012 and beyond, while leaving in place the language making the existing rules applicable only to years before 2012. The reconciliation act further amended the Senate version by adding a new section 1854(b)(1)(C)(iii) governing the amount of rebates. As a result, there are no specific statutory requirements in place after 2011 with respect to how rebates are to be applied, while leaving in place the obligation in section 1854(b)(1)(C)(i) to pay rebates, and provisions governing the amount of such rebates.

In our review of bids under section 1854(a)(6) CMS accordingly proposes to apply the same rules for use of rebate dollars for 2012 that applied for 2011, meaning that MA organizations could continue to use rebate dollars only for the purposes set forth in section 1854(b)(1)(C)(ii).

Section B. Changes to the Medicare Advantage Ratebook

County rates represent the upper limit that the government will pay Medicare Advantage Plans, on a standardized basis, per person per month for coverage of original Medicare benefits. Prior to 2011, county rates were based on average FFS costs or the prior year rate grown by the MA growth percentage. In 2011, the county rates were frozen at 2010 levels. Beginning with 2012, the Affordable Care Act (ACA) specifies that MA county rates will be directly related to a percentage of average fee-for-service (FFS) costs, and establishes a transition during which a blended benchmark will be used to blend rates based on pre-ACA rules and rates based on ACA rules. As discussed in Section A, ACA rates are based on a function of FFS costs and the quality rating of the plan.

In conjunction with implementing the ACA's requirement to transition the county rates to be based only on a function of FFS costs, we have performed a detailed review of the current methodology used to develop these costs. Our review included both the calculation of the United States Per Capita Cost (USPCC) and the Average Geographic Adjustment (AGA) methodology. Adjustments to the AGA for a given county cause each county's share relative to the national average to change marginally. However, adjustments to the relative share of national expenditure as measured by the AGA have no effect on the overall USPCC. As part of this review, we identified several areas for improvement in the calculation and we are proposing to update the methodology as discussed below.

Exclude Hospice Claims: When a beneficiary enrolled in a Part C plan enters Hospice, traditional Medicare claims are paid on a fee-for-service (FFS) basis and no payment is made to the Part C plan sponsor for these claims. Accordingly, the calculation of the USPCC excludes all claims for beneficiaries in Hospice status. Historically, all FFS claims, including those for beneficiaries in Hospice status, have been included in the FFS tabulations used in calculation of the average geographic adjustment (AGA) factors. For 2012, the county average FFS costs will be based on 2005 through 2009 FFS tabulations. CMS proposes to tabulate the 2009 FFS costs for members that are not in Hospice status for the 2012 rate calculation. For 2013 and subsequent years, we will compute each new year added to the historic cost base under the new method, thereby transitioning this change over a five year period. This change will have a negligible effect for most counties. For 2012, we expect 9 small counties would have an impact of more than 1%.

Exclude Cost Plan Data: Cost plan beneficiaries generally have Part A claims paid on fee-for-service (FFS) basis and certain Part B claims on a capitated basis. To date, all FFS claims, including those for beneficiaries enrolled in Cost plans, have been included in the FFS tabulations used in calculation of the average geographic adjustment (AGA) factors and in the calculation of the FFS USPCC. For 2012, the county average FFS costs will be based on 2005 through 2009 FFS tabulations. CMS proposes to tabulate the 2009 FFS costs for beneficiaries that are not enrolled in Cost plans for the 2012 rate calculation. For 2013 and subsequent years, we will to compute each new year added to the historic cost base under the new method, thereby transitioning this change over a five year period. In addition, starting with 2012, we will exclude FFS costs for Cost plan enrollees from the total FFS USPCC. This change will have a negligible effect for most counties. For 2012, we expect 30 counties would have an impact of more than 1%.

*County rates in Puerto Rico***:** Medicare enrollment, cost and use in Puerto Rico is different than in the states. A far greater proportion of beneficiaries enroll in Medicare Advantage plans (67% in Puerto Rico vs 24% nationally) and those that do remain in fee-for-service are much less likely to enroll in Part B (46% in Puerto Rico vs 91% nationally). While most mainland beneficiaries are automatically enrolled in Part B, and must opt out to decline it, Puerto Rican beneficiaries are required to opt-in to Part B coverage. In addition, Medicare fee-for-service payment rates tend to be lower. We analyzed the FFS cost development to ensure that they adequately take into account the unique factors in Puerto Rico.

The tabulation of FFS payments in the Commonwealth is appropriate for determining FFS costs and serving as the basis for MA payment rates. However, the tabulation of FFS payments for Part A and/or Part B FFS beneficiaries may not be appropriate for basing payments to plans that serve Part A and Part B individuals.

We performed a study to measure the effect on the standardized FFS per-capita costs separately for Part A and/or Part B beneficiaries and for Part A and Part B beneficiaries. The results of this study indicated that the standardized costs for Part A and Part B beneficiaries in Puerto Rico are on average 5% higher than Part A and/or Part B beneficiaries while there were only nominal differences between these populations in non-Puerto Rico counties. Since enrollment in Medicare Advantage is generally limited to beneficiaries enrolled in both Part A and Part B, we are proposing to tabulate FFS costs in Puerto Rico for beneficiaries enrolled in both Part A and Part B. Similar to the treatment of Hospice and Cost plan claims above, we are proposing to modify the 2009 FFS tabulation resulting in a transition over a five year period. This change will result in an average increase of 0.2% in the blended benchmark for Puerto Rico counties in 2012.

Variations in Small Counties: The current method for calculating fee-for-service (FFS) costs attempts to minimize the effect of random fluctuations by relying on five years' worth of cost in determining the average geographic adjustment (AGA) factor. Even following this approach, counties with small enrollment commonly experience a significant amount of cost variation each year. To address this issue, we performed a study on introducing credibility theory to the rate setting process.

Our study included evaluating counties with alternative minimum levels of FFS beneficiaries. Counties over this threshold would be considered fully credible while counties with fewer enrollees would be considered partially credible. The FFS experience for partially credible plans would be blended with the applicable manual rate. The applicable manual rate will be one of two values:

1) For counties that are part of a Core Based Statistical Area (CBSA) (either Metropolitan or Micropolitan Statistical Area), the applicable manual rate would be the weighted average of all of the counties in that Core Based Statistical Area in the same state.
2) For counties that are not part of a CBSA, the applicable manual rate would be the weighted average of all of the non-CBSA counties in that state.

The weighting used for the small counties experience was the square root of the average number of FFS enrollees over the five year period included in the AGA calculation divided by the threshold amount with the balance of the weight being applied to the manual rate. After calculating the revised rate for the low enrollment county, the low enrollment county rates for each state were restandardized so that each state's share of the AGA remains constant.

The results of the study are that incorporating such an approach greatly reduces the annual fluctuation in FFS cost for counties with low enrollment. Since there was a significant reduction in the fluctuation with the threshold set at 1,000 enrollees, we are proposing implementing this approach for calculating FFS costs for counties with less than 1,000 enrollees.

There are 380 counties with enrollment under 1,000. We expect 79 counties would have greater than a 1% impact and 29 very small counties would have an impact of more than 2%.

Section C. IME Phase Out

Section 161 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) requires CMS to phase out indirect medical education (IME) amounts from MA capitation rates. PACE programs are excluded from the IME payment phase-out. Payment to teaching facilities for indirect medical education expenses for MA plan enrollees will continue to be made under fee-for-service Medicare.

For purposes of making this adjustment, we will first calculate 2012 FFS rates including the IME amount. This initial amount will serve as the basis for calculating the IME reduction that we will carve out of the 2012 rates. The absolute effect of the IME phase-out on each county will be determined by the amount of IME included in the initial FFS rate. By statute, however, the maximum reduction for any specific county in 2012 is 1.8% of the FFS rate. To help plans identify the impact, CMS will separately identify the amount of IME for each county rate in the 2012 ratebook. We will also publish the rates with and without the IME reduction for the year.

Section D. Adjustment to FFS Per Capita Costs for VA-DOD Costs

Section 1853(c)(1)(D)(iii) of the Act directs the Secretary to make an appropriate adjustment to the payment rates to reflect CMS' "estimate, on a per capita basis, of the amount of additional payments that would have been made in the area involved under this title if individuals entitled to benefits under this title had not received services from facilities of the Department of Defense (DoD) or the Department of Veterans Affairs." In the 2010 Advance Notice, dated February 20, 2009, we concluded that there was insufficient evidence to incorporate any VA adjustment into the rate making process.

As stated in the 2011 Advance Notice, we have obtained TRICARE eligibility data from the DoD. TRICARE is the DoD's health care program that covers eligible Uniformed Services beneficiaries for medical care. The vast majority of TRICARE beneficiaries are enrolled in the TRICARE For Life (TFL) option, which pays secondary to Medicare. Another TRICARE option, available to TRICARE/Medicare dual-eligibles, is the Uniformed Services Family Health Plan (USFHP). The USFHP is available to TRICARE members who live near selected civilian medical facilities through which the plan delivers care. Non-emergency care must be obtained through the USFHP hospital and doctor network. USFHP is primary to Medicare (with very few exceptions) and bills are not generally submitted to Medicare.

In lieu of obtaining cost, use, and diagnosis data at the beneficiary level, the methodology used is the same as was used to analyze the VA data in 2010. The analysis was performed separately for all DoD and USFHP-only enrollees and compares the average FFS costs to determine if there are

significant differences between the DoD groups and the total Medicare population. To approximate an adjustment to the county fee for service (FFS) payment rates, we analyzed the cost impact of removing the dual-eligibles from the Medicare claims and enrollment[3]. Specifically, we calculated the ratio of standardized per capita costs of all Medicare beneficiaries excluding dual-eligibles (DoD) to all Medicare beneficiaries (or all beneficiaries) for each county. The calculations were based on FFS data for calendar years 2004-2006.

We analyzed the ratios in counties with at least 10 members in the respective groups and found that there was no statistical significance of the DoD ratios, but did find that the USFHP-only ratios were significant. Accordingly, adjustments will be made to counties with at least 10 USFHP members. CMS will adjust the FFS rates by the ratios calculated. Based on applying the adjustments to the 2009 FFS rates, the average monthly FFS rate will increase in 138 affected counties by approximately $1.85, with a range of a decrease of $0.10 to an increase of $12.04; fifteen counties will experience increases in FFS rates of $5.00 or more. This adjustment was also announced in the 2011 Advance Notice, but was not implemented because of the rate freeze that was mandated by the Affordable Care Act.

Section E. Clinical Trials

In 2012, we will continue the policy of paying on a fee-for-service basis for qualified clinical trial items and services provided to MA plan members that are covered under the relevant National Coverage Determinations on clinical trials.

Section F. ESRD Payments

Updates to the ESRD ratebook are discussed in this section. Pursuant to Section 1853(a)(1)(H) of the Act, CMS has the authority to establish "separate rates of payment" with respect to ESRD beneficiaries.

F1. Transition to New ESRD Payment

CMS concludes the phase-in of the revised State capitation rates used to determine payments for enrollees in dialysis and transplant status in 2012. The transition schedule was first announced in the 2008 Advance Notice. The full transition schedule is as follows:

[3] For this analysis, dual-eligibles are defined as those Medicare beneficiaries who are also eligible to receive care through the Department of Defense.

	Old Ratebook	Revised Ratebook
2008	75%	25%
2009	50%	50%
2010	25%	75%
2011	25%	75%
2012	0%	100%

F2. ESRD State Rates

For 2012, CMS has revised the underlying dialysis rates based on FFS costs. To calculate dialysis State rates, CMS used Medicare FFS claims data for beneficiaries in dialysis status between the years 2006 and 2009 to determine the average geographic adjustment (AGA) for each State and to determine the 2009 national average per capita FFS dialysis cost. The State AGAs were standardized to the proposed 2012 ESRD risk adjustment model. CMS then adjusted the 2009 national average by each State AGA to determine revised 2009 State rates and trended these rates to 2012 using the ESRD dialysis growth trend. The final rate for 2012 will be the estimated 2012 fee-for-service amount. The final 2012 State rates will be developed by taking into account the MIPPA '08 carve-out of indirect medical education (IME) and the $5.25 ESRD user fee.

F3. Functioning Graft

For 2012, CMS will pay Functioning Graft enrollees based on the blended benchmark for the county minus the amount of any rebate dollars (if any) allocated to reduce plan enrollees' Part B premium and/or Part D basic premium, where the blended benchmark depends on the quality bonus payment (QBP) for the contract within which the person is enrolled. For example, if a beneficiary is enrolled in a contract with 3 stars, the payment for that beneficiary will be the 3 star QBP benchmark for the beneficiary's county of residence, multiplied by the functioning graft risk score for that beneficiary.

Section G. Location of Network Areas for PFFS Plans in Plan Year 2013

Section 162(a)(1) of MIPPA amended section 1852(d) of the Social Security Act by creating a new requirement for MA organizations offering certain non-employer MA PFFS plans in network areas to enter into signed contracts with a sufficient number of providers to meet the access standards applicable to coordinated care plans. Specifically, MIPPA requires that non-employer MA PFFS plans that are offered in a network area (as defined in section 1852(d)(5)(B) of the Social Security Act) must meet the access standards described in section 1852(d)(4)(B) of the Social Security Act through signed contracts with providers. These PFFS plans may no longer meet access standards by establishing payment rates that are not less than the rates that apply under Original Medicare and having providers deemed to be contracted as described in 42 CFR 422.216(f).

Network area is defined in section 1852(d)(5)(B) of the Social Security Act, for a given plan year, as the area that the Secretary identifies (in the announcement of the risk and other factors to be used in adjusting MA capitation rates for each MA payment area for the previous plan year) as "having at least 2 network-based plans (as defined in section 1852(d)(5)(C) of the Social Security Act) with enrollment as of the first day of the year in which the announcement is made." The list of network areas for plan year 2013 will appear in the *Announcement of Calendar Year (CY) 2012 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies* and will also be available on the CMS website at http://www.cms.hhs.gov/PrivateFeeforServicePlans/. We will use January 1, 2011 enrollment data to identify the location of network areas for plan year 2013.

Section H. End of Medicare Advantage Medical Savings Account (MSA) Plan Demonstration Program

In a July 13, 2006, Federal Register Notice (CMS-4123-N) we announced the availability of an opportunity to participate in an MA MSA demonstration project. In the Federal Register notice we said that waivers provided under our demonstration authority would allow interested entities to offer products that more closely resemble high deductible health plans that are offered in conjunction with health savings accounts to the non-Medicare population. We initially established a deadline of July 21, 2006, for applicants that wanted to participate in the MA MSA demonstration program for 2007. We also asked applicants that wanted to participate in the program in 2008 to submit a notice of intent to us as soon as possible.

Overall we had one applicant that participated in the MSA demonstration program in calendar year 2007. There has been no activity under this demonstration program since then. We are not seeking extension of this demonstration program and will not accept applications for participation in this program for plan years 2012 and thereafter.

Section I. Employer Group Waiver Plan (EGWP)[4] Bidding

MedPAC's March 2009 Report to Congress notes that in 2009 the average bid for employer group plans was 109% of the FFS rate, whereas for all other MA plans the average bid was

[4] Employer Group Waiver Plans (EGWPs) are defined in Chapter 9 of the Medicare Managed Care Manual - http://www.cms.gov/manuals/downloads/mc86c09.pdf - as Customized employer group MA plans offered exclusively to employer/union group health plan sponsors [that] include: (1) plans offered by MAOs to employers/unions (these plans are hereinafter referred to as "800 series" plans because their plan benefit packages are enumerated in the CMS Health Plan Management System (HPMS) with identifiers in the 800s to distinguish them from individual plans offered by MAOs); and (2) plans offered by employers/unions that directly contract with CMS (hereinafter referred to as "Direct Contract" plans). These "800 series" and Direct Contract MAOs are referred to collectively as employer/union-only group waiver plans ("EGWPs").

100% of the FFS rate. MedPAC also notes that "[e]mployer group plans consistently bid higher than plans open to all Medicare beneficiaries." They also state that "conceptually, the closer the bid is to the benchmark the better it is for the plans and employer, because a higher bid brings in more revenue for Medicare, potentially offsetting expenses that would have required a higher pay-in from employers." Further, MedPAC says one would expect "economies of scale" in employer group plans, from the perspective of enrollment and marketing costs. MA plans that exclusively serve employer/union groups do not compete in the open market, but are offered privately to only those groups pre-selected by the MAO.

CMS has found, in reviewing bids from recent years, that the projected medical costs for EGWP members exceed those of members in individual market plans while the projected risk of EGWP members is lower than for individual MA plan enrollees.

CMS invites public comments on the factors that may explain the discrepancy between the bidding behavior of EGWPs and other types of MA plans. Further, we solicit public comments on potential ways to address these differences.

In the following chart we document the bid ratios and average risk scores in MA EGWP and individual enrollment plans over the last three years.

Risk Scores and Bid Ratios EGWP vs. Non-EGWP[5]	**2008**	**2009**	**2010**
Weighted Average Projected Risk Score (EGWP)	0.964	0.951	0.949
Weighted Average Projected Risk Score (Non-EGWP)	1.002	1.002	0.986
EGWP over Non-EGWP	-3.81%	-5.09%	-3.75%
Weighted Average Plan A/B Bid (EGWP)	$725.46	$744.10	$752.26
Weighted Average Plan A/B Bid (Non-EGWP)	$687.85	$720.72	$726.99
EGWP over Non-EGWP	5.47%	3.24%	3.48%
Weighted Average Standardized Plan A/B Bid (EGWP)	$753.23	$784.40	$803.74
Weighted Average Standardized Plan A/B Bid (Non-EGWP)	$671.47	$708.74	$733.96
EGWP over Non-EGWP	12.18%	10.67%	9.51%

RISK ADJUSTMENT

Section J. CMS-HCC Risk Adjustment Model

In the 2011 Announcement, CMS indicated that it intended to implement an updated version of the CMS-HCC risk adjustment model in 2012. CMS also provided information on this model.

[5] Note that we have not adjusted for differences in service areas between EGWP and non-EGWP plan bids to account for theoretical distortions caused by ratebook rules that set benchmarks far above FFS costs in some areas.

However, CMS is proposing not to implement the new model for Part C for 2012 in order to minimize change during 2012, the first year of the blended benchmarks under the Affordable Care Act.

Section K. Recalibration of the ESRD Risk Adjustment Model

In 2012, CMS will implement an updated version of the ESRD risk adjustment model. The ESRD model dialysis segment is calibrated using the appropriate ESRD population. Therefore, the resulting coefficients reflect the relative cost and diagnosis coding for this subgroup of beneficiaries.[6] All of the components of the ESRD model were recalibrated for 2012:

- Dialysis: The ESRD dialysis risk adjustment model is a single set of coefficients for both community and institutional enrollees in dialysis status. The ESRD dialysis model is calibrated using diagnoses and expenditure data for all beneficiaries in FFS who are in dialysis status.
- Dialysis new enrollee: The dialysis new enrollee factors are estimated using data from all FFS beneficiaries in dialysis status. These factors represent the average projected spending based on demographic factors. The set of demographic-only new enrollee factors are applied to beneficiaries in dialysis status that do not have 12 months of Part B in the data collection year.
- Transplant: Transplant factors are estimated for the first three months following a transplant. The first month's factor is the largest, as that is the month within which the transplant takes place, with months 2 and 3 smaller for post-transplant recovery.
- Functioning graft: A number of the HCC relative factors in both the functioning graft community and institutional segments of the ESRD model are constrained. First, kidney-related conditions are constrained to zero. The HCC for Dialysis Status (HCC134) is constrained to zero, since this is a population defined by having a functioning kidney and not being in dialysis status. We have also constrained nephritis (HCC134), and acute and chronic kidney conditions (HCC134 through HCC 140,) to be zero since there is concern that the functioning graft population is more likely to be inconsistently coded with these conditions without any real health difference. Second, there is a set of functioning graft "add on" factors which vary depending on the amount of time that has elapsed since kidney transplant. These "add on" factors take into account the cost of additional treatment and immunosuppressant drugs.

Disabled-Disease Interactions: The Disabled-Disease Interactions in the ESRD dialysis model have increased from six to seven as a result of adding two Disabled-Disease Interactions and removing one Disabled-Disease Interaction. The two additional disabled-disease interactions

[6] The recalibrated ESRD model has a different numbering system than prior versions.

are: Disabled*Chronic Pancreatitis and Disabled*Complications of Specified Implanted Device or Graft. The disabled-disease interaction that was removed is: Disabled*Disorders of immunity.

Disease Interactions: The Disease Interactions in the ESRD dialysis model have increased from four to five as a result of adding four Disease Interactions and removing three Disease Interactions. The four additional disease interactions are:

Sepsis * Cardiorespiratory Failure
Cancer * Immune Disorders
Diabetes * Congestive Heart Failure
Chronic Obstructive Pulmonary Disease * Cardiorepiratory Failure

The three disease interactions that were removed are:

Diabetes Mellitus * Congestive Heart Failure
Diabetes Mellitus * Cerebrovascular Disease
Chronic Obstructive Pulmonary Disease * Cerebrovascular Disease * Coronary Artery Disease

Data Submission
CMS will post mappings of ICD-9 codes to the new ESRD model HCCs with the publication of the Advance Notice. MA organizations and PACE organizations will be required to submit all ICD-9 codes mapped to the payment model HCCs for dates of service starting January 1, 2011, and may choose to submit all these ICD-9 codes for dates of services starting July 1, 2010, so that they can be included in the calculation of the initial 2012 risk scores.

Section L. Adjustment for MA Coding Pattern Differences

CMS is proposing an MA coding pattern difference adjustment of 3.41% for payment year 2012.

Section M. Frailty Adjustment

Frailty Adjustment for Programs of All Inclusive Care for the Elderly (PACE) organizations.

As noted in the 2008 Announcement (published April 2, 2007), CMS will fully transition to the new frailty factors in 2012 for PACE organizations. CMS will use the results from each PACE organization's 2011 Health Outcome Survey-Modified (HOS-M) survey to calculate each contract-level frailty score for CY2012. CMS will not apply negative contract-level frailty scores (in other words, the frailty score for any PACE contract with a negative frailty score will be set to zero).

Eligible individuals who wish to participate in a PACE organization must voluntarily enroll. The PACE service package must include all Medicare and Medicaid services provided by that State. PACE enrollees also must: 1) be at least 55 years of age, 2) live in the PACE service area,

3) be screened by a team of doctors, nurses, and other health professionals as meeting that state's nursing facility level of care, and 4) at the time of enrollment, be able to safely live in a community setting.

The ADL distribution of the enrollees in all PACE organizations is shown below. As shown, 40 percent of enrollees had 5-6 ADL limitations in 2010.

Percent of Enrollees with:	2009	2010
0 ADLs	13.6%	12.9%
1-2 ADLs	23.1%	23.3%
3-4 ADLs	24.3%	23.4%
5-6 ADLs	39.0%	40.4%

Frailty Adjustment for Fully Integrated Dual Eligible (FIDE) SNPs

Under Section 3205(b) of the Affordable Care Act (ACA), CMS may pay a frailty adjustment to fully integrated dual eligible (FIDE) SNPs if the SNP has similar average levels of frailty to the PACE program. FIDE SNPs are also required by the ACA to have capitated contracts with States for Medicaid benefits, including long-term care.

CMS requires MA organizations to collect Health Outcome Survey data at the contract level for quality reporting purposes. Historically, we have used this contract level data to calculate frailty for PACE organizations and dual-eligible demonstrations. However, this approach must be modified to measure frailty in dual eligible SNPs because SNPs are organized at the plan benefit package level rather than the contract level. This means that dual eligible SNPs co-exist within the same contract with other types of SNP plans and non-SNP plans. Because the frailty level of individual PBPs may not be similar to the contract-level frailty, valid PBP-level frailty scores cannot be calculated using the current sampling methodology. Therefore, MA organizations will need to contract with a vendor to field the survey at the PBP level if CMS is to be able to calculate a frailty score for any FIDE SNP that exists at a sub-contract level.

CMS has allowed MAOs that anticipate offering a FIDE SNP in 2012 to field the HOS at the PBP level in 2011. This will allow CMS to calculate the FIDE SNP's frailty score. These HOS data will be collected in early 2011.

CMS invites comments on the appropriate criteria that should be used to determine if a FIDE SNP has "similar average levels of frailty (as determined by the Secretary) as the PACE program", as required by the Affordable Care Act. We are considering using distributions of ADLs, or perhaps average frailty scores, to implement this portion of the statute. CMS is also considering using multivariate analyses to model the relationship of disease scores and frailty. In the final rate announcement, we will establish our methodology for determining if a FIDE SNP has a level of frailty that is similar to the PACE program.

We also invite comment on how to calculate frailty scores for very low enrollment SNPs (under 30 members) and for "new" dual eligible SNPs. In this context "new" indicates SNPs in MA contracts that have been in existence less than 3 years and have had no dual eligible SNPs in the contract in that time.

Section N. Normalization Factors

When we calibrate a risk adjustment model and normalize the risk scores to 1.0, we produce a fixed set of dollar expenditures and coefficients appropriate to the population and data for that calibration year. When the model with fixed coefficients is used to predict expenditures for other years, predictions for prior years are lower and predictions for succeeding years are higher than for the calibration year. Because average predicted expenditures increase after the model calibration year due to coding and population changes, CMS applies a normalization factor to adjust beneficiaries' risk scores so that the average risk score is 1.0 in subsequent years.

The normalization factor is derived by first using the appropriate model to predict risk scores over a number of years. Next, we trend the risk scores to determine the annual percent change in the risk score. This annual trend is then compounded by the number of years between the model denominator year and the payment year to produce the normalization factor.

Below are the preliminary normalization factors for each model. The final normalization factors will be published in the 2012 Announcement, to be released April 4, 2011.

N1. Normalization Factor for the CMS-HCC Model

The preliminary 2012 normalization factor for the aged-disabled model is 1.079, which will adjust for risk score growth over the five years from the denominator year of 2007 to the payment year of 2012.

N2. Normalization Factor for the ESRD Dialysis Model

The preliminary 2012 normalization factor for the ESRD dialysis model is 1.012, which will adjust for risk score growth over the three years from the denominator year of 2009 to the payment year of 2012.

N3. Normalization Factor for Functioning Graft Enrollees' Risk Scores

The preliminary 2012 normalization factor for the Functioning Graft segment of the ESRD risk adjustment model is: 1.051, which will adjust for risk score growth over the three years from the denominator year of 2009 to the payment year of 2012.

N4. Normalization Factor for the Rx Hierarchical Condition Category (RxHCC) Model

The preliminary 2012 normalization factor for the RxHCC model is 1.032, which will adjust for risk score growth over the three years from the denominator year of 2009 to the payment year of 2012.

Section O. ESRD MSP Factor

CMS has recalculated the MSP adjuster for ESRD beneficiaries. The current ESRD MSP adjustment factor of 0.215 will be revised; the preliminary 2012 ESRD MSP factor is 0.189. CMS will continue to apply the ESRD MSP adjustment to individual-level payments.

Section P. Affordable Care Act-Mandated Risk Adjustment Evaluation

The Affordable Care Act amended section 1853(a)(1)(C)(iii)(III) and (IV) of the Social Security Act to require CMS to periodically evaluate and revise its risk adjustment system "to, as accurately as possible, account for higher medical and care coordination costs associated with frailty, individuals with multiple, comorbid chronic conditions, and individuals with a diagnosis of mental illness, and also to account for costs that may be associated with higher concentration of beneficiaries with those conditions." In addition, the statute requires that CMS shall publish, as part of a Rate Announcement, a description of any evaluation conducted under this requirement during the preceding year and any revisions made to the model as a result of such evaluation.

CMS is currently conducting an analysis of the risk adjustment system, as required under section 1853, and will publish our results in the 2012 Rate Announcement, to be published April 4, 2011.

Section Q. Encounter Data Collection

In the final 2009 inpatient prospective payment system (IPPS) rule, published August 19, 2008 - 73 FR 48434 ff – we revised 42 CFR 422.310(d) to clarify that CMS has the authority to require MA organizations to submit encounter data for each item and service provided to MA plan enrollees. Consistent with this authority, we will require MA organizations to submit encounter data for dates of service January 1, 2012, and later.

With the exception of encounter data on Durable Medical Equipment (DME) encounters, which CMS will begin collecting on May 7, 2012, MA plans will be required to submit data for all other types of institutional and professional services provided to MA plan enrollees on or after January 1, 2012. MA plans will see significant differences between the current Risk Adjustment System (RAS) and the new Encounter Data Processing System (EDPS). Most notably, data collection changes from the 5 elements currently collected to all of the elements on the HIPAA 5010 version of the X12 standards. Use of the HIPAA 5010 format is required to align with

federal law that mandates use of the HIPAA 5010 format as of January 1, 2012. In addition, the timing of required data submissions for MA plans will change from quarterly to a more frequent schedule to accommodate the increase in volume of data and more complex editing and reporting. MA plans will be required to enter into new EDI agreements with the Encounter Data Front-end System, in addition to the EDI agreements already present in the Front-end Risk Adjustment System (FERAS).

To mitigate risk, CMS will maintain parallel systems and continue running the current RAS until testing of the EDPS is 100 percent complete. CMS will provide outreach and education to assist the industry in its transition to the new process. CMS will capture industry feedback throughout the design and implementation phase of the EDPS. CMS will host 13 workgroup sessions. These sessions will allow the industry to participate in knowledge sharing and problem solving as CMS identifies best practices in the areas of third party submission, chart reviews and audits, capitated and staff model plans, PACE organizations, and the editing and storing of data. In addition, CMS will host industry-wide meetings to provide updates throughout 2011on its progress of implementing EDPS. CMS will also be preparing quarterly newsletters for the industry to provide updates and new information.

§1876 Cost HMO/Competitive Medical Plan (CMP) and §1833 Health Care Pre-Payment Plan (HCPP) Diagnostic and Encounter Data Submission

In a memorandum dated September 30, 2004, we notified §1876 Cost contracting HMOs/CMPs that they were required to submit diagnostic data (medical and drug-related) for dates of service after July 1, 2004. We informed HMOs/CMPs that we would provide payment for the full reasonable cost for gathering and transmitting such data to CMS, consistent with 42 CFR 417.550 et seq.

As indicated elsewhere in this notice, we will begin collecting encounter data in 2012.

While our authority to collect encounter data from MA organizations derives from the authority in §1853(a)(3)(B) to collect encounter data for purposes of risk adjustment, we are requiring §1876 Cost HMOs/CMPs and §1833 HCPPs to submit such data under our authority in §1876(h)(3), §1833(a)(1)(A) and §1861(v) to determine "reasonable costs." Specifically, in the case of HMOs/CMS, we are requiring the submission of encounter data under our authority in 42 C.F.R. §417.568(b)(1) to require submission of "adequate cost and statistical data. . .that can be verified by qualified auditors," and 42 C.F.R. §427.576(b)(2)(iii) to require "[a]ny other information required by CMS" for purposes of final settlement of payment amounts due. In the case of HCPPs under our authority in 42 C.F.R. §417.806(c) to access "records of the HCPP… that pertain to the determination of amounts payable for covered Part B services furnished its Medicare enrollees and 42 C.F.R. §417.871(b)(2)(iii) to require "other data as specified by

CMS" for purposes of final settlement of payment amounts due. Data reflecting encounters will assist us in verifying the accuracy and validity of the costs claimed on cost reports.

We will require Cost plans to continue submitting diagnostic data and to begin submitting encounter data in a manner consistent with the risk mitigation strategy we will follow for MA plans. Thus, while both systems (diagnostic and encounter data) are in operation, we will provide payment for the full reasonable cost for gathering and transmitting such data to CMS under both systems, consistent with 42 CFR 417.550 et seq. Once we transition solely to encounter data, we will provide payment for the full reasonable cost solely of encounter data.

In addition to assisting us in verifying the accuracy and validity of cost reports, encounter data from HCPPs will assist us in calibrating the Part C and Part D risk adjustment models. In addition, in the absence of encounter data for HCPP enrollees, the risk scores for them under Part D would be inaccurate. Also, should HCPP enrollees later join a Part C plan, risk adjusted payments to that plan would also be inaccurate.

Therefore, beginning in 2012, we will reimburse HCPPs for the full reasonable cost for gathering and transmitting encounter data to CMS, consistent with 42 CFR 417.550 et seq., in order to mitigate the administrative burden of this requirement on them.

Section R. Risk Adjustment Processing System (RAPS) File Changes

On January 16, 2009, the U.S. Department of Health and Human Services (HHS) released the final rule (45 CFR Part 162) mandating that all entities covered by the Health Insurance Portability and Accountability Act (HIPAA) must implement medical coding sets using the International Classification of Diseases, Tenth Revision (ICD-10) on **October 1, 2013**.

In a related action released the same day, HHS mandated that transaction standards for all electronic health care claims must switch from the X12 standard version 4010/40101A to version 5010 by **January 1, 2012**. Among the changes in version 5010, it will now accommodate the use of the ICD-10 code sets, which are not supported in the current X12 version 4010/40101A.

Effective **January 1, 2012**, CMS is modifying the format of the RAPS file currently used in the risk adjustment data collection and storage process, to accommodate the ICD-10 mandate.

Two changes will be made to the file. First, the Diagnosis field currently using the International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM), 5 character codes, will be changed to 7 character codes to accommodate the expanded ICD-10 clinical modification (CM) codes. Second, there will be a new field added to the RAPS file. This field will indicate which version of the diagnosis codes, revision 9 or revision 10, is stored in the diagnosis field. While the change from ICD-9 to ICD-10 will be a complete cutover on October 1, 2013, the

diagnosis type indicator is required to allow the processing of adjustments to previously submitted data.

CMS will provide further information regarding implementation of the updated RAPS file (formatting and requirements for testing and certification through our regular outreach and communication channels).

Section S. Risk Adjustment Data Validation (RADV)

CMS will continue conducting contract-level Risk Adjustment Data Validation audits on Medicare Advantage (MA) organizations in 2012. To facilitate automated RADV audit activity, all MA organizations must have systems and telecommunications capabilities consistent with the following standards:

- Microsoft Internet Explorer (IE) 7.x or 8.x
- Configuration of security settings in Internet Explorer to:
  - Add the cms.radvcdat.com domain to the list of trusted sites
  - Prompt for file downloads
  - Enable native XMLHTTP support
  - Enable SSL 2.0 & 3.0 / TLS 1.0
  - Disable pop-up blocker for cms.radvcdat.com domain
- An active land-line telephone number

Attachment III. Changes in the Payment Methodology for Medicare Part D for CY 2012

Section A. Prospective Coverage Gap Discount Program (CGDP) Payments

Overview

Section 3301 of the Affordable Care Act (ACA) established the Coverage Gap Discount Program (CGDP) in contract year 2011. Under this program, pharmaceutical manufacturers generally provide an approximately 50% discount to non-low income subsidy eligible (non-LIS) beneficiaries receiving applicable (brand) drugs in the coverage gap phase of the Part D benefit. The discounts made available under this program are considered incurred costs and therefore, are applied towards each beneficiary's true out-of-pocket costs (TrOOP).

For additional information regarding this program, please see the May 21, 2010 HPMS memorandum entitled, "Medicare Coverage Gap Discount Program Beginning in 2011: Revised Part D Sponsor Guidance and Response to Summary Public Comments on the Draft Guidance."

Calculation Methodology for 2012 Prospective CGDP Payments

CMS will provide monthly prospective payments to Part D sponsors for the manufacturer discounts made available to their enrollees under the CGDP. These prospective CGDP payments will be determined based on the projections in each Part D sponsor's bid and their current enrollment. In Worksheet 6A of the Part D bids, "Gap Coverage," Part D sponsors will project the brand drug cost sharing amounts for 2012 for non-LIS beneficiaries in the coverage gap. The monthly prospective CGDP payment for each enrollee will be calculated by dividing the total projected non-LIS brand cost sharing amounts by the non-LIS enrollment projected in each sponsor's bid and multiplying the resulting quotient by 50%. Once the bids are finalized, the prospective CGDP payment amount for each plan will be made available to Part D sponsors on the Part C & D Bid and Premium Information page in the Health Plan Management System (HPMS).

CMS will determine the monthly prospective CGDP payments for each plan by multiplying the plan-specific prospective CGDP payment amount estimated in the Part D bid by the number of non-LIS beneficiaries enrolled in the Part D plan. We invite public comment on whether the calculation of the prospective coverage gap discount payment to Part D sponsors should be adjusted to account for fill fees. Please note that prospective CGDP payments will not be provided to EGWPs because these plans do not submit Part D bids. Program of the All Inclusive Care for the Elderly (PACE) organizations will also not receive prospective CGDP payments due to LIS enrollment in Dual Eligible PACE plans and the absence of beneficiary cost sharing in Medicare-only PACE plans.

Section B. Cost Sharing for Applicable Beneficiaries in the Coverage Gap

The Affordable Care Act, as enacted in section 3301 and amended by section 1101, phases in a reduction in beneficiary cost sharing for drugs in the coverage gap phase of the Medicare Part D benefit. This reduction in cost sharing begins in CY 2011 and continues through CY 2020, ultimately resulting in 75% cost sharing for applicable drugs, prior to the application of any manufacturer discounts, and 25% cost sharing for other covered Part D drugs (non-applicable drugs). Applicable drugs are defined at section 1860D-14A(g)((2) of the statute and are generally brand covered Part D drugs that are either approved under a new drug application (NDA) under section 505(b) of the Federal Food, Drug, and Cosmetic Act or, in the case of a biologic product, licensed under section 351 of the Public Health Service Act (BLA). Non-applicable drugs are covered Part D drugs that do not meet the definition of an applicable drug (i.e. generic drugs). The cost sharing reductions, in conjunction with the coverage gap discount program, will serve to effectively close the Medicare Part D benefit coverage gap for non-LIS beneficiaries by CY 2020.

Thus, in 2012, the coinsurance under basic prescription drug coverage for certain beneficiaries is reduced for non-applicable covered Part D drugs purchased during the coverage gap phase of the Part D benefit. The coinsurance charged to eligible beneficiaries will be equal to 86% or actuarially equivalent to an average expected payment of 86%. To be eligible for this reduced cost sharing, a Part D enrollee must have gross covered drug costs above the initial coverage limit and true out-of-pocket costs (TrOOP) below the out-of-pocket threshold. Medicare beneficiaries will not be eligible for this reduced cost sharing if they are enrolled in a qualified retiree prescription drug plan or are entitled to the low-income subsidy.

The 86% coinsurance for non-applicable drugs in the coverage gap represents an increase in plan liability and a reduction in beneficiary cost sharing. Therefore, the 14% plan liability for non-applicable drugs in the coverage gap will not count toward TrOOP. Part D sponsors must account for this reduced cost sharing and increased plan liability when developing their Part D bids for contract year 2012. In 2012, there will be no reduction in cost sharing for applicable drugs purchased in the coverage gap with the exception of the manufacturer discounts from the coverage gap discount programs. Thus, there will be no change in plan liability for applicable drugs in the coverage gap in 2012.

Section C. Update of the Rx-HCC Model

The RxHCC risk adjustment model, which predicts plan liability, has separate segments for LIS and non-LIS, while the denominator across all segments is a uniform industry average. CMS anticipates that the impact of increased plan liability as a result of the cost sharing reduction for non-applicable (generic) drugs described in section B above will result in differential risk scores changes for LIS and non-LIS beneficiaries. This is because plan liability for non-LIS populations, relative to LIS populations, will likely increase as the reduction of non-applicable

drug cost sharing is only for non-LIS beneficiaries. Therefore, the RxHCC model will be recalibrated to factor in the impact of the new Medicare Part D benefit structure. Specifically, for non-LIS beneficiaries, CMS will calculate plan liability using data from the 2008 prescription drug event (PDE) records as follows:

$$(CPP - 0.8 \times GDCA) + (0.14 \times GDCB \text{ for non-applicable drugs in the gap})$$

CPP refers to the aggregate amounts paid by Part D sponsors for covered Part D drugs under the defined standard benefit as reported on the "Covered D Plan Paid Amount" field on the PDE records. GDCA and GDCB refer to the gross drug costs incurred above and below the out-of-pocket threshold respectively as reported on the PDE records. The first term in the equation above reflects our current definition of plan liability: CPP minus the reinsurance subsidy provided by CMS for covered Part D drug costs in the catastrophic phase of the Part D benefit. The second term signifies the addition of a factor reflecting 14% of the gross drug costs for non-applicable drugs in the gap. While beneficiary behavioral changes in response to the cost sharing changes are unknown at this point, CMS will take into account changes in plan liability for non-applicable drugs that are purchased in the coverage gap in the RxHCC model for 2012.

When we recalibrated the RxHCC risk adjustment model for 2012, we also updated the denominator used across all segments of the RxHCC model from 2008 to 2009. The new denominator is $1,107.82.

Section D. De Minimis Premium Policy

Under the Affordable Care Act (ACA) §3303(a), a PDP or MA-PD may volunteer to waive the portion of the monthly adjusted basic beneficiary premium that is a *de minimis* amount above the low-income benchmark for a subsidy eligible individual. CMS is prohibited from reassigning LIS members from plans who volunteer to waive the de minimis amount based on the fact that the monthly beneficiary premium under the plan was greater than the low-income benchmark premium amount.

The purpose of the *de minimis* premium policy is to permit LIS beneficiaries to remain enrolled in their current plans without paying a premium, even if the plan's premium exceeded the LIS benchmark by a de minimis amount. Because partial-subsidy-eligible beneficiaries pay more than a de minimis premium, and because non-LIS beneficiaries are not entitled to a waiver of premium under section 3303, Part D sponsors may not rely on the de minimis policy to waive any part of their Part D premiums for partial subsidy or non-LIS beneficiaries.

Section E. Payment Reconciliation

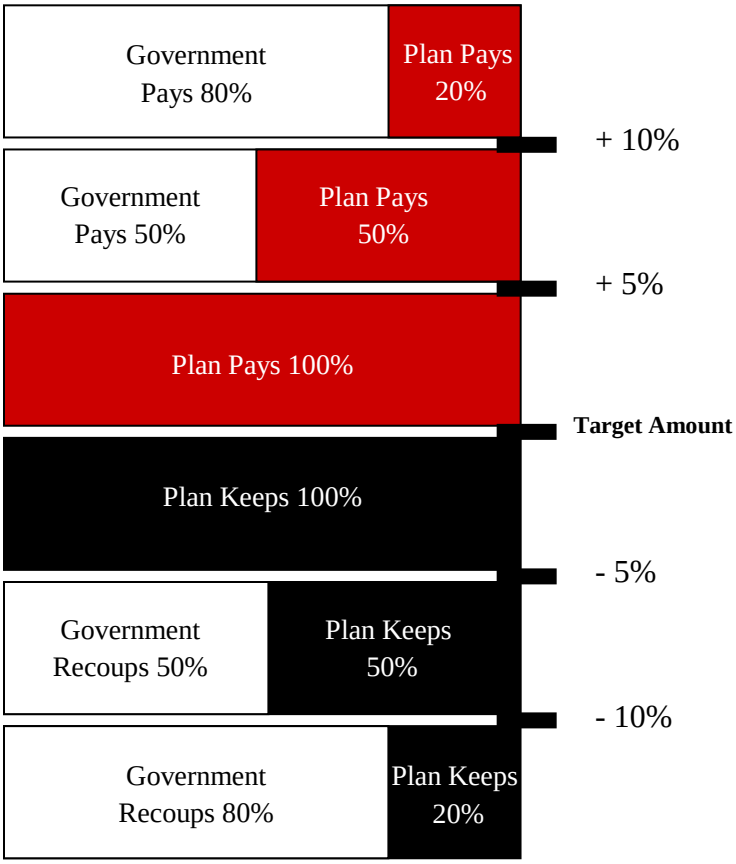
Pursuant to section 1860D-15(e) (3)(C) of the Act and the regulations at 42 CFR 423.336 (a)(2)(ii), CMS may establish higher risk percentages for Part D risk sharing beginning in

contract year 2012. The risk sharing payments provided by CMS limit Part D sponsors' exposure to unexpected drug expenses. Establishing higher Part D risk percentages would increase the risk associated with providing the Part D benefit and reduce the risk sharing amounts provided (or recouped) by CMS.

CMS has evaluated the risk sharing amounts provided by CMS for 2006 – 2009 to assess whether they have decreased or stabilized. A steady decline or stabilization in the Part D risk sharing amounts would suggest that Part D sponsors have significantly improved in their ability to predict Part D expenditures. However, CMS has found that risk sharing amounts continue to vary significantly for Part D sponsors. In addition, the aggregate risk sharing amount paid by CMS varies significantly from year to year. Therefore, CMS will apply no changes to the current risk percentages for contract year 2012. We will continue to evaluate the risk sharing amounts each year to determine if higher risk percentages should be applied for Part D risk sharing.

Thus, the risk percentages and payment adjustments for Part D risk sharing are unchanged from contract year 2011. The risk percentages for the first and second thresholds remain at 5% and 10% of the target amount respectively for 2012. The payment adjustments for the first and second corridors are 50% and 80% respectively. Please see Figure 1 below which illustrates the risk corridors for 2012.

Figure 1. Part D Risk Corridors for 2012



Risk sharing when a plan's adjusted allowable risk corridor costs (AARCC) exceed the target amount:

For the portion of a plan's adjusted allowable risk corridor costs (AARCC) that is between the target amount and the first threshold upper limit (105% of the target amount), the Part D sponsor pays 100% of this amount. For the portion of the plan's AARCC that is between the first threshold upper limit and the second threshold upper limit (110% of the target amount), the government pays 50% and the plan pays 50%. For the portion of the plan's AARCC that exceeds the second threshold upper limit, the government pays 80% and the plan pays 20%.

Risk sharing when a plan's adjusted allowable risk corridor costs (AARCC) are below the target amount:

If a plan's AARCC is between the target amount and the first threshold lower limit (95% of the target amount), the plan keeps 100% of the difference between the target amount and the plan's AARCC. If a plan's AARCC is between the first threshold lower limit and the second threshold lower limit (90% of the target amount), the government recoups 50% of the difference between the first threshold lower limit and the plan's AARCC. The plan would keep 50% of the difference between the first threshold lower limit and the plan's AARCC as well as 100% of the

difference between the target amount and first threshold lower limit. If a plan's AARCC is less than the second threshold lower limit, the government recoups 80% of the difference between the plan's AARCC and the second threshold lower limit as well as 50% of the difference between the first and second threshold lower limits. In this case, the plan would keep 20% of the difference between the plan's AARCC and the second threshold lower limit, 50% of the difference between the first and second threshold lower limits, and 100% of the difference between the target amount and the first threshold lower limit.

Section F. Medicare Part D Benefit Parameters: Annual Adjustments for Defined Standard Benefit in 2012

In accordance with section 1860D-2(b) of the Social Security Act (the Act), CMS must update the statutory parameters for the defined standard Part D prescription drug benefit each year. These parameters include the annual deductible, initial coverage limit (ICL), annual out-of-pocket (OOP) threshold, and minimum copayments for costs above the annual out-of-pocket threshold. As required by statute, the parameters for the defined standard benefit are indexed to the percentage increase in average per capita total Part D drug expenses for Medicare beneficiaries.

Accordingly, the actuarial value of the drug benefit increases along with any increase in Part D drug expenses, and the defined standard Part D benefit continues to cover a constant share of Part D drug expenses from year to year. The Part D benefit parameters are updated using two indexing methods specified by statute: (i) the annual percentage increase in average expenditures for Part D drugs per eligible beneficiary or the "annual percentage increase", and (ii) the annual percentage increase in the Consumer Price Index (CPI) (all items, U.S. city average).

As required by statute, the first indexing method, the "annual percentage increase," is used to update the following Part D benefit parameters:

(i) the deductible, initial coverage limit, and out-of-pocket threshold for the defined standard benefit;
(ii) minimum copayments for costs above the annual out-of-pocket threshold;
(iii) maximum copayments below the out-of-pocket threshold for certain low-income full subsidy eligible enrollees;
(iv) the deductible for partial low-income subsidy (LIS) eligible enrollees; and
(v) maximum copayments above the out-of-pocket threshold for partial LIS eligible enrollees.

Updates to Part D Benefit Parameters

The benefit parameters listed above will be increased by 3.34% for 2012 as summarized by Table III-1 below. This increase reflects the 2011 annual percentage trend of 4.67% as well as a

multiplicative update of -1.27% for prior year revisions. Please see Attachment IV for additional information on the calculation of the annual percentage increase.

Per 42 CFR 423.886(b)(3), the cost threshold and cost limit for qualified retiree prescription drug plans are updated after 2006 in the same manner as the deductible and out-of-pocket threshold for the defined standard benefit. Thus, the "annual percentage increase" will be used to update these parameters as well. The cost threshold and cost limit for qualified retiree prescription drug plans will be increased by 3.34% from their 2011 values.

Updates to Co-Payments for Certain Full Benefit Dual Eligible Individuals

The statute requires CMS to use the second indexing method, the annual percentage increase in the CPI, to update the maximum copayments below the out-of-pocket threshold for full benefit dual eligible enrollees with incomes that do not exceed 100% of the Federal poverty line. These maximum copayments will be increased by 0.98% for 2012 as summarized in Table III-1 below.

This increase reflects the 2011 annual percentage trend in CPI of 1.42%, as well as a multiplicative update of -0.43% for prior year revisions. Please see Attachment IV for additional information on the calculation of the annual percentage increase in the CPI.

Determining Total Covered Part D Spending at Out-of-Pocket Threshold

Each year, CMS releases the Total Covered Part D Spending at the Out-of-Pocket Threshold, which is the amount of total drug spending required to attain out-of-pocket threshold in the defined standard benefit. Due to reductions in beneficiary cost sharing for drugs in the coverage gap phase for applicable (i.e. non-LIS) beneficiaries per section 1860D-2, the total covered Part D spending may be different for applicable and non-applicable (i.e. LIS) beneficiaries. Therefore, CMS is releasing the two values described below:

- Total Covered Part D Spending at Out-of-Pocket Threshold for Non-Applicable Beneficiaries – this is the amount of total drug spending for a non-applicable (i.e. LIS) beneficiary to attain the out-of-pocket threshold in the defined standard benefit. If the beneficiary has additional prescription drug coverage through a group health plan, insurance, government-funded health program or similar third party arrangement, this amount may be higher. This amount is calculated based on 100% cost sharing in the deductible and coverage gap phases and 25% in the initial coverage phase.

- Estimated Total Covered Part D Spending at Out-of-Pocket Threshold for Applicable Beneficiaries – this is an *estimate* of the average amount of total drug spending for an applicable (i.e. non-LIS) beneficiary to attain the out-of-pocket threshold in the defined standard benefit. If the beneficiary has additional prescription drug coverage through a group health plan, insurance, government-funded health program or similar third party arrangement. This amount is estimated based on 100% cost sharing in the deductible, 25% in the initial coverage phase, and in the coverage gap, 86% for non-applicable

(generic) drugs and 100% for applicable (brand) drugs. Please see Attachment IV for additional information on the calculation of the estimated total covered Part D spending for applicable beneficiaries.

Enhanced alternative coverage plans must use these values when mapping enhanced alternative coverage plans to the defined standard benefit, as the Total Covered Part D Spending at the Out-of-pocket Threshold is necessary to calculate the covered plan paid (CPP) amounts reported on the prescription drug event (PDE) records.

Table III-1. Updated Part D Benefit Parameters for Defined Standard Benefit, Low-Income Subsidy, and Retiree Drug Subsidy

Annual Percentage Increases

	Annual percentage trend for 2011	Prior year revisions	Annual percentage increase for 2011
Applied to all parameters but (1)	4.67%	-1.27%	3.34%
CPI (all items, U.S. city average): Applied to (1)	1.42%	-0.43%	0.98%

Part D Benefit Parameters

	2011	2012
Standard Benefit		
Deductible	$310	$320
Initial Coverage Limit	$2,840	$2,930
Out-of-Pocket Threshold	$4,550	$4,700
Total Covered Part D Spending at Out-of-Pocket Threshold for Non-Applicable Beneficiaries (2)	$6,447.50	$6,657.50
Estimated Total Covered Part D Spending for Applicable Beneficiaries (3)	$6,483.72	$6,730.39
Minimum Cost-Sharing in Catastrophic Coverage Portion of the Benefit		
Generic/Preferred Multi-Source Drug	$2.50	$2.60
Other	$6.30	$6.50
Full Subsidy-Full Benefit Dual Eligible (FBDE) Individuals		
Deductible	$0.00	$0.00
Copayments for Institutionalized Beneficiaries (category code 3)	$0.00	$0.00
Maximum Copayments for Non-Institutionalized Beneficiaries		
Up to or at 100% FPL (category code 2)		
Up to Out-of-Pocket Threshold (1)	$1.10	$1.10
Generic/Preferred Multi-Source Drug (4)	$3.30	$3.30
Other (4)	$0.00	$0.00
Above Out-of-Pocket Threshold		
Over 100% FPL (category code 1)		
Up to Out-of-Pocket Threshold	$2.50	$2.60
Generic/Preferred Multi-Source Drug	$6.30	$6.50
Other		
Above Out-of-Pocket Threshold	$0.00	$0.00
Full Subsidy-Non-FBDE Individuals		
Eligible for QMB/SLMB/QI, SSI or applied and income at or below 135% FPL and resources ≤ $6,680 (individuals) or ≤ $10,020 (couples) (5)(category code 1)		
Deductible	$0.00	$0.00
Maximum Copayments up to Out-of-Pocket Threshold		
Generic/Preferred Multi-Source Drug	$2.50	$2.60
Other	$6.30	$6.50
Maximum Copayments above Out-of-Pocket Threshold	$0.00	$0.00
Partial Subsidy		
Applied and income below 150% FPL and resources below $11,140 (individual) or $22,260 (couple)(category code 4)		
Deductible	$63.00	$65.00
Coinsurance up to Out-of-Pocket Threshold	15%	15%
Maximum Copayments above Out-of-Pocket Threshold		
Generic/Preferred Multi-Source Drug	$2.50	$2.60
Other	$6.30	$6.50
Retiree Drug Subsidy Amounts		
Cost Threshold	$310	$320
Cost Limit	$6,300	$6,500

(1) CPI adjustment applies to copayments for non-institutionalized beneficiaries up to or at 100% FPL.
(2) For beneficiaries who are *not* considered an "applicable beneficiary" as defined at section 1860D-14A(g)(1) and therefore are not eligible for the coverage gap discount program (i.e. LIS beneficiaries), this is the amount of total drug spending required to attain out-of-pocket threshold in the defined standard benefit if the beneficiary does not have prescription drug coverage through a group health plan, insurance, government-funded health program or similar third party arrangement. Enhanced alternative plans must use this value when mapping enhanced alternative coverage plans to the defined standard benefit, for the purposes of calculating the covered plan paid amounts (CPP) reported on the prescription drug event (PDE) records.
(3) For beneficiaries who are considered an "applicable beneficiary" as defined at section 1860D-14A(g)(1) and therefore are eligible for the coverage gap discount program (i.e. non-LIS beneficiaries), this is the estimated average amount of total drug spending required to attain the out-of-pocket threshold in the defined standard benefit if beneficiary does not have prescription drug coverage through a group health plan, insurance, government-funded health program or similar third party arrangement. Enhanced alternative plans must use this value when mapping enhanced alternative coverage to the defined standard benefit, for purposes of calculating the covered plan paid amounts (CPP) reported on the prescription drug event (PDE) records.
(4) The increases to the LIS deductible, generic/preferred multi-source drugs and other drugs copayments are applied to the unrounded 2011 values of $63.12, $1.10, and $3.31, respectively.
(5) The actual amount of resources allowable will be updated for contract year 2012.

Attachment IV. Medicare Part D Benefit Parameters for the Defined Standard Benefit: Annual Adjustments for 2012

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) directs CMS to update the statutory parameters for the defined standard Part D drug benefit each year. These parameters include the standard deductible, initial coverage limit, and catastrophic coverage threshold, and minimum copayments for costs above the annual out-of-pocket threshold. In addition, CMS is statutorily required to update the parameters for the low income subsidy benefit and the cost threshold and cost limit for qualified retiree prescription drug plans eligible for the Retiree Drug Subsidy. Included in this notice are (i) the methodologies for updating these parameters, (ii) the updated parameter amounts for the Part D defined standard benefit and low-income subsidy benefit for 2012, and (iii) the updated cost threshold and cost limit for qualified retiree prescription drug plans.

As required by statute, the parameters for the defined standard benefit formula are indexed to the percentage increase in average per capita total Part D drug expenses for Medicare beneficiaries. Accordingly, the actuarial value of the drug benefit increases along with any increase in drug expenses, and the defined standard Part D benefit continues to cover a constant share of drug expenses from year to year.

All of the Part D benefit parameters are updated using one of two indexing methods specified by statute: (i) the annual percentage increase in average expenditures for Part D drugs per eligible beneficiary, and (ii) the annual percentage increase in the Consumer Price Index (CPI) (all items, U.S. city average).

I. Annual Percentage Increase in Average Expenditures for Part D Drugs Per Eligible Beneficiary

Section 1860D-2(b)(6) of the Social Security Act defines the "annual percentage increase" as "the annual percentage increase in average per capita aggregate expenditures for covered Part D drugs in the United States for Part D eligible individuals, as determined by the Secretary for the 12-month period ending in July of the previous year using such methods as the Secretary shall specify." The following parameters are updated using the "annual percentage increase":

Deductible: From $310 in 2011 and rounded to the nearest multiple of $5.

Initial Coverage Limit: From $2,840 in 2011 and rounded to the nearest multiple of $10.

Out-of-Pocket Threshold: From $4,550 in 2011 and rounded to the nearest multiple of $50.

Minimum Cost-Sharing in the Catastrophic Coverage Portion of the Benefit: From $2.50 per generic or preferred drug that is a multi-source drug, and $6.30 for all other drugs in 2011, and rounded to the nearest multiple of $0.05.

Maximum Copayments below the Out-of-Pocket Threshold for certain Low Income Full Subsidy Eligible Enrollees: From $2.50 per generic or preferred drug that is a multi-source drug, and $6.30 for all other drugs in 2011, and rounded to the nearest multiple of $0.05.

Deductible for Low Income (Partial) Subsidy Eligible Enrollees: From $63[7] in 2011 and rounded to the nearest $1.

Maximum Copayments above the Out-of-Pocket Threshold for Low Income (Partial) Subsidy Eligible Enrollees: From $2.50 per generic or preferred drug that is a multi-source drug, and $6.30 for all other drugs in 2011, and rounded to the nearest multiple of $0.05.

II. Annual Percentage Increase in Consumer Price Index, All Urban Consumers (all items, U.S. city average)

Section 1860D-14(a)(4) of the Social Security Act specifies that the annual percentage increase in the CPI, All Urban Consumers (all items, U.S. city average) as of September of the previous year is used to update the maximum copayments below the out-of-pocket threshold for full benefit dual eligible enrollees with incomes that do not exceed 100% of the Federal poverty line. These copayments are increased from $1.10 per generic or preferred drug that is a multi-source drug, and $3.30 for all other drugs in 2011[8], and rounded to the nearest multiple of $0.05 and $0.10, respectively.

III. Calculation Methodology

Annual Percentage Increase

For the 2007 and 2008 contract years, the annual percentage increases, as defined in section 1860D-2(b)(6) of the Social Security Act, were based on the National Health Expenditure (NHE) prescription drug per capita estimates because sufficient Part D program data was not available. Beginning with the 2009 contract year, the annual percentage increases are based on Part D program data. For the 2012 contract year benefit parameters, Part D program data is used to calculate the annual percentage trend as follows:

[7] Consistent with the statutory requirements of 1860D-14(a)(4)(B) of the Social Security Act, the update for the deductible for low income (partial) subsidy eligible enrollees is applied to the unrounded 2011 value of $63.12.

[8] Consistent with the statutory requirements of 1860D-14(a)(4)(A) of the Social Security Act, the copayments are increased from the unrounded 2011 values of $1.10 per generic or preferred drug that is a multi-source drug, and $3.31 for all other drugs.

$$\frac{August\,2010 - July\,2011}{August\,2009 - July\,2010} = \frac{\$2{,}924.44}{\$2{,}793.88} = 1.0467$$

In the formula, the average per capita cost for August 2009 – July 2010 ($2,793.88) is calculated from actual Part D prescription drug event (PDE) data and the average per capita cost for August 2010 – July 2011 ($2,924.44) is calculated based on actual Part D PDE data incurred from August – December, 2010 and projected through July, 2011.

The 2012 benefit parameters reflect the 2011 annual percentage trend as well as a revision to the prior estimates for prior years' annual percentage increases. Based on updated NHE prescription drug per capita costs and PDE data, the annual percentage increases are now estimated as summarized by Table III-2.

Table III-2. Revised Prior Years' Annual Percentage Increases

Year	Prior Estimates of Annual Percentage Increases	Revised Annual Percentage Increases
2007	6.48%	6.74%
2008	5.12%	5.36%
2009	4.42%	4.44%
2010	3.22%	3.07%
2011	4.63%	2.96%

Accordingly, the 2012 benefit parameters reflect a multiplicative update of -1.27% for prior year revisions. In summary, the 2011 parameters outlined in section I are updated by 3.34% for 2012 as summarized by Table III-3.

Table III-3. Annual Percentage Increase

Annual percentage trend for July 2011	4.67%
Prior year revisions	-1.27%
Annual percentage increase for 2012	3.34%

Note: Percentages are multiplicative, not additive. Values are carried to additional decimal places and may not agree to the rounded values presented above.

Annual Percentage Increase in Consumer Price Index, All Urban Consumers (all items, U.S. city average)

The annual percentage increase in the CPI as of September of the previous year referenced in section 1860D-14(a)(4)(A)(ii) is interpreted to mean that, for contract year 2012, the September 2011 CPI should be used in the calculation of the index. To ensure that plan sponsors and CMS

have sufficient time to incorporate the cost-sharing requirements into benefit, marketing material and systems development, the methodology to calculate this update includes an estimate of the September 2011 CPI based on the projected amount included in the President's FY2012 Budget. The September 2010 value is from the Bureau of Labor Statistics. The annual percentage trend in CPI for contract year 2012 is calculated as follows:

$$\frac{\text{Projected September 2011 CPI}}{\text{Actual September 2010 CPI}} \; or \; \frac{221.550}{218.439} = 1.0142$$

(Source: President's FY2012 Budget and Bureau of Labor Statistics, Department of Labor)

The 2012 benefit parameters reflect the 2011 annual percentage trend in the CPI, as well as a revision to the prior estimate for the 2010 annual percentage increase. The 2011 parameter update reflected an annual percentage trend in CPI of 1.58%. Based on the actual reported CPI for September 2010, the September 2010 CPI increase is now estimated to be 1.14%. Thus, the 2012 update reflects a multiplicative -0.43% correction for prior year revisions. In summary, the cost sharing items outlined in section II are updated by 1.01% for 2012 as summarized by Table III-4.

Table III-4. Cumulative Annual Percentage Increase in CPI

Annual percentage trend for September 2011	1.42%
Prior year revisions	-0.43%
Annual percentage increase for 2011	1.01%

Note: Percentages are multiplicative, not additive. Values are carried to additional decimal places and may not agree to the rounded values presented above.

Estimated Total Covered Part D Spending at Out-of-Pocket Threshold for Applicable Beneficiaries

For 2012, the Total Covered Part D Spending at OOP Threshold for Applicable Beneficiaries is $6,730.39. The Total Covered Part D Spending at OOP Threshold for Applicable Beneficiaries is calculated as the ICL plus 100% beneficiary cost sharing in the coverage gap divided by the weighted gap coinsurance factor. This value is calculated assuming 100% cost sharing in the deductible phase, 25% in the initial coverage phase, and in the coverage gap, 86% for non-applicable (generic) drugs and 100% for applicable (brand) drugs.

Total Covered Part D Spending at OOP Threshold for Applicable Beneficiaries is calculated for 2012 as follows:

$$\text{ICL} + \frac{\text{100\% beneficiary cost sharing in the gap}}{\text{weighted gap coinsurance factor}} \quad \textit{or} \quad \$2930 + \frac{\$3727.50}{98.082\%} = \$6{,}730.39$$

where 100% of the beneficiary cost sharing in the gap is the estimated total drug spending in the gap assuming 100% coinsurance.

100% beneficiary cost sharing in the gap is calculated as follows for 2012:

OOP threshold – OOP costs up to the ICL *or* $4,700 - $972.50 = $3,727.50

Weighted gap coinsurance factor is calculated for 2012 as follows:

(Brand GDCB % for non-LIS × 100% cost sharing for applicable drugs) + (Generic GDCB % for non-LIS × 86% cost sharing for non-applicable drugs) *or* (86.3% × 100%) + (13.7% × 86%) = 98.082%

where:

- Brand GDCB % for non-LIS is the percentage of gross covered drug costs below the out-of-pocket threshold for applicable beneficiaries attributable to applicable (brand) drugs as reported on the 2010 PDE records;
- Gap cost sharing for applicable drugs is the coinsurance incurred by applicable beneficiaries for applicable (brand) drugs in coverage gap;
- Generic GDCB % for non-LIS is the percentage of gross covered drug costs below the out-of-pocket threshold for applicable beneficiaries attributable to non-applicable (generic) drugs as reported on the 2010 PDE records; and
- Gap cost sharing for non-applicable drugs is the coinsurance incurred by applicable beneficiaries for non-applicable (generic) drugs in coverage gap.

IV. Retiree Drug Subsidy Amounts

As outlined in §423.886(b)(3) of the regulations implementing the Part D benefit, the cost threshold and cost limit for qualified retiree prescription drug plans that end in years after 2006 are adjusted in the same manner as the annual Part D deductible and out-of-pocket threshold are adjusted under §423.104(d)(1)(ii) and (d)(5)(iii)(B), respectively. Specifically, they are adjusted by the "annual percentage increase" as defined previously in this document and the cost threshold is rounded the nearest multiple of $5 and the cost limit is rounded to the nearest multiple of $50. The cost threshold and cost limit are defined as $310 and $6,300, respectively, for plans that end in 2010, and, as $310 and $6,300, respectively, for plans that end in 2011. For 2012, the cost threshold is $320 and the cost limit is $6,500.

Attachment V. Preliminary ESRD, and Rx-HCC Risk Adjustment Factors

Tables

Table 1. Preliminary ESRD Model Continuing Enrollee Dialysis Relative Factors

Variable	Relative Factors
Female	
0-34 Years	0.598
35-44 Years	0.598
45-54 Years	0.598
55-59 Years	0.606
60-64 Years	0.619
65-69 Years	0.686
70-74 Years	0.702
75-79 Years	0.717
80-84 Years	0.739
85-89 Years	0.745
90-94 Years	0.745
95 Years or Over	0.745
Male	
0-34 Years	0.589
35-44 Years	0.589
45-54 Years	0.589
55-59 Years	0.599
60-64 Years	0.609
65-69 Years	0.661
70-74 Years	0.686
75-79 Years	0.695
80-84 Years	0.736
85-89 Years	0.752
90-94 Years	0.752
95 Years or Over	0.752
Medicaid, Originally Disabled, and Originally ESRD Interactions with Age and Sex	
Medicaid_Female_Aged	0.052
Medicaid_Female_NonAged (Age <65)	0.057
Medicaid_Male_Aged	0.065
Medicaid_Male_NonAged (Age <65)	0.033
Originally Disabled_Female[2]	0.049
Originally Disabled_Male[2]	0.045
Originally ESRD_Female[3]	-0.062
Originally ESRD_Male[3]	-0.045

Disease Group	Description Label	RelativeFactors
HCC1	HIV/AIDS	0.171
HCC2	Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock	0.077
HCC6	Opportunistic Infections	0.080
HCC8	Metastatic Cancer and Acute Leukemia	0.251
HCC9	Lung and Other Severe Cancers	0.172
HCC10	Lymphoma and Other Cancers	0.106
HCC11	Colorectal, Bladder, and Other Cancers	0.058
HCC12	Breast, Prostate, and Other Cancers and Tumors	0.031
HCC17	Diabetes with Acute Complications	0.202
HCC18	Diabetes with Chronic Complications	0.087
HCC19	Diabetes without Complication	0.075
HCC21	Protein-Calorie Malnutrition	0.037
HCC22	Morbid Obesity	0.132
HCC23	Other Significant Endocrine and Metabolic Disorders	0.004
HCC27	End-Stage Liver Disease	0.201
HCC28	Cirrhosis of Liver	0.085
HCC29	Chronic Hepatitis	0.053
HCC33	Intestinal Obstruction/Perforation	0.057
HCC34	Chronic Pancreatitis	0.039
HCC35	Inflammatory Bowel Disease	0.056
HCC39	Bone/Joint/Muscle Infections/Necrosis	0.068
HCC40	Rheumatoid Arthritis and Inflammatory Connective Tissue Disease	0.075
HCC46	Severe Hematological Disorders	0.148
HCC47	Disorders of Immunity	0.031
HCC48	Coagulation Defects and Other Specified Hematological Disorders	0.076

Disease Group	Description Label	RelativeFactors
HCC51	Dementia With Complications	0.127
HCC52	Dementia Without Complication	0.060
HCC54	Drug/Alcohol Psychosis	-
HCC55	Drug/Alcohol Dependence	-
HCC57	Schizophrenia	0.136
HCC58	Major Depressive, Bipolar, and Paranoid Disorders	0.084
HCC70	Quadriplegia	0.206
HCC71	Paraplegia	0.206
HCC72	Spinal Cord Disorders/Injuries	0.105
HCC73	Amyotrophic Lateral Sclerosis and Other Motor Neuron Disease	-
HCC74	Cerebral Palsy	0.068
HCC75	Polyneuropathy	0.056
HCC76	Muscular Dystrophy	-
HCC77	Multiple Sclerosis	0.069
HCC78	Parkinson's and Huntington's Diseases	0.055
HCC79	Seizure Disorders and Convulsions	0.069
HCC80	Coma, Brain Compression/Anoxic Damage	0.118
HCC82	Respirator Dependence/Tracheostomy Status	0.295
HCC83	Respiratory Arrest	0.114
HCC84	Cardio-Respiratory Failure and Shock	0.062
HCC85	Congestive Heart Failure	0.072
HCC86	Acute Myocardial Infarction	0.092
HCC87	Unstable Angina and Other Acute Ischemic Heart Disease	0.092
HCC88	Angina Pectoris	0.044
HCC96	Specified Heart Arrhythmias	0.071
HCC99	Cerebral Hemorrhage	0.077
HCC100	Ischemic or Unspecified Stroke	0.077
HCC103	Hemiplegia/Hemiparesis	0.076
HCC104	Monoplegia, Other Paralytic Syndromes	0.076
HCC106	Atherosclerosis of the Extremities with Ulceration or Gangrene	0.279
HCC107	Vascular Disease with Complications	0.084
HCC108	Vascular Disease	0.051
HCC110	Cystic Fibrosis	0.065
HCC111	Chronic Obstructive Pulmonary Disease	0.065
HCC112	Fibrosis of Lung and Other Chronic Lung Disorders	0.054
HCC114	Aspiration and Specified Bacterial Pneumonias	0.081
HCC115	Pneumococcal Pneumonia, Empyema, Lung Abscess	0.015
HCC122	Proliferative Diabetic Retinopathy and Vitreous Hemorrhage	-
HCC124	Exudative Macular Degeneration	-
HCC157	Pressure Ulcer of Skin with Necrosis Through to Muscle, Tendon, or Bone	0.171
HCC158	Pressure Ulcer of Skin with Full Thickness Skin Loss	0.171
HCC159	Pressure Ulcer of Skin with Partial Thickness Skin Loss	0.171
HCC160	Pressure Pre-Ulcer Skin Changes or Unspecified Stage	0.171
HCC161	Chronic Ulcer of Skin, Except Pressure	0.118
HCC162	Severe Skin Burn or Condition	0.049
HCC166	Severe Head Injury	0.118
HCC167	Major Head Injury	0.015
HCC169	Vertebral Fractures without Spinal Cord Injury	0.050
HCC170	Hip Fracture/Dislocation	0.040
HCC173	Traumatic Amputations and Complications	0.041
HCC176	Complications of Specified Implanted Device or Graft	-
HCC186	Major Organ Transplant or Replacement Status	0.159
HCC188	Artificial Openings for Feeding or Elimination	0.047
HCC189	Amputation Status, Lower Limb/Amputation Complications	0.114
Disease Interactions		
SEPSIS_CARD_RESP_FAIL	Sepsis*Cardiorespiratory Failure	0.100
CANCER_IMMUNE	Cancer*Immune Disorders	0.093
DIABETES_CHF	Diabetes*Congestive Heart Failure	0.020
CHF_COPD	Congestive Heart Failure*Chronic Obstructive Pulmonary Disease	0.018
COPD_CARD_RESP_FAIL	Chronic Obstructive Pulmonary Disease*Cardiorespiratory Failure	0.013

Disease Group	Description Label	RelativeFactors
NonAged (Age <65)/Disease Interactions		
NONAGED_HCC6	NonAged, Opportunistic Infections	0.074
NONAGED_HCC34	NonAged, Chronic Pancreatitis	0.116
NONAGED_HCC46	NonAged, Severe Hematological Disorders	0.038
NONAGED_HCC54	NonAged, Drug/Alcohol Psychosis	0.166
NONAGED_HCC55	NonAged, Drug/Alcohol Dependence	0.166
NONAGED_HCC110	NonAged, Cystic Fibrosis	0.369
NONAGED_HCC176	NonAged, Complications of Specified Implanted Device or Graft	0.046

NOTES:

1. The CMS ESRD Dialysis Denominator used to calculate the relative factors is $75,564.91.

[2] Originally Disabled indicates beneficiary originally entered Medicare due to a condition other than ESRD.

[3] Originally ESRD indicates beneficiary originally entered Medicare due to ESRD. Beneficiaries that are Originally ESRD cannot be Originally Disabled.

The estimate for HCC 160 is based on pressure ulcer, any stage, for all anatomical sites codes. The estimated coefficient for HCC 160 is also assigned to HCCs 157, 158, and 159 in the constrained regression because the ICD9 codes for the stages of pressure ulcers are not implemented until FY09.

In the "disease interactions," the variables are defined as follows:
Sepsis = HCC 2.
Cardiorespiratory Failure = HCCs 82-84.
Cancer = HCCs 8-12.
Immune Disorders = HCC 47.
Diabetes = HCCs 17, 18, 19.
Congestive Heart Failure = HCC 85.
Chronic Obstructive Pulmonary Disease = HCCs 110-111.

SOURCE: RTI International analysis of 2006/2007 Medicare 100% ESRD sample claims and enrollment data.

Table 2. Preliminary ESRD Model Demographic Relative Factors for New Enrollees in Dialysis Status

	Non-Medicaid & Non-Originally Disabled	Medicaid & Non-Originally Disabled	Non-Medicaid & Originally Disabled	Medicaid & Originally Disabled
Female				
0-34 Years	0.848	0.966	1.075	1.193
35-44 Years	0.848	0.966	1.075	1.193
45-54 Years	0.848	0.966	1.075	1.193
55-59 Years	0.883	1.001	1.110	1.228
60-64 Years	0.902	1.020	1.128	1.246
65-69 Years	1.021	1.120	1.248	1.347
70-74 Years	1.065	1.165	1.292	1.392
75-79 Years	1.123	1.222	1.350	1.449
80-84 Years	1.128	1.227	1.354	1.454
85 Years or Over	1.142	1.241	1.369	1.468
Male				
0-34 Years	0.735	0.842	0.957	1.065
35-44 Years	0.775	0.883	0.998	1.105
45-54 Years	0.811	0.919	1.034	1.141
55-59 Years	0.843	0.951	1.066	1.173
60-64 Years	0.867	0.975	1.090	1.197
65-69 Years	0.974	1.088	1.197	1.311
70-74 Years	1.030	1.144	1.253	1.367
75-79 Years	1.072	1.186	1.295	1.409
80-84 Years	1.105	1.219	1.327	1.441
85 Years or Over	1.120	1.234	1.342	1.456

NOTES:

1. The CMS ESRD Dialysis Denominator used to calculate the relative factors is $75,564.91.

2. Originally disabled terms refer to people originally entitled to Medicare for reasons of disability other than ESRD.

SOURCE: RTI International analysis of 2006/2007 Medicare 100% ESRD sample claims and enrollment data.

Table 3. Preliminary ESRD Kidney Transplant CMS-HCC Model Relative Factors for Transplant Beneficiaries

	Beneficiaries	**Kidney Transplant** *Actual Dollars*	**Kidney Transplant Relative Risk Factor**
Month 1	8,412	36,618.30	5.815
Months 2 and 3	16,188	5,540.51	0.880
Total (Actual Months 1-3)		**47,569.19**	

NOTES:

1. Kidney transplant is identified by DRG 302 for discharge dates through September 30, 2007 and by MS-DRG 652 for discharge dates from October 1, 2007 on.

2. The transplant month payments were computed by aggregating the costs for each of the three monthly payments.

3. The transplant factor is calculated in this manner: (kidney transplant month's dollars/Dialysis Denominator)*12. The CMS ESRD Dialysis Denominator value used was $75,564.91.

SOURCE: RTI International analysis of 2006/2007 Medicare 100% ESRD sample claims and enrollment data.

Table 4. Preliminary ESRD Model Functioning Graft Relative Factors for Community Population

Variable	Relative Factor
Functioning Graft Factors	
Aged 65+, with duration since transplant of 4-9 months	2.635
Aged <65, with duration since transplant of 4-9 months	2.582
Aged 65+, with duration since transplant of 10 months or more	1.268
Aged <65, with duration since transplant of 10 months or more	1.170
Female	
0-34 Years	0.198
35-44 Years	0.212
45-54 Years	0.274
55-59 Years	0.359
60-64 Years	0.416
65-69 Years	0.283
70-74 Years	0.346
75-79 Years	0.428
80-84 Years	0.517
85-89 Years	0.632
90-94 Years	0.755
95 Years or Over	0.775
Male	
0-34 Years	0.079
35-44 Years	0.119
45-54 Years	0.165
55-59 Years	0.292
60-64 Years	0.332
65-69 Years	0.309
70-74 Years	0.378
75-79 Years	0.464
80-84 Years	0.565
85-89 Years	0.647
90-94 Years	0.776
95 Years or Over	0.963
Medicaid and Originally Disabled Interactions with Age and Sex	
Medicaid_Female_Aged	0.213
Medicaid_Female_NonAged (Age <65)	0.104
Medicaid_Male_Aged	0.210
Medicaid_Male_NonAged (Age <65)	0.113
Originally Disabled_Female_Age ≥65	0.244
Originally Disabled_Male_Age ≥65	0.171

Disease Group	Description Label	Relative Factor
HCC1	HIV/AIDS	0.492
HCC2	Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock	0.520
HCC6	Opportunistic Infections	0.557
HCC8	Metastatic Cancer and Acute Leukemia	2.425
HCC9	Lung and Other Severe Cancers	1.006
HCC10	Lymphoma and Other Cancers	0.695
HCC11	Colorectal, Bladder, and Other Cancers	0.330
HCC12	Breast, Prostate, and Other Cancers and Tumors	0.180
HCC17	Diabetes with Acute Complications	0.344
HCC18	Diabetes with Chronic Complications	0.344
HCC19	Diabetes without Complication	0.124
HCC21	Protein-Calorie Malnutrition	0.653
HCC22	Morbid Obesity	0.342
HCC23	Other Significant Endocrine and Metabolic Disorders	0.240
HCC27	End-Stage Liver Disease	1.003
HCC28	Cirrhosis of Liver	0.425
HCC29	Chronic Hepatitis	0.313
HCC33	Intestinal Obstruction/Perforation	0.337
HCC34	Chronic Pancreatitis	0.257
HCC35	Inflammatory Bowel Disease	0.279
HCC39	Bone/Joint/Muscle Infections/Necrosis	0.423
HCC40	Rheumatoid Arthritis and Inflammatory Connective Tissue Disease	0.376

Disease Group	Description Label	Relative Factor
HCC46	Severe Hematological Disorders	1.078
HCC47	Disorders of Immunity	0.306
HCC48	Coagulation Defects and Other Specified Hematological Disorders	0.258
HCC51	Dementia With Complications	0.616
HCC52	Dementia Without Complication	0.343
HCC54	Drug/Alcohol Psychosis	0.358
HCC55	Drug/Alcohol Dependence	0.358
HCC57	Schizophrenia	0.471
HCC58	Major Depressive, Bipolar, and Paranoid Disorders	0.318
HCC70	Quadriplegia	1.075
HCC71	Paraplegia	0.868
HCC72	Spinal Cord Disorders/Injuries	0.441
HCC73	Amyotrophic Lateral Sclerosis and Other Motor Neuron Disease	1.016
HCC74	Cerebral Palsy	0.036
HCC75	Polyneuropathy	0.281
HCC76	Muscular Dystrophy	0.460
HCC77	Multiple Sclerosis	0.482
HCC78	Parkinson's and Huntington's Diseases	0.555
HCC79	Seizure Disorders and Convulsions	0.252
HCC80	Coma, Brain Compression/Anoxic Damage	0.533
HCC82	Respirator Dependence/Tracheostomy Status	1.732
HCC83	Respiratory Arrest	0.769
HCC84	Cardio-Respiratory Failure and Shock	0.326
HCC85	Congestive Heart Failure	0.361
HCC86	Acute Myocardial Infarction	0.283
HCC87	Unstable Angina and Other Acute Ischemic Heart Disease	0.283
HCC88	Angina Pectoris	0.210
HCC96	Specified Heart Arrhythmias	0.276
HCC99	Cerebral Hemorrhage	0.371
HCC100	Ischemic or Unspecified Stroke	0.333
HCC103	Hemiplegia/Hemiparesis	0.481
HCC104	Monoplegia, Other Paralytic Syndromes	0.212
HCC106	Atherosclerosis of the Extremities with Ulceration or Gangrene	1.313
HCC107	Vascular Disease with Complications	0.417
HCC108	Vascular Disease	0.288
HCC110	Cystic Fibrosis	0.388
HCC111	Chronic Obstructive Pulmonary Disease	0.388
HCC112	Fibrosis of Lung and Other Chronic Lung Disorders	0.294
HCC114	Aspiration and Specified Bacterial Pneumonias	0.691
HCC115	Pneumococcal Pneumonia, Empyema, Lung Abscess	0.212
HCC122	Proliferative Diabetic Retinopathy and Vitreous Hemorrhage	0.223
HCC124	Exudative Macular Degeneration	0.248
HCC134	Dialysis Status	—
HCC135	Acute Renal Failure	—
HCC136	Chronic Kidney Disease, Stage 5	—
HCC137	Chronic Kidney Disease, Severe (Stage 4)	—
HCC138	Chronic Kidney Disease, Moderate (Stage 3)	—
HCC139	Chronic Kidney Disease, Mild or Unspecified (Stages 1-2 or Unspecified)	—
HCC140	Unspecified Renal Failure	—
HCC141	Nephritis	—
HCC157	Pressure Ulcer of Skin with Necrosis Through to Muscle, Tendon, or Bone	1.071
HCC158	Pressure Ulcer of Skin with Full Thickness Skin Loss	1.071
HCC159	Pressure Ulcer of Skin with Partial Thickness Skin Loss	1.071
HCC160	Pressure Pre-Ulcer Skin Changes or Unspecified Stage	1.071
HCC161	Chronic Ulcer of Skin, Except Pressure	0.473
HCC162	Severe Skin Burn or Condition	0.458
HCC166	Severe Head Injury	0.533
HCC167	Major Head Injury	0.141
HCC169	Vertebral Fractures without Spinal Cord Injury	0.441
HCC170	Hip Fracture/Dislocation	0.363
HCC173	Traumatic Amputations and Complications	0.379
HCC176	Complications of Specified Implanted Device or Graft	0.668
HCC186	Major Organ Transplant or Replacement Status	0.203
HCC188	Artificial Openings for Feeding or Elimination	0.609

Disease Group	Description Label	Relative Factor
HCC189	Amputation Status, Lower Limb/Amputation Complications	0.804
Disease Interactions		
SEPSIS_CARD_RESP_FAIL	Sepsis*Cardiorespiratory Failure	0.634
CANCER_IMMUNE	Cancer*Immune Disorders	1.101
DIABETES_CHF	Diabetes*Congestive Heart Failure	0.237
CHF_COPD	Congestive Heart Failure*Chronic Obstructive Pulmonary Disease	0.255
CHF_RENAL	Congestive Heart Failure*Renal Disease	—
COPD_CARD_RESP_FAIL	Chronic Obstructive Pulmonary Disease*Cardiorespiratory Failure	0.420
NonAged (Age <65)/Disease Interactions		
NONAGED_HCC6	NonAged, Opportunistic Infections	0.564
NONAGED_HCC34	NonAged, Chronic Pancreatitis	0.757
NONAGED_HCC46	NonAged, Severe Hematological Disorders	0.818
NONAGED_HCC54	NonAged, Drug/Alcohol Psychosis	0.432
NONAGED_HCC55	NonAged, Drug/Alcohol Dependence	0.147
NONAGED_HCC110	NonAged, Cystic Fibrosis	2.397
NONAGED_HCC176	NonAged, Complications of Specified Implanted Device or Graft	—

NOTES:

1. The coefficients estimated for this model are the Functioning Graft add-on factors for being in a month after the 3 months accounted for in the Transplant segment of the ESRD system. Early months post-transplant incur higher Medicare spending than later months. The model differentiates the six months, months 4-9, from months further from the transplant period.

2. Originally disabled terms refer to people originally entitled to Medicare for reasons of disability other than ESRD.

3. The Denominator used to calculate the relative factors is $8,034.71.

In the "disease interactions," the variables are defined as follows:

Sepsis = HCC 2.
Cardiorespiratory Failure = HCCs 82-84.
Cancer = HCCs 8-12.
Immune Disorders = HCC 47.
Diabetes = HCCs 17, 18, 19.
Congestive Heart Failure = HCC 85.
Chronic Obstructive Pulmonary Disease = HCCs 110-111.
Renal Disease = HCCs 134-141.

SOURCE: RTI International analysis of 2006/2007 100% ESRD sample claims and enrollment data and 2006/2007 Medicare 5% sample.

Table 5. Preliminary ESRD Model Functioning Graft Relative Factors for Institutionalized Population

Variable	Relative Factor
Functioning Graft Factors	
Aged 65+, with duration since transplant of 4-9 months	2.635
Aged <65, with duration since transplant of 4-9 months	2.582
Aged 65+, with duration since transplant of 10 months or more	1.268
Aged <65, with duration since transplant of 10 months or more	1.170
Female	
0-34 Years	0.783
35-44 Years	0.723
45-54 Years	0.700
55-59 Years	0.805
60-64 Years	0.773
65-69 Years	1.004
70-74 Years	0.947
75-79 Years	0.874
80-84 Years	0.792
85-89 Years	0.699
90-94 Years	0.594
95 Years or Over	0.465
Male	
0-34 Years	0.994
35-44 Years	0.658
45-54 Years	0.687
55-59 Years	0.814
60-64 Years	0.877
65-69 Years	1.148
70-74 Years	1.195
75-79 Years	1.168
80-84 Years	1.104
85-89 Years	1.046
90-94 Years	0.928
95 Years or Over	0.842
Medicaid and Originally Disabled Interactions with Age and Sex	
Medicaid	0.126
Originally Disabled_Age ≥65	0.026

Disease Group	Description Label	Relative Factor
HCC1	HIV/AIDS	1.374
HCC2	Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock	0.471
HCC6	Opportunistic Infections	0.541
HCC8	Metastatic Cancer and Acute Leukemia	0.928
HCC9	Lung and Other Severe Cancers	0.610
HCC10	Lymphoma and Other Cancers	0.363
HCC11	Colorectal, Bladder, and Other Cancers	0.255
HCC12	Breast, Prostate, and Other Cancers and Tumors	0.165
HCC17	Diabetes with Acute Complications	0.434
HCC18	Diabetes with Chronic Complications	0.434
HCC19	Diabetes without Complication	0.187
HCC21	Protein-Calorie Malnutrition	0.343
HCC22	Morbid Obesity	0.353
HCC23	Other Significant Endocrine and Metabolic Disorders	0.248
HCC27	End-Stage Liver Disease	0.637
HCC28	Cirrhosis of Liver	0.343
HCC29	Chronic Hepatitis	0.343
HCC33	Intestinal Obstruction/Perforation	0.302
HCC34	Chronic Pancreatitis	0.175
HCC35	Inflammatory Bowel Disease	0.250
HCC39	Bone/Joint/Muscle Infections/Necrosis	0.386
HCC40	Rheumatoid Arthritis and Inflammatory Connective Tissue Disease	0.222
HCC46	Severe Hematological Disorders	0.638

Disease Group	Description Label	Relative Factor
HCC47	Disorders of Immunity	0.436
HCC48	Coagulation Defects and Other Specified Hematological Disorders	0.197
HCC51	Dementia With Complications	—
HCC52	Dementia Without Complication	—
HCC54	Drug/Alcohol Psychosis	0.051
HCC55	Drug/Alcohol Dependence	0.051
HCC57	Schizophrenia	0.274
HCC58	Major Depressive, Bipolar, and Paranoid Disorders	0.274
HCC70	Quadriplegia	0.497
HCC71	Paraplegia	0.497
HCC72	Spinal Cord Disorders/Injuries	0.191
HCC73	Amyotrophic Lateral Sclerosis and Other Motor Neuron Disease	0.294
HCC74	Cerebral Palsy	—
HCC75	Polyneuropathy	0.256
HCC76	Muscular Dystrophy	0.247
HCC77	Multiple Sclerosis	—
HCC78	Parkinson's and Huntington's Diseases	0.110
HCC79	Seizure Disorders and Convulsions	0.173
HCC80	Coma, Brain Compression/Anoxic Damage	0.103
HCC82	Respirator Dependence/Tracheostomy Status	1.567
HCC83	Respiratory Arrest	0.611
HCC84	Cardio-Respiratory Failure and Shock	0.346
HCC85	Congestive Heart Failure	0.226
HCC86	Acute Myocardial Infarction	0.394
HCC87	Unstable Angina and Other Acute Ischemic Heart Disease	0.394
HCC88	Angina Pectoris	0.366
HCC96	Specified Heart Arrhythmias	0.227
HCC99	Cerebral Hemorrhage	0.175
HCC100	Ischemic or Unspecified Stroke	0.175
HCC103	Hemiplegia/Hemiparesis	0.063
HCC104	Monoplegia, Other Paralytic Syndromes	0.063
HCC106	Atherosclerosis of the Extremities with Ulceration or Gangrene	0.773
HCC107	Vascular Disease with Complications	0.257
HCC108	Vascular Disease	0.146
HCC110	Cystic Fibrosis	0.323
HCC111	Chronic Obstructive Pulmonary Disease	0.323
HCC112	Fibrosis of Lung and Other Chronic Lung Disorders	0.252
HCC114	Aspiration and Specified Bacterial Pneumonias	0.239
HCC115	Pneumococcal Pneumonia, Empyema, Lung Abscess	0.194
HCC122	Proliferative Diabetic Retinopathy and Vitreous Hemorrhage	0.366
HCC124	Exudative Macular Degeneration	0.178
HCC134	Dialysis Status	—
HCC135	Acute Renal Failure	—
HCC136	Chronic Kidney Disease, Stage 5	—
HCC137	Chronic Kidney Disease, Severe (Stage 4)	—
HCC138	Chronic Kidney Disease, Moderate (Stage 3)	—
HCC139	Chronic Kidney Disease, Mild or Unspecified (Stages 1-2 or Unspecified)	—
HCC140	Unspecified Renal Failure	—
HCC141	Nephritis	—
HCC157	Pressure Ulcer of Skin with Necrosis Through to Muscle, Tendon, or Bone	0.284
HCC158	Pressure Ulcer of Skin with Full Thickness Skin Loss	0.284
HCC159	Pressure Ulcer of Skin with Partial Thickness Skin Loss	0.284
HCC160	Pressure Pre-Ulcer Skin Changes or Unspecified Stage	0.284
HCC161	Chronic Ulcer of Skin, Except Pressure	0.226
HCC162	Severe Skin Burn or Condition	—
HCC166	Severe Head Injury	0.103
HCC167	Major Head Injury	—
HCC169	Vertebral Fractures without Spinal Cord Injury	0.179
HCC170	Hip Fracture/Dislocation	—
HCC173	Traumatic Amputations and Complications	0.067
HCC176	Complications of Specified Implanted Device or Graft	0.668
HCC186	Major Organ Transplant or Replacement Status	0.203
HCC188	Artificial Openings for Feeding or Elimination	0.658

Disease Group	Description Label	Relative Factor
HCC189	Amputation Status, Lower Limb/Amputation Complications	0.384
Disease Interactions		
CHF_COPD	Congestive Heart Failure*Chronic Obstructive Pulmonary Disease	0.159
CRFAIL_COPD	Cardiorespiratory Failure*Chronic Obstructive Pulmonary Disease	0.524
SEPSIS_PRESSURE_ULCER	Sepsis*Pressure Ulcer	0.538
SEPSIS_ARTIF_OPENINGS	Sepsis*Artificial Openings for Feeding or Elimination	0.453
ARTIF_OPENINGS_PRESSURE_ULCER	Artificial Openings for Feeding or Elimination*Pressure Ulcer	0.361
DIABETES_CHF	Diabetes*Congestive Heart Failure	0.143
COPD_ASP_SPEC_BACT_PNEUM	Chronic Obstructive Pulmonary Disease*Aspiration and Specified Bacterial Pneumonias	0.249
ASP_SPEC_BACT_PNEUM_PRES_ULCER	Aspiration and Specified Bacterial Pneumonias*Pressure Ulcer	0.325
SEPSIS_ASP_SPEC_BACT_PNEUM	Sepsis*Aspiration and Specified Bacterial Pneumonias	0.387
SCHIZOPHRENIA_COPD	Schizophrenia*Chronic Obstructive Pulmonary Disease	0.187
SCHIZOPHRENIA_CHF	Schizophrenia*Congestive Heart Failure	0.220
SCHIZOPHRENIA_SEIZURES	Schizophrenia*Seizure Disorders and Convulsions	0.303
NonAged (Age <65)/Disease Interactions		
NONAGED_HCC85	NonAged, Congestive Heart Failure	0.320
NONAGED_PRESSURE_ULCER	NonAged, Pressure Ulcer	0.421
NONAGED_HCC161	NonAged, Chronic Ulcer of the Skin, Except Pressure Ulcer	0.337
NONAGED_HCC39	NonAged, Bone/Joint Muscle Infections/Necrosis	0.624
NONAGED_HCC77	NonAged, Multiple Sclerosis	0.344
NONAGED_HCC6	NonAged, Opportunistic Infections	0.914

NOTES:

1. The coefficients estimated for this model are the Functioning Graft add-on factors for being in a month after the 3 months accounted for in the Transplant segment of the ESRD system. Early months post-transplant incur higher Medicare spending than later months. The model differentiates the six months, months 4-9, from months further from the transplant period.

2. Originally disabled terms refer to people originally entitled to Medicare for reasons of disability other than ESRD.

3. The Denominator used to calculate the relative factors is $8,034.71.

In the "Disease interactions" and "NonAged interactions," the variables are defined as follows:

Sepsis = HCC 2.
Cardiorespiratory Failure = HCCs 82-84.
Diabetes = HCCs 17, 18, 19.
Congestive Heart Failure = HCC 85.
Chronic Obstructive Pulmonary Disease = HCCs 110-111.
Pressure Ulcer = HCCs 157-160.
Artificial Openings for Feeding or Elimination = HCC 188.
Aspiration and Specified Bacterial Pneumonias = HCC 114.
Schizophrenia = HCC 57.
Seizure Disorders and Convulsions = HCC 79.
Chronic Ulcer of Skin, except Pressure = HCC 161.
Bone/Joint/Muscle Infections/Necrosis = HCC 39.
Multiple Sclerosis = HCC 77.
Opportunistic Infections = HCC 6.

SOURCE: RTI International analysis of 2006/2007 100% ESRD sample claims and enrollment data and 2006/2007 Medicare 5% sample.

Table 6. Preliminary ESRD Model Demographic Relative Factors for Functioning Graft New Enrollees Duration Since Transplant of 4-9 Months

	Non-Medicaid & Non-Originally Disabled	Medicaid & Non-Originally Disabled	Non-Medicaid & Originally Disabled	Medicaid & Originally Disabled
Female				
0-34 Years	3.033	3.362	–	–
35-44 Years	3.180	3.509	–	–
45-54 Years	3.388	3.717	–	–
55-59 Years	3.554	3.883	–	–
60-64 Years	3.659	3.988	–	–
65 Years	3.133	3.644	3.753	4.263
66 Years	3.174	3.646	3.821	4.292
67 Years	3.210	3.682	3.857	4.328
68 Years	3.229	3.701	3.876	4.347
69 Years	3.256	3.727	3.902	4.373
70-74 Years	3.368	3.862	3.955	4.449
75-79 Years	3.571	3.994	4.130	4.553
80-84 Years	3.745	4.169	4.304	4.728
85-89 Years	3.908	4.332	4.467	4.891
90-94 Years	4.000	4.423	4.559	4.982
95 Years or Over	3.875	4.298	4.434	4.858
Male				
0-34 Years	2.824	3.241	–	–
35-44 Years	3.030	3.446	–	–
45-54 Years	3.212	3.628	–	–
55-59 Years	3.403	3.819	–	–
60-64 Years	3.533	3.950	–	–
65 Years	3.174	3.726	3.738	4.289
66 Years	3.232	3.783	3.751	4.302
67 Years	3.262	3.813	3.781	4.332
68 Years	3.290	3.842	3.809	4.361
69 Years	3.311	3.863	3.830	4.382
70-74 Years	3.449	4.000	3.965	4.515
75-79 Years	3.685	4.195	4.124	4.635
80-84 Years	3.904	4.414	4.343	4.853
85-89 Years	4.074	4.584	4.513	5.023
90-94 Years	4.249	4.759	4.688	5.198
95 Years or Over	4.315	4.826	4.754	5.265

NOTES:
1. The table entries are derived from the Graft New Enrollee model. 2. Originally Disabled terms refer to people originally entitled to Medicare for reasons of disability other than ESRD. In this model, Originally Disabled is defined only for beneficiaries age 65 and greater.

3. The Denominator used to calculate the relative factors is $8,034.71.

SOURCE: RTI International analysis of 2006/2007 100% ESRD sample claims and enrollment data and 2006/2007 Medicare 5% sample.

Table 7. Preliminary ESRD Model Demographic Relative Factors for Functioning Graft New Enrollees Duration Since Transplant of 10 Months or More

	Non-Medicaid & Non-Originally Disabled	Medicaid & Non-Originally Disabled	Non-Medicaid & Originally Disabled	Medicaid & Originally Disabled
Female				
0-34 Years	1.621	1.951	–	–
35-44 Years	1.768	2.098	–	–
45-54 Years	1.976	2.306	–	–
55-59 Years	2.142	2.472	–	–
60-64 Years	2.247	2.577	–	–
65 Years	1.766	2.277	2.386	2.896
66 Years	1.808	2.279	2.454	2.925
67 Years	1.844	2.315	2.490	2.961
68 Years	1.862	2.334	2.509	2.980
69 Years	1.889	2.360	2.535	3.006
70-74 Years	2.001	2.495	2.588	3.082
75-79 Years	2.204	2.627	2.763	3.186
80-84 Years	2.378	2.802	2.938	3.361
85-89 Years	2.541	2.965	3.101	3.524
90-94 Years	2.633	3.056	3.192	3.615
95 Years or Over	2.508	2.931	3.067	3.491
Male				
0-34 Years	1.412	1.829	–	–
35-44 Years	1.618	2.035	–	–
45-54 Years	1.800	2.217	–	–
55-59 Years	1.991	2.408	–	–
60-64 Years	2.122	2.538	–	–
65 Years	1.807	2.359	2.371	2.922
66 Years	1.865	2.416	2.384	2.935
67 Years	1.895	2.446	2.414	2.965
68 Years	1.924	2.475	2.442	2.994
69 Years	1.944	2.496	2.463	3.015
70-74 Years	2.082	2.633	2.598	3.149
75-79 Years	2.318	2.829	2.757	3.268
80-84 Years	2.537	3.047	2.976	3.486
85-89 Years	2.707	3.217	3.146	3.657
90-94 Years	2.882	3.392	3.321	3.831
95 Years or Over	2.948	3.459	3.387	3.898

NOTES:

1. The table entries are derived from the Graft New Enrollee model. 2. Originally Disabled terms refer to people originally entitled to Medicare for reasons of disability other than ESRD. In this model, Originally Disabled is defined only for beneficiaries age 65 and greater.

3. The Denominator used to calculate the relative factors is $8,034.71.

SOURCE: RTI International analysis of 2006/2007 100% ESRD sample claims and enrollment data and 2006/2007 Medicare 5% sample.

Table 8. Preliminary list of Disease Hierarchies for the Revised ESRD Model

DISEASE HIERARCHIES

Hierarchical Condition Category (HCC)	If the Disease Group is Listed in this column…	…Then drop the HCC(s) listed in this column
	Hierarchical Condition Category (HCC) LABEL	
8	Metastatic Cancer and Acute Leukemia	9,10,11,12
9	Lung and Other Severe Cancers	10,11,12
10	Lymphoma and Other Cancers	11,12
11	Colorectal, Bladder, and Other Cancers	12
17	Diabetes with Acute Complications	18,19
18	Diabetes with Chronic Complications	19
27	End-Stage Liver Disease	28,29,80
28	Cirrhosis of Liver	29
46	Severe Hematological Disorders	48
51	Dementia With Complications	52
54	Drug/Alcohol Psychosis	55
57	Schizophrenia	58
70	Quadriplegia	71,72,103,104,169
71	Paraplegia	72,104,169
72	Spinal Cord Disorders/Injuries	169
82	Respirator Dependence/Tracheostomy Status	83,84
83	Respiratory Arrest	84
86	Acute Myocardial Infarction	87,88
87	Unstable Angina and Other Acute Ischemic Heart Disease	88
99	Cerebral Hemorrhage	100
103	Hemiplegia/Hemiparesis	104
106	Atherosclerosis of the Extremities with Ulceration or Gangrene	107,108,161,189
107	Vascular Disease with Complications	108
110	Cystic Fibrosis	111,112
111	Chronic Obstructive Pulmonary Disease	112
114	Aspiration and Specified Bacterial Pneumonias	115
134	Dialysis Status	135,136,137,138,139,140,141
135	Acute Renal Failure	136,137,138,139,140,141
136	Chronic Kidney Disease, Stage 5	137,138,139,140,141
137	Chronic Kidney Disease, Severe (Stage 4)	138,139,140,141
138	Chronic Kidney Disease, Moderate (Stage 3)	139,140,141
139	Chronic Kidney Disease, Mild or Unspecified (Stages 1-2 or Unspecified)	140,141
140	Unspecified Renal Failure	141
157	Pressure Ulcer of Skin with Necrosis Through to Muscle, Tendon, or Bone	158,159,160,161
158	Pressure Ulcer of Skin with Full Thickness Skin Loss	159,160,161
159	Pressure Ulcer of Skin with Partial Thickness Skin Loss	160,161
160	Pressure Pre-Ulcer Skin Changes or Unspecified Stage	161
166	Severe Head Injury	80,167

How Payments are Made with a Disease Hierarchy EXAMPLE: If a beneficiary triggers HCCs 140 (Unspecified Renal Failure) and 141 (Nephritis), then HCC 141 will be dropped. In other words, payment will always be associated with the HCC in column 1, if a HCC in column 3 also occurs during the same collection period. Therefore, the organization's payment will be based on HCC 140 rather than HCC 141.

Table 9. Preliminary RxHCC Model Relative Factors for Continuing Enrollees

		Continuing Enrollee (CE) RxHCC Model Segments				
Variable	**Disease Group**	Community, Non-Low Income, Age>=65	Community, Non-Low Income, Age<65	Community, Low Income, Age>=65	Community, Low Income, Age<65	Institutional
Female						
0-34 Years		-	0.260	-	0.397	1.525
35-44 Years		-	0.471	-	0.587	1.546
45-54 Years		-	0.579	-	0.659	1.461
55-59 Years		-	0.568	-	0.630	1.384
60-64 Years		-	0.570	-	0.606	1.331
65 Years		0.410	-	0.440	-	1.422
66 Years		0.410	-	0.440	-	1.422
67 Years		0.410	-	0.440	-	1.422
68 Years		0.410	-	0.440	-	1.422
69 Years		0.410	-	0.440	-	1.422
70-74 Years		0.406	-	0.430	-	1.343
75-79 Years		0.413	-	0.428	-	1.287
80-84 Years		0.423	-	0.423	-	1.234
85-89 Years		0.432	-	0.414	-	1.181
90-94 Years		0.430	-	0.391	-	1.110
95 Years or Over		0.405	-	0.322	-	0.965
Male						
0-34 Years		-	0.240	-	0.426	1.552
35-44 Years		-	0.395	-	0.552	1.512
45-54 Years		-	0.522	-	0.592	1.443
55-59 Years		-	0.517	-	0.560	1.350
60-64 Years		-	0.531	-	0.531	1.299
65 Years		0.416	-	0.360	-	1.360
66 Years		0.416	-	0.360	-	1.360
67 Years		0.416	-	0.360	-	1.360
68 Years		0.416	-	0.360	-	1.360
69 Years		0.416	-	0.360	-	1.360
70-74 Years		0.407	-	0.352	-	1.316
75-79 Years		0.398	-	0.347	-	1.274
80-84 Years		0.392	-	0.336	-	1.246
85-89 Years		0.394	-	0.336	-	1.225
90-94 Years		0.419	-	0.357	-	1.182
95 Years or Over		0.423	-	0.350	-	1.079
Originally Disabled Interactions with Sex						
Originally Disabled		-	-	-	-	0.027
Originally Disabled_Female		0.070	-	0.100	-	-
Originally Disabled_Female_Age 65		-	-	-	-	-
Originally Disabled_Female_Age 66-69		-	-	-	-	-
Originally Disabled_Female_Age 70-74		-	-	-	-	-
Originally Disabled_Female_Age 75+		-	-	-	-	-
Originally Disabled_Male		0.021	-	0.089	-	-
Originally Disabled_Male_Age 65		-	-	-	-	-
Originally Disabled_Male_Age 66-69		-	-	-	-	-
Originally Disabled_Male_Age 70-74		-	-	-	-	-
Originally Disabled_Male_Age 75+		-	-	-	-	-

Disease Coefficients	Description Label	Community, Non-Low Income, Age>=65	Community, Non-Low Income, Age<65	Community, Low Income, Age>=65	Community, Low Income, Age<65	Institutional
RXHCC1	HIV/AIDS	1.599	2.337	2.082	2.496	1.058
RXHCC5	Opportunistic Infections	0.118	0.130	0.082	0.176	0.083
RXHCC8	Chronic Myeloid Leukemia	1.651	2.073	2.059	2.329	1.037
RXHCC9	Multiple Myeloma and Other Neoplastic Disorders	1.095	1.278	0.997	1.192	0.546
RXHCC10	Breast, Lung, and Other Cancers and Tumors	0.206	0.209	0.233	0.249	0.101
RXHCC11	Prostate and Other Cancers and Tumors	0.039	0.052	0.114	0.062	0.082
RXHCC14	Diabetes with Complications	0.251	0.188	0.270	0.266	0.154
RXHCC15	Diabetes without Complication	0.175	0.152	0.209	0.218	0.110
RXHCC18	Diabetes Insipidus and Other Endocrine and Metabolic Disorders	0.247	0.577	0.183	0.612	0.124
RXHCC19	Pituitary, Adrenal Gland, and Other Endocrine and Metabolic Disorders	0.045	0.065	0.029	0.059	0.061
RXHCC20	Thyroid Disorders	0.038	0.095	0.045	0.102	0.037
RXHCC21	Morbid Obesity	0.042	0.016	0.037	0.048	0.067
RXHCC23	Disorders of Lipoid Metabolism	0.119	0.131	0.139	0.178	0.063
RXHCC25	Chronic Viral Hepatitis	0.077	0.041	0.216	0.109	—
RXHCC30	Chronic Pancreatitis	0.091	0.174	0.045	0.074	0.021
RXHCC31	Pancreatic Disorders and Intestinal Malabsorption, Except Pancreatitis	0.034	0.075	0.034	0.074	0.021
RXHCC32	Inflammatory Bowel Disease	0.268	0.257	0.186	0.309	0.075
RXHCC33	Esophageal Reflux and Other Disorders of Esophagus	0.136	0.114	0.158	0.172	0.074
RXHCC38	Aseptic Necrosis of Bone	0.056	0.166	0.043	0.229	0.068
RXHCC40	Psoriatic Arthropathy	0.321	0.449	0.560	0.992	0.374
RXHCC41	Rheumatoid Arthritis and Other Inflammatory Polyarthropathy	0.172	0.264	0.193	0.383	0.095
RXHCC42	Systemic Lupus Erythematosus, Other Connective Tissue Disorders, and Inflammatory Spondylopathies	0.125	0.249	0.158	0.261	0.086
RXHCC45	Osteoporosis, Vertebral and Pathological Fractures	0.093	0.162	0.123	0.178	0.028
RXHCC47	Sickle Cell Anemia	0.140	0.089	0.131	0.425	0.035
RXHCC48	Myelodysplastic Syndromes, Except High-Grade	0.209	0.371	0.293	0.226	0.420
RXHCC49	Immune Disorders	0.151	0.255	0.128	0.271	0.142
RXHCC50	Aplastic Anemia and Other Significant Blood Disorders	0.045	0.089	0.058	0.072	0.035
RXHCC54	Alzheimer`s Disease	0.471	0.264	0.304	0.181	0.015
RXHCC55	Dementia, Except Alzheimer`s Disease	0.253	0.098	0.141	0.048	—
RXHCC58	Schizophrenia	0.433	0.574	0.633	0.940	0.334
RXHCC59	Bipolar Disorders	0.364	0.442	0.419	0.664	0.287
RXHCC60	Major Depression	0.274	0.350	0.302	0.430	0.202
RXHCC61	Specified Anxiety, Personality, and Behavior Disorders	0.163	0.224	0.215	0.430	0.172
RXHCC62	Depression	0.139	0.177	0.143	0.226	0.115
RXHCC63	Anxiety Disorders	0.057	0.127	0.086	0.179	0.115
RXHCC65	Autism	0.180	0.325	0.486	0.648	0.172
RXHCC66	Profound or Severe Mental Retardation/Developmental Disability	0.028	0.325	0.486	0.393	—
RXHCC67	Moderate Mental Retardation/Developmental Disability	0.028	0.173	0.396	0.288	—
RXHCC68	Mild or Unspecified Mental Retardation/Developmental Disability	0.011	0.051	0.234	0.141	—
RXHCC71	Myasthenia Gravis, Amyotrophic Lateral Sclerosis and Other Motor Neuron Disease	0.185	0.306	0.156	0.308	0.059
RXHCC72	Spinal Cord Disorders	0.064	0.170	0.071	0.094	—
RXHCC74	Polyneuropathy	0.089	0.215	0.081	0.179	0.059
RXHCC75	Multiple Sclerosis	0.448	0.796	0.485	1.313	0.121
RXHCC76	Parkinson`s Disease	0.420	0.501	0.290	0.286	0.154
RXHCC78	Intractable Epilepsy	0.364	0.640	0.347	0.897	0.123

Disease Coefficients	Description Label	Community, Non-Low Income, Age>=65	Community, Non-Low Income, Age<65	Community, Low Income, Age>=65	Community, Low Income, Age<65	Institutional
RXHCC79	Epilepsy and Other Seizure Disorders, Except Intractable Epilepsy	0.221	0.269	0.166	0.363	0.077
RXHCC80	Convulsions	0.110	0.129	0.097	0.225	0.039
RXHCC81	Migraine Headaches	0.115	0.229	0.109	0.197	0.144
RXHCC83	Trigeminal and Postherpetic Neuralgia	0.095	0.179	0.105	0.151	0.081
RXHCC86	Pulmonary Hypertension and Other Pulmonary Heart Disease	0.253	0.395	0.286	0.338	0.122
RXHCC87	Congestive Heart Failure	0.177	0.091	0.242	0.106	0.098
RXHCC88	Hypertension	0.168	0.077	0.215	0.094	0.063
RXHCC89	Coronary Artery Disease	0.146	0.083	0.130	0.045	0.017
RXHCC93	Atrial Arrhythmias	0.062	0.046	0.022	—	0.013
RXHCC97	Cerebrovascular Disease, Except Hemorrhage or Aneurysm	0.065	—	0.049	—	—
RXHCC98	Spastic Hemiplegia	0.146	0.241	0.055	0.146	0.013
RXHCC100	Venous Thromboembolism	0.014	0.048	—	0.083	—
RXHCC101	Peripheral Vascular Disease	0.057	0.030	0.091	0.063	—
RXHCC103	Cystic Fibrosis	0.199	0.692	0.219	1.320	0.114
RXHCC104	Chronic Obstructive Pulmonary Disease and Asthma	0.199	0.125	0.217	0.200	0.114
RXHCC105	Pulmonary Fibrosis and Other Chronic Lung Disorders	0.113	0.125	0.096	0.199	0.038
RXHCC106	Gram-Negative/Staphylococcus Pneumonia and Other Lung Infections	—	0.079	—	0.042	0.027
RXHCC111	Diabetic Retinopathy	0.094	0.082	0.078	0.038	0.034
RXHCC113	Open-Angle Glaucoma	0.142	0.101	0.152	0.122	0.100
RXHCC120	Kidney Transplant Status	0.275	0.165	0.379	0.399	0.329
RXHCC121	Dialysis Status	0.220	0.295	0.278	0.526	0.211
RXHCC122	Chronic Kidney Disease Stage 5	0.118	0.138	0.128	0.164	0.108
RXHCC123	Chronic Kidney Disease Stage 4	0.118	0.138	0.128	0.164	0.108
RXHCC124	Chronic Kidney Disease Stage 3	0.100	0.138	0.113	0.164	0.080
RXHCC125	Chronic Kidney Disease Stage 1, 2, or Unspecified	0.040	0.059	0.035	0.070	0.041
RXHCC126	Nephritis	0.040	0.034	0.035	0.068	0.013
RXHCC142	Chronic Ulcer of Skin, Except Pressure	0.042	0.060	0.027	0.060	—
RXHCC145	Pemphigus	0.111	0.146	0.120	0.254	—
RXHCC147	Psoriasis, Except with Arthropathy	0.106	0.186	0.202	0.284	0.124
RXHCC156	Narcolepsy and Cataplexy	0.274	0.344	0.161	0.432	0.102
RXHCC166	Lung Transplant Status	0.948	0.912	0.949	1.093	0.696
RXHCC167	Major Organ Transplant Status, Except Lung, Kidney, and Pancreas	0.415	0.378	0.409	0.471	0.329
RXHCC168	Pancreas Transplant Status	0.275	0.165	0.379	0.345	0.329
Non-Aged Disease Interactions						
NonAged_RXHCC1	HIV/AIDS	-	-	-	-	1.074
NonAged_RXHCC58	Schizophrenia	-	-	-	-	0.382
NonAged_RXHCC59	Bipolar Disorders	-	-	-	-	0.238
NonAged_RXHCC60	Major Depression	-	-	-	-	0.112
NonAged_RXHCC61	Specified Anxiety, Personality, and Behavior Disorders	-	-	-	-	0.112
NonAged_RXHCC62	Depression	-	-	-	-	0.056
NonAged_RXHCC63	Anxiety Disorders	-	-	-	-	0.032
NonAged_RXHCC65	Autism	-	-	-	-	0.112
NonAged_RXHCC75	Multiple Sclerosis	-	-	-	-	0.467
NonAged_RXHCC78	Intractable Epilepsy	-	-	-	-	0.199
NonAged_RXHCC79	Epilepsy and Other Seizure Disorders, Except Intractable Epilepsy	-	-	-	-	0.040
NonAged_RXHCC80	Convulsions	-	-	-	-	0.034

Note:
The relative risk scores in this table were calculated by dividing the parameter estimates by the Part D national average predicted expenditures (CMS Part D Denominator). The Part D Denominator value used was $1,107.82. This Part D Denominator is based on the combined PDP and MA-PD populations, and it includes adjustments for new model diagnoses not yet submitted by the MA-PD population.

Source: RTI Analysis of 100% 2008 PDE, 2007 NCH, 2008 HPMS, 2008 CME, and 2007-2008 Denominator.

Table 10. Preliminary RxHCC Model Relative Factors for New Enrollees, Non-Low Income

Variable	Baseline – Not Concurrently ESRD, Not Originally Disabled	Concurrently ESRD, Not Originally Disabled	Originally Disabled, Not Concurrently ESRD	Originally Disabled, Concurrently ESRD
Female				
0-34 Years	0.476	0.908	-	-
35-44 Years	0.793	1.225	-	-
45-54 Years	1.061	1.493	-	-
55-59 Years	1.124	1.556	-	-
60-64 Years	1.170	1.601	-	-
65 Years	0.755	1.187	1.151	1.583
66 Years	0.751	1.183	0.899	1.330
67 Years	0.751	1.183	0.899	1.330
68 Years	0.751	1.183	0.899	1.330
69 Years	0.751	1.183	0.899	1.330
70-74 Years	0.737	1.168	0.737	1.168
75-79 Years	0.674	1.106	0.674	1.106
80-84 Years	0.646	1.078	0.646	1.078
85-89 Years	0.566	0.997	0.566	0.997
90-94 Years	0.566	0.997	0.566	0.997
95 Years or Over	0.566	0.997	0.566	0.997
Male				
0-34 Years	0.322	0.754	-	-
35-44 Years	0.608	1.040	-	-
45-54 Years	0.874	1.306	-	-
55-59 Years	0.926	1.358	-	-
60-64 Years	1.013	1.445	-	-
65 Years	0.771	1.203	1.020	1.451
66 Years	0.757	1.188	0.757	1.188
67 Years	0.757	1.188	0.757	1.188
68 Years	0.757	1.188	0.757	1.188
69 Years	0.757	1.188	0.757	1.188
70-74 Years	0.719	1.151	0.719	1.151
75-79 Years	0.638	1.070	0.638	1.070
80-84 Years	0.540	0.972	0.540	0.972
85-89 Years	0.462	0.894	0.462	0.894
90-94 Years	0.462	0.894	0.462	0.894
95 Years or Over	0.462	0.894	0.462	0.894

NOTES:

1. The Part D Denominator used to calculate relative factors is $1,107.82. This Part D Denominator is based on the combined PDP and MA-PD populations. MA-PD risk scores were adjusted to account for new model diagnoses not yet submitted for the MA-PD population.

2. Originally Disabled is defined as originally entitled to Medicare by disability only (OREC = 1).

3. Concurrently ESRD is defined as at least one month of ESRD status—dialysis (D), transplant (1, 2, 5, 6 or N), or post-graft (G, R or Y) in the payment year (2008 in the model calibration).

Source: RTI Analysis of 100% 2008 PDE SAF, 2007-2008 HPMS, 2008 CME, and 2007-2008 Denominator.

Table 11. Preliminary RxHCC Model Relative Factors for New Enrollees, Low Income

Variable	Baseline – Not Concurrently ESRD and Not Originally Disabled	Concurrently ESRD, Not Originally Disabled	Originally Disabled, Not Concurrently ESRD	Originally Disabled, Concurrently ESRD
Female				
0-34 Years	0.875	1.413	-	-
35-44 Years	1.217	1.755	-	-
45-54 Years	1.253	1.792	-	-
55-59 Years	1.142	1.681	-	-
60-64 Years	1.116	1.654	-	-
65 Years	0.851	1.390	1.040	1.579
66 Years	0.587	1.126	0.742	1.280
67 Years	0.587	1.126	0.742	1.280
68 Years	0.587	1.126	0.742	1.280
69 Years	0.587	1.126	0.742	1.280
70-74 Years	0.598	1.137	0.753	1.291
75-79 Years	0.652	1.191	0.807	1.345
80-84 Years	0.684	1.222	0.839	1.377
85-89 Years	0.683	1.221	0.837	1.376
90-94 Years	0.683	1.221	0.837	1.376
95 Years or Over	0.683	1.221	0.837	1.376
Male				
0-34 Years	0.820	1.358	-	-
35-44 Years	1.093	1.632	-	-
45-54 Years	1.054	1.592	-	-
55-59 Years	0.914	1.452	-	-
60-64 Years	0.866	1.404	-	-
65 Years	0.674	1.212	0.772	1.311
66 Years	0.437	0.975	0.538	1.077
67 Years	0.437	0.975	0.538	1.077
68 Years	0.437	0.975	0.538	1.077
69 Years	0.437	0.975	0.538	1.077
70-74 Years	0.449	0.987	0.550	1.089
75-79 Years	0.477	1.016	0.477	1.016
80-84 Years	0.470	1.009	0.470	1.009
85-89 Years	0.507	1.045	0.507	1.045
90-94 Years	0.507	1.045	0.507	1.045
95 Years or Over	0.507	1.045	0.507	1.045

NOTES:

1. The Part D Denominator used to calculate relative factors is $1,107.82. This Part D Denominator is based on the combined PDP and MA-PD populations. MA-PD risk scores were adjusted to account for new model diagnoses not yet submitted for the MA-PD population.

2. Originally Disabled is defined as originally entitled to Medicare by disability only (OREC = 1).

3. Concurrently ESRD is defined as at least one month of ESRD status—dialysis (D), transplant (1, 2, 5, 6 or N), or post-graft (G, R or Y) in the payment year (2008 in the model calibration).

Source: RTI Analysis of 100% 2008 PDE SAF, 2007-2008 HPMS, 2008 CME, and 2007-2008 Denominator.

Table 12. Preliminary RxHCC Model Relative Factors for New Enrollees, Institutional

Variable	Baseline – Not Concurrently ESRD	Concurrently ESRD
Female		
0-34 Years	2.095	2.326
35-44 Years	2.095	2.326
45-54 Years	2.012	2.243
55-59 Years	1.975	2.205
60-64 Years	1.917	2.148
65 Years	1.988	2.218
66 Years	1.783	2.013
67 Years	1.783	2.013
68 Years	1.783	2.013
69 Years	1.783	2.013
70-74 Years	1.616	1.846
75-79 Years	1.551	1.781
80-84 Years	1.378	1.609
85-89 Years	1.214	1.445
90-94 Years	1.214	1.445
95 Years or Over	1.214	1.445
Male		
0-34 Years	2.118	2.348
35-44 Years	2.118	2.348
45-54 Years	2.059	2.289
55-59 Years	1.938	2.169
60-64 Years	1.792	2.023
65 Years	1.790	2.020
66 Years	1.683	1.914
67 Years	1.683	1.914
68 Years	1.683	1.914
69 Years	1.683	1.914
70-74 Years	1.573	1.804
75-79 Years	1.539	1.769
80-84 Years	1.505	1.736
85-89 Years	1.293	1.523
90-94 Years	1.293	1.523
95 Years or Over	1.293	1.523

NOTES:
1. The Part D Denominator used to calculate relative factors is $1,107.82. This Part D Denominator is based on the combined PDP and MA-PD populations. MA-PD risk scores were adjusted to account for new model diagnoses not yet submitted for the MA-PD population.

2. Concurrently ESRD is defined as at least one month of ESRD status—dialysis (D), transplant (1, 2, 5, 6 or N), or post-graft (G, R or Y) in the payment year (2008 in the model calibration).3. The Part D New Enrollee Institutional sample does not have an Originally Disabled add-on (set to $0 because of regression results).

Source: RTI Analysis of 100% 2008 PDE SAF, 2007-2008 HPMS, 2008 CME, and 2007-2008 Denominator.

Table 13. Preliminary list of Disease Hierarchies for the Revised RxHCC Model

DISEASE HIERARCHIES		
Rx Hierarchical Condition Category (RxHCC)	**If the Disease Group is Listed in this column…**	**…Then drop the RxHCC(s) listed in this column**
	Rx Hierarchical Condition Category (RxHCC) LABEL	
8	Chronic Myeloid Leukemia	9,10,11,48,50
9	Multiple Myeloma and Other Neoplastic Disorders	10,11,48,50
10	Breast, Lung, and Other Cancers and Tumors	11
14	Diabetes with Complications	15
18	Diabetes Insipidus and Other Endocrine and Metabolic Disorders	19
30	Chronic Pancreatitis	31
40	Psoriatic Arthropathy	41,42,147
41	Rheumatoid Arthritis and Other Inflammatory Polyarthropathy	42
47	Sickle Cell Anemia	50
48	Myelodysplastic Syndromes, Except High-Grade	50
54	Alzheimer's Disease	55
58	Schizophrenia	59,60,61,62,63,65,66,67,68
59	Bipolar Disorders	60,61,62,63
60	Major Depression	61,62,63
61	Specified Anxiety, Personality, and Behavior Disorders	62,63
62	Depression	63
65	Autism	61,62,63,66,67,68
66	Profound or Severe Mental Retardation/Developmental Disability	67,68
67	Moderate Mental Retardation/Developmental Disability	68
78	Intractable Epilepsy	79,80
79	Epilepsy and Other Seizure Disorders, Except Intractable Epilepsy	80
86	Pulmonary Hypertension and Other Pulmonary Heart Disease	87,88
87	Congestive Heart Failure	88
103	Cystic Fibrosis	104,105
104	Chronic Obstructive Pulmonary Disease and Asthma	105
120	Kidney Transplant Status	121,122,123,124,125,126,168
121	Dialysis Status	122,123,124,125,126
122	Chronic Kidney Disease Stage 5	123,124,125,126
123	Chronic Kidney Disease Stage 4	124,125,126
124	Chronic Kidney Disease Stage 3	125,126
125	Chronic Kidney Disease Stage 1, 2, or Unspecified	126
166	Lung Transplant Status	167,168
167	Major Organ Transplant Status, Except Lung, Kidney, and Pancreas	168

SOURCE: RTI International.

Attachment VI: 2012 Call Letter

Table of Contents

How to Use This Call Letter

The 2012 Call Letter contains information on the Part C and Part D programs. Also, we indicate when certain sections apply to cost-reimbursed HMOs, PACE programs, and employer and union-sponsored group health plans (EGWPs).

Over the past year, CMS has committed its resources to improving the quality of plan choices for beneficiaries who elect to enroll in Medicare Advantage and prescription drug plans. As part of this effort, CMS published a proposed regulation (4144-P) on November 22, 2010 that would make revisions to the Parts C and D regulations. CMS is currently reviewing comments submitted by the public and is in the process of developing the policies for the final rule.

Since this year's final Call Letter will be released close to the expected final publication of the final rule (4144-F), the content is limited to clarification of current policy and operational guidance. However, requirements contained in the final rule may be included in this year's final Call Letter, even if they have not been included in this draft Call Letter. The Call Letter is divided into three sections: Program Updates, Improving Information Sharing & Transparency with Sponsors, and Improving the Beneficiary Experience. These three sections contain information about Part C and Part D. We remind sponsoring organizations to continue to familiarize themselves with statutory requirements, regulations, and guidance governing the MA and Part D programs, including the Medicare Advantage and Prescription Drug Benefit Manuals. CMS will separately issue technical and procedural clarifications regarding bid and formulary submissions, benefits, HPMS data, CMS marketing models, and other operational issues of interest to sponsoring organizations.

Also note that this year some of the calendar items have dates that are earlier than for the 2011 contract year. This is as a result of the earlier Annual Enrollment Period (AEP) as compared to years past. Items with earlier due dates are indicated in the chart. Organizations and CMS need to work together to ensure contracting deadlines are met.

We hope this information helps you implement and comply with CMS policies and procedures as you prepare either to offer a plan for the first time or continue offering plans under the MA and/or Part D programs.

If you have questions concerning this Call Letter, please contact: Heather Rudo at Heather.Rudo@cms.hhs.gov (Part C issues) and Julie Gover at Julie.Gover2@cms.hhs.gov (Part D issues).

Section 1 - Program updates

2012 MA, MA-PD, Part D and Cost-Based Plan Calendar **(All dates, unless identified as statutory, are subject to change)**					
2011 ***Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D sponsors also apply to MA and cost-based plans offering a Part D benefit.**		***Part C**	***Part D sponsors**	**Cost**	**Date earlier than last year**
January 4, 2011	Release of the 2012 MAO/MAPD/PDP/SAE Applications in the Health Plan management System (HPMS)	✓	✓	✓	
January 5 & 12, 2011	Industry training on 2012 Applications	✓	✓	✓	
February 24, 2011	2012 Applications are due to CMS	✓	✓	✓	
March 2011	CMS releases guidance concerning updates to Parent Organization designations in HPMS	✓	✓	✓	✓
March 4, 2011	Initial Submission deadline for risk adjustment data with dates of service January 1, 2010 through December 31, 2010.	✓		✓	
March 25, 2011	Release of the 2012 Formulary Submission Module in HPMS	✓	✓		
March 25 2011	Release of the 2012 Medication Therapy Management Module (MTMP) in HPMS		✓		
Early April 2011	CY 2012 OOPC estimates for each plan and an OOPC model will be made available to plan sponsors in SAS to download from the CMS website that will assist plans in meeting meaningful difference and total beneficiary cost requirements prior to bid submission.	✓	✓		
Early April 2011	Release additional guidance regarding potentially duplicative plans, low enrollment plans and benefits review standards for 2012 bid submission.	✓	✓		
TBD	Conference call with industry to discuss the 2012 Call Letter.	✓	✓	✓	
Early April 2011	Information about renewal options for contract year 2012 (including HPMS crosswalk charts) will be provided to plans.	✓	✓		
April 4, 2011	2012 Final Call Letter released. Announce CY 2011 MA Capitation Rates and MA and Part D Payment Policies. *(applies to Part C and Part D sponsors only)*	✓	✓	✓	
April 4, 2011	2012 MTMP submission deadline		✓		
April 8, 2011	Release of the 2012 Plan Creation, Plan Benefit Package (PBP), and Bid Pricing Tool (BPT) Software of HPMS.	✓	✓		

2012 MA, MA-PD, Part D and Cost-Based Plan Calendar **(All dates, unless identified as statutory, are subject to change)**					
2011 ***Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D sponsors also apply to MA and cost-based plans offering a Part D benefit.**		***Part C**	***Part D sponsors**	**Cost**	**Date earlier than last year**
April 15, 2011	Release of the 2012 PBP online Training Module	✓	✓		
April 15, 2011	Parent Organization Update requests from sponsors due to CMS (instructional memo to be released on March 25, 2011)	✓	✓	✓	✓
April 18, 2011	2012 Formulary Submissions due from all sponsors offering Part D (11:59 p.m. EDT). Transition Attestations due to CMS *(Part D sponsors only)*	✓	✓		
April 12-13, 2011	Medicare Advantage and Part D Spring Conference	✓	✓	✓	✓
April/May 2011	CMS contacts MAOs with low enrollment plans	✓	✓	✓	
May 2011	Final ANOC/EOC, LIS rider, EOB, formularies, transition notice, provider directory, and pharmacy directory models for 2012 will be available for all organizations. (Models containing significant revisions will be released for public comment prior to this date).	✓	✓		
May 2, 2011	Voluntary Non-Renewal. CMS strongly encourages MA and MA-PD plans to notify us of an intention to non-renew a county or counties for individuals, but continue the county for "800 series" EGWP members, by May 2, 2011.	✓		✓	
May 2, 2011	*Voluntary non-renewal*: CMS strongly encourages Part D sponsors to notify us of any type of service area reduction, or conversion to offering employer-only contracts by May 2, 2011, so that we can make the required changes in HPMS to facilitate sponsors' ability to correctly upload their bids in June.		✓		
May 13, 2011	Release of the 2012 Bid Upload Functionality in HPMS	✓	✓	✓	
Late-May/June 2011	CMS sends eligibility determinations to applicants based on review of the 2012 applications for new contracts or service area expansions.	✓	✓	✓	

2012 MA, MA-PD, Part D and Cost-Based Plan Calendar **(All dates, unless identified as statutory, are subject to change)**					
2011 ***Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D sponsors also apply to MA and cost-based plans offering a Part D benefit.**		***Part C**	***Part D sponsors**	**Cost**	**Date earlier than last year**
Late May, 2011	Release of HITECH identifying information for MA EPs and MA-affiliated hospitals and for attestation of qualifying MA organizations not offering MA HMO plans in HPMS.	✓	✓	✓	
Late Spring/Early Summer 2011	Update Medicare Marketing Guidelines for CY 2012.	✓	✓	✓	
June 1, 2011	Final date to submit 2011 HITECH methodology for estimating portion of MA EP salary attributable to providing Part B services.	✓	✓	✓	
June 3, 2011	Release of the 2010 DIR Submission Module in HPMS		✓		
June 3, 2011	2012 MTMP Annual Review completed	✓	✓	✓	
June 6, 2011	Release of the 2012 Marketing Module in HPMS	✓	✓	✓	
June 6, 2011	Release of the 2012 Actuarial Certification Module in HPMS	✓	✓	✓	
June 6, 2011	Deadline for submission of CY 2012 bids for all MA plans, MA-PD plans, PDPs, cost-based plans offering a Part D benefit, "800 series" EGWP and direct contract EGWP applicants and renewing organizations; deadline for cost-based plans wishing to appear in the 2011 Medicare Options Compare to submit PBPs (11:59 p.m. PDT). Voluntary Non-Renewal. Deadline for MA , MA-PD p, PDPs and Cost-Based organizations to submit a contract non-renewal, service area reduction, or Plan Benefit Package (PBP) level non-renewal notice to CMS for CY 2012.	✓	✓	✓	
June to Early September, 2011	CMS completes review and approval of 2012 bid data. Submit attestations, contracts, and final actuarial certifications.	✓	✓		

2012 MA, MA-PD, Part D and Cost-Based Plan Calendar **(All dates, unless identified as statutory, are subject to change)**					
2011 ***Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D sponsors also apply to MA and cost-based plans offering a Part D benefit.**		***Part C**	***Part D sponsors**	**Cost**	**Date earlier than last year**
June 13, 2011	Deadline for submitting Supplemental Formulary files, Free First Fill file, Partial Gap file, Excluded Drug file, Over the Counter (OTC) drug file, and Home Infusion file through HPMS.	✓	✓		
Late June, 2011	Release of the 2012 SB hardcopy Change Request Module) on HPMS.	✓	✓	✓	
June 30, 2011	Final date to submit CY 2012 marketing materials for assured CMS' review and approval. NOTE: This date does not apply to CY 2012 file and use materials since these may be filed with the appropriate CMS regional office five calendar days prior to their use.	✓	✓	✓	
Late June 2011	Non-Renewal. CMS to issue an acknowledgement letter to all MA, MA-PD, PDP and Medicare cost-based plans that have notified CMS they are non-renewing or reducing their service area.	✓	✓	✓	
Late June 2011	Industry training on revised Medicare Marketing Guidelines and model documents.	✓	✓	✓	
July1, 2011	Submission date for contracting MAOs (new and expanding) to provide CMS with a ratified contract with the State in order to operate a Medicaid dual eligible SNP for CY 2012.	✓			
July 5, 2011	Plans are expected to submit non-model Low Income Subsidy (LIS) riders to the regional office for review.		✓		
July 25, 2011	Submission deadline for agent/broker compensation structures due to CMS.	✓	✓	✓	
Late July/Early August, 2011	Release of the 2012 Part D national average monthly bid amount, the Medicare Part D base beneficiary premium, the Part D regional low-income premium subsidy amounts, and the Medicare Advantage regional PPO benchmarks. Rebate reallocation period begins after release of the above amounts.	✓	✓	✓	✓

2012 MA, MA-PD, Part D and Cost-Based Plan Calendar **(All dates, unless identified as statutory, are subject to change)**					
2011 ***Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D sponsors also apply to MA and cost-based plans offering a Part D benefit.**		***Part C**	***Part D sponsors**	**Cost**	**Date earlier than last year**
Late July/Early August, 2011	CMS encourages cost-based plans to submit their summary of benefits (SBs) by this date so that materials can be reviewed and approved prior to the publishing of "Medicare Options Compare" and the *Medicare & You* handbook. SBs must be submitted by this date to be assured of being included.			✓	
August 1, 2011	Plans are expected to submit model Low Income Subsidy (LIS) riders to the regional office for review.		✓		
Mid – August, 2011	CMS will release model final beneficiary notification letters.				✓
August 25 – August 29, 2011	If applicable, plans preview the 2012 *Medicare & You* plan data in HPMS prior to printing of the CMS publication (not applicable to EGWPs).	✓	✓	✓	✓
Late August 2011	Contracting Materials submitted to CMS	✓	✓	✓	
End of August/Early September 2011	Plan preview period of star ratings in HPMS	✓	✓		
August 31 – September 2, 2011	First CY 2012 Medicare Plan Finder (MPF) Preview and (Out-of-Pocket Cost) OOPC Preview	✓	✓	✓	✓
September, 2011	CMS begins accepting plan correction requests upon contract approval.	✓	✓	✓	
September 2, 2011	Initial Submission deadline for risk adjustment data with dates of service from July 1, 2010 through June 30, 2011.	✓		✓	
September 13 – September16, 2011	Second CY 2012 Medicare Plan Finder (MPF) Preview and (Out-of-Pocket Cost) OOPC Preview	✓	✓	✓	✓
Mid-September 2011	All 2012 contracts fully executed (signed by both parties: Part C/Part D sponsor and CMS)	✓	✓	✓	
Sept 15 – Sept 30, 2011	CMS mails the 2012 *Medicare & You* handbook to Medicare beneficiaries.	✓	✓	✓	✓

2012 MA, MA-PD, Part D and Cost-Based Plan Calendar **(All dates, unless identified as statutory, are subject to change)**					
2011 ***Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D sponsors also apply to MA and cost-based plans offering a Part D benefit.**		***Part C**	***Part D sponsors**	**Cost**	**Date earlier than last year**
September 30, 2011	CY 2012 standardized, combined Annual Notice of Change (ANOC)/Evidence of Coverage (EOC) is due to current members of all MA plans, MA-PD plans, PDPs, and cost-based plans offering Part D. MA and MA-PD plans must ensure current members receive the combined ANOC/EOC by September 30th. Organizations are not required to mail the Summary of Benefits (SB) to existing members when using the combined, standardized ANOC/EOC; however the SB must be available upon request. Exception: Dual eligible SNPs that are fully integrated with the State must mail an ANOC with the SB for member receipt by September 30, 2011 and then send the EOC for member receipt by December 31, 2011. Dual eligible SNPs that send a combined, standardized ANOC/EOC for member receipt by September 30, 2011 are not required to send an SB to current members; however, the SB must be made available upon request. All plans offering Part D must mail their LIS riders and abridged or comprehensive formularies before this date to ensure receipt by members by September 30th Note: Plan sponsors must send the ANOC/EOC to enrollees for receipt by September 30th. No additional materials may be sent prior to the beginning of when marketing activities may begin on October 1.	✓	✓	✓	✓

2012 MA, MA-PD, Part D and Cost-Based Plan Calendar **(All dates, unless identified as statutory, are subject to change)**					
2011 ***Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D sponsors also apply to MA and cost-based plans offering a Part D benefit.**		***Part C**	***Part D sponsors**	**Cost**	**Date earlier than last year**
October 1, 2011	Plans may begin CY 2012 marketing activities. Once an organization begins marketing CY 2012 plans, the organization must cease marketing CY 2011 plans through mass media or direct mail marketing (except for age-in mailings). Organizations may still provide CY 2011 materials upon request, conduct one-on-one sales appointments and process enrollment applications. Plans are required to include information in CY 2011 marketing and enrollment materials to inform potential enrollees about the possibility of plan (benefit) changes beginning January 1, 2012. Last day for Part D sponsors to request plan benefit package (PBP) plan corrections via HPMS.	✓	✓	✓	
October 1, 2011	Deadline for cost-based, MA, and MA-PD organizations to request a plan correction to the plan benefit package (PBP). Deadline for cost-based, MA and MA-PD organizations to request of a SB hard copy change.	✓		✓	
October 3, 2011	Non-Renewal. The final beneficiary non-renewal notification letter must be a personalized letter and received by PDP, MA, MA-PD enrollees by October 3, 2011. PDP, MA, MA-PD organizations may not market to beneficiaries of non-renewing plans until after October 3, 2011.	✓	✓	✓	
October 6, 2011	Plan ratings go live on Medicare Plan Finder	✓	✓		
October 6, 2011	Tentative date for 2012 plan benefit data and plan drug beneit information to be displayed on Medicare Plan Finder (not applicable to EGWPs).	✓	✓	✓	
October 15, 2011	Part D sponsors must post PA and ST criteria on their websites for the 2012 contract year.		✓		

2012 MA, MA-PD, Part D and Cost-Based Plan Calendar **(All dates, unless identified as statutory, are subject to change)**					
2011 ***Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D sponsors also apply to MA and cost-based plans offering a Part D benefit.**		***Part C**	***Part D sponsors**	**Cost**	**Date earlier than last year**
October 15, 2011	2012 Annual Coordinated Election Period begins. All organizations must hold open enrollment (for EGWPs, see Chapter 2 of the Medicare Managed Care Manual, Section 30.1). Medicare Marketing Guidelines require that all plans mail a CY 2012 EOC to each new member no later than when they notify the new member of acceptance of enrollment. Organizations offering Part D must mail their Low Income Subsidy Rider (LIS) and abridged or comprehensive formularies with the EOC for new members. New members with an effective date of January 1, 2012 or later do not need to (but may) receive the ANOC portion of the standardized/combined ANOC/EOC.	✓	✓	✓	✓
November 2, 2011	Cost-Based organizations must mail the personalized final beneficiary non-renewal notification in time to be received by enrollees by November 2, 2011.			✓	
November 11, 2011	Notices of Intent to Apply (NOIA) for CY 2013 due for MA, MA-PD, PDPs, and "800 series" EGWPS and Direct Contract EGWPs.	✓	✓	✓	
November – December, 2011	Non-Renewal. CMS to issue "close out" information and instructions to MA plans, MA-PD plans, PDPs, and cost-based plans that are non-renewing or reducing service areas.	✓	✓	✓	
December 1, 2011	Medicare cost-based plans not offering Part D must send the combined ANOC/EOC for receipt by members by December 1, 2011.			✓	
December 1, 2011	Non-Renewal. Cost-based plans must publish notice of non-renewal.			✓	
December 7, 2011	Annual Coordinated Election Period Ends.	✓	✓		✓
December 31, 2011	Dual eligible SNPs that are fully integrated with the State and did not send an EOC with the ANOC by September 30, 2011, must send the EOC by December 31, 2011.	✓			

2012 MA, MA-PD, Part D and Cost-Based Plan Calendar **(All dates, unless identified as statutory, are subject to change)**					
2011 ***Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D sponsors also apply to MA and cost-based plans offering a Part D benefit.**		***Part C**	***Part D sponsors**	**Cost**	**Date earlier than last year**
December 31, 2011	MAOs must disenroll members who enrolled prior to January 1, 2010, into a SNP that was previously designated as a "disproportionate share" SNP and who did not meet the special needs criteria as of December 31, 2009 and members who enrolled prior to January 1, 2010, into a C-SNP that no longer targeted the individual's chronic condition(s) as of January 1, 2010.	✓			
2012					
January 1, 2012	Plan Benefit Period Begins.	✓	✓	✓	
January 1 – February 14, 2012	MA Annual 45 Day Disenrollment Period (ADP).	✓			
January 4, 2012	Release of CY 2013 MAO/MAPD/PDP/SAE/EGWP applications.	✓	✓	✓	
Mid January, 2012	Industry training on CY 2013 applications.	✓	✓	✓	
January 31, 2012	Final Submission deadline for risk adjustment data with dates of service January 1, 2010 through December 31, 2010	✓		✓	
February 23, 2012	Applications due for CY 2013.	✓	✓	✓	
March 2, 2012	Initial Submission deadline for risk adjustment data with dates of service January 1, 2011 through December 31, 2011	✓		✓	
September 7, 2012	Initial Submission deadline for risk adjustment data with dates of service from July 1, 2011 through June 30, 2012	✓		✓	

Part D Sponsor Bids and the Platino Program

When Part D sponsors seek to offer a plan in the Commonwealth of Puerto Rico as part of the Platino program, the Part D bids must reflect only basic benefits. Any supplemental benefits required by the Commonwealth (the Platino program's coverage of excluded drugs and/or cost-sharing buy-downs) should not be included as part of the plan sponsor's Part D bid. As discussed previously in our Call Letter for calendar year 2010, the supplemental benefits are negotiated between the Commonwealth and the Part D sponsor and are never part of the

Medicare Part D bid submitted to CMS. CMS does not evaluate nor approve the Commonwealth's benefits provided by the Platino program.

CMS will revise the Health Plan Management System's (HPMS) Plan Benefit Package to reflect submissions of bids specific to the Platino program for 2012. Plan sponsors will not be able to validate bids for enhanced plans that apply to Platino programs.

Coordination of Benefits (COB) User Fees

CMS is authorized to impose user fees on Part D sponsors for the transmittal of information necessary for certain benefit coordination activities between sponsors and other entities providing prescription drug coverage. CMS may review and update this user fee annually to reflect the costs associated with such COB activities. For contract year 2011, the Part D COB user fee was decreased to $1.17 per enrollee per year. In April 2011, CMS will implement the MARx Redesign and Modernization project which, among other changes, will enable daily enrollment transaction processing and reporting, multiple 4Rx spans within the beneficiary enrollment history, and reinstatement of erroneous disenrollments. These changes will significantly improve the timeliness and accuracy of information on beneficiary coverages. Some of the other functions financed through these fees include the operations of the TrOOP Facilitation Contractor (supporting real-time electronic E1, Nx and FIR transactions), the Coordination of Benefits Contractor (supporting exchange and collection of information on other insurance or liability coverages for Medicare beneficiaries, and the facilitation of information on coverage gap discount program Part D drug cost reimbursements. Our projection of the incremental on-going costs of related activities in 2012 indicates the Part D COB user fee must be increased to $1.62 per enrollee per year for contract year 2012. The 2012 COB user fee will be collected at a monthly rate of $0.18 for the first 9 months of the coverage year (for an annual rate of $0.135 per enrollee per month) for a total user fee of $1.62 per enrollee per year. Part D sponsors should account for this COB user fee when developing their 2012 bids. We welcome comments from Part D sponsors and other entities providing prescription drug coverage on ways we might improve the quality, reliability and timeliness of beneficiary coverage-related data required to correctly coordinate benefits and track TrOOP.

ESRD Drugs

Effective January 1, 2011, the bundled prospective payment system (PPS) for renal dialysis services provided by an end-stage renal disease (ESRD) dialysis facility includes the limited number of oral equivalents of injectable drugs and biologics used in the treatment of ESRD that were formerly reimbursed under Part D. Therefore, sponsors are reminded that the costs related to these oral drugs with injectable equivalents must be excluded from the 2012 plan bids.

Submission of Quality Improvement Projects (QIPs) and Chronic Care Improvement Programs

Each MA organization that offers one or more MA plan must, for each of those plans, have an ongoing Quality Improvement (QI) Program that meets the applicable requirements of 42 CFR §422.152. CMS will request, on an annual basis, that QIPs and CCIPs be submitted for purposes of ongoing quality improvement monitoring. To ensure that these projects are evaluated in a consistent manner, CMS will require all plans, including those that have been deemed by an accrediting organization, to submit the QIPs and CCIPs for CY2012 on the appropriate templates.

Guidance describing the QIP and CCIP templates, scoring methodology, benchmarks, and any CMS identified QIP and/or CCIP topics will be forthcoming. The guidance will also specify that in future years we anticipate that the project submission date may be earlier in the calendar year to allow sufficient time for CMS review.

Proposed Initiative to Promote Enrollment in Fully Integrated SNPs

CMS is now considering an initiative to promote enrollment of dual eligible beneficiaries in fully integrated, high quality Special Needs Plans (SNPs). The initiative would test the impact of certain plan design flexibilities in the 2013 contract year. To qualify, SNPs would have to be an existing plan in the 2011 and 2012 plan years, be of high quality, and demonstrate that they offer a truly integrated product, e.g., a capitated contract for the full array of Medicaid services, including primary, acute, behavioral, and long term.

We are interested in comments on this proposed initiative, including specifically:

- What criteria should be used for a SNP to be considered "high quality?"
- What specific plan design flexibilities would promote improved care delivery and streamlined administration?
- What incentives (such as seamless enrollment transitions) would best promote plan participation in this initiative?
- What additional care coordination or beneficiary protection requirements would be appropriate for participating SNPs?

All Dual Eligible SNPs Required to Contract with State Medicaid Agencies

As required by section 164 of MIPPA and revised by section 3205 of the Affordable Care Act, all Dual Eligible Special Needs Plans will be required to have contracts with the state Medicaid

agencies in the states within which they operate starting in Contract Year 2013. However, pursuant to section 3205 of the Affordable Care Act, existing D-SNPs that are not expanding their service areas can continue to operate without a state contract through December 31, 2012. The contract between the MA dual eligible SNP and the State Medicaid agency must document each entity's roles and responsibilities with regard to dual eligible individuals. The required elements of the contract are discussed in 42 CFR § 422.107.

- Proposed Contract Submission Requirements:

Effective for the CY 2013 MA Application, CMS is working to align the contract submission deadline with the MA Application deadline in late February so SNP approval can occur simultaneously with the MA contracting process. As such, CMS is considering an earlier contract submission date.

Involuntary Disenrollment of Ineligible or "Disproportionate Share" SNP Enrollees

As provided under the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), Special Needs Plans (SNPs) may only enroll individuals who meet the plan's specific eligibility criteria. They may no longer enroll and serve a "disproportionate share" of individuals who do not meet the targeted criteria or condition. Similarly, MIPPA limits enrollment in chronic care SNPs (C-SNPs) to individuals with certain chronic conditions, as specified by CMS. Rather than require MA organizations offering these SNPs to involuntarily disenroll these members as of December 31, 2009, because they did not meet the SNP's targeted criteria, CMS required the MAOs to allow these individuals to continue to be enrolled through 2011, in order to provide affected beneficiaries sufficient time to review and understand their options and to make another election. Details of current guidance can be found in a September 9, 2010, memorandum entitled "Transition Guidance for Non-Special Needs Enrollees in MA Special Needs Plans (SNPs) beyond January 1, 2010." Additionally, the requirement to disenroll individuals who do not meet SNPs' targeted criteria does not apply to enrollees who are in a designated grace period after losing special needs status. These individuals, however, will have to be disenrolled at the end of their grace period in accordance with existing CMS policy.

SNPs that include members who enrolled under the two circumstances described above will be required to disenroll those individuals if they do not request enrollment in a different plan prior to January 1, 2012. In order to facilitate this process, MAOs offering SNPs will be required to provide their CMS account manager with information regarding the total number of non-special needs individuals enrolled in these SNPs as of January 1, 2010. The deadline for providing this information to CMS is June 30, 2011. This accounting will assist MAOs with notifying and disenrolling these individuals for the 2012 plan benefit year. MAOs must notify each individual on or before October 1, 2011, that he/she will be disenrolled effective January 1, 2012, and will need to enroll in another plan prior to that date if he/she wants MA coverage for 2012. MAOs

will not be permitted to transition these current enrollees into other non-SNP MA plans offered by the organization, but are permitted to market other plans to these individuals, consistent with Medicare Marketing Guidelines. CMS will provide a model beneficiary disenrollment notice as part of the annual non-renewal and service area reduction guidance. MAOs must retain any of these enrollees whose circumstances change and who attain special needs status prior to CY 2012.

Enrollees who lose special needs status in 2011 must be notified and disenrolled, if necessary, in accordance with the requirements in section 50.2.5 of the MA Enrollment and Disenrollment Guidance.

MAO and PDP Sponsor Renewal/Non-Renewal Options for CY 2012

In this Call Letter, we provide comprehensive guidance regarding the plan renewal and non-renewal options available to MAOs and PDP sponsors for CY 2012. In addition, we clarify aspects of our non-renewal policies with respect to section 1876 cost contract plans.

As a result of business decisions, or pre- or post-bid discussions with CMS, MAOs and PDP sponsors may choose to change their current year offerings for the following contract year. Each year, current MAOs and PDP sponsors are required to complete the Health Plan Management System (HPMS) Plan Crosswalk in a way that reflects Plan Benefit Package (PBP) renewal and non-renewal decisions and delineates, for enrollment purposes, the relationships between PBPs offered under each of their contracts for the coming contract year. MAOs and Part D sponsors must also adhere to certain notification requirements, as specified in this guidance. While most renewal options must be completed using the HPMS Plan Crosswalk, there are limited exceptions to this requirement. These exceptions are described in Appendices A-1, A-2, B-1 and B-2 of this Call Letter.

Overall, this renewal and non-renewal guidance is based on two underlying principles: (1) the maximization of beneficiary choice; and (2) the protection of enrollment choices beneficiaries have previously made. We believe that beneficiaries should have the opportunity to make active enrollment elections into Original Medicare, a healthcare plan option, or a PDP option that best fits their particular needs.

As provided under 42 CFR §§ 422.254, 422.256, 423.265, and 423.272, CMS reviews bids to ensure that an organization's or sponsor's benefit packages offered in a service area are substantially different from others offered by the organization or sponsor in the same area with respect to key plan characteristics such as premiums, cost-sharing, formulary structure, or benefits offered. In addition, under 42.CFR §§ 422.506 and 423.507, we may non-renew plans that do not meet minimum enrollment thresholds after a specified length of time. This Call Letter contains information about how these requirements will be operationalized for CY 2012.

Although many of the renewal options outlined in this guidance are permissible despite year-to-year changes in benefits, premiums, and cost-sharing, we urge organizations and sponsors to maintain comparable benefits across contract years to the greatest extent possible in order to ensure that enrollees' enrollment elections remain valid. Section 3209 of the Affordable Care Act of 2010 provides CMS with authority to deny plan bids if an organization's or sponsor's proposed PBP includes significant increases in cost sharing or decreases in benefits offered. CMS is currently undergoing notice-and-comment rulemaking to implement this provision for CY 2012.

Appendices A-1, A-2, B-1 and B-2 outline all permissible renewal and non-renewal options for CY 2012 for MAOs and PDP sponsors including their method of effectuation, systems enrollment activities, enrollment procedures, and required beneficiary notifications. MAOs offering special needs plans (SNPs) should note the options for SNP transitions, such as those involving renewing SNPs with ineligible or "disproportionate share" members and other transitions potentially affected by State contracting efforts. CMS will also provide precise technical instructions for completing the HPMS Plan Crosswalk for each MAO or PDP sponsor renewal or non-renewal option in the HPMS Bid Submission User Manual scheduled to be released on May 13, 2011. Organizations and sponsors should note that we have eliminated some exceptions that were allowed in previous years and modified previous options available under the HPMS Plan Crosswalk based on our previously articulated principles. Organizations and sponsors should also be aware that an approval of a bid does not necessarily mean a submitted HPMS Plan Crosswalk or crosswalk exception meets CMS requirements and will be accepted by CMS. **If a renewal or non-renewal scenario is not outlined in Appendices A-1, A-2, B-1, or B-2, it is not a permissible renewal option for CY 2012.**

Each renewal and non-renewal option outlined in Appendices A-2 and B-2 includes, where applicable, instructions or deadlines for requesting particular renewal options that organizations and sponsors cannot themselves effectuate in the HPMS Plan Crosswalk. To ensure smooth year-to-year transitions, organizations and sponsors should communicate early with CMS staff and comply with all established deadlines. Organizations and sponsors will *not* be able to make changes to their HPMS Plan Crosswalks once bids are submitted to CMS in June 2011. After that point, CMS will only make changes to organizations' and sponsors' HPMS Plan Crosswalks under exceptional circumstances. Furthermore, any renewal options that require organizations and sponsors to submit manual enrollment transactions must be completed both correctly and completely pursuant to instructions that CMS will release later this year.

Section 2 – IMPROVING INFORMATION sharing & transparency with sponsors

Clarification of Parent Organization Information for MA Organizations and PDP Sponsors

CMS is increasingly focused on the relationship between MA organizations and PDP sponsors and their parent organizations in our administration of the Part C and D programs. For example, CMS makes auto-enrollment and reassignment determinations by allocating enrollees among PDP sponsors' parent organizations, not among the sponsors themselves. Also, in certain situations, CMS will look to an MA organization's parent organization to make a determination concerning its qualification for quality bonus payments. Therefore, it is crucial that all MA organizations and PDP sponsors accurately report their parent organization status to CMS and keep such information up-to-date in CMS records.

CMS considers a parent organization to be the legal entity that owns a controlling interest in a PDP sponsor or MA organization (both referred to as "contracting organizations"). More specifically, for Part C and D reporting purposes, the parent organization is the "ultimate" parent, or the top entity in a hierarchy (which may include other parent organizations) of subsidiary organizations which is not itself a subsidiary of any corporation.

CMS is providing this clarification in part because there have been instances where contracting organizations have reported information concerning their immediate parent rather than their ultimate parent. Such inaccuracies create the risk that CMS makes incorrect program implementation determinations or conducts duplicative work.

CMS acknowledges that in fact many contracting organizations are not subsidiaries to a parent company. However, for purposes of program administration, CMS must have a parent organization name associated with each contracting organization. Therefore, when applicable, contracting organizations should identify themselves as their own "parent organization" in CMS records.

All contracting organizations are required to report parent organization information to CMS as part of their applications for qualification for a Medicare contract. CMS has also provided guidance through HPMS to organizations alerting them to their obligation to keep such information up-to-date in our records. As part of this effort, contracting organizations must pay special attention to the impact of changes of ownership among entities in their corporate ownership chain that may have an effect on the identity of the contracting organization's ultimate parent. Also, contracting organizations should always be prepared to provide the most conclusive documentation available to them of their relationship to their parent organization upon request from CMS. Such documentation may consist of financial statements, articles of incorporation, contracts, or filings with regulatory authorities.

Contracting organizations can view their parent organization assignments within the Basic Contract Management Module in HPMS. The parent organization assignment can be accessed using the following navigation path: Contract Management > Basic Contract Management > Select Contract Number > Plan Management Data. Parent organization data is also available in the General Information Report under Contract Reports and in the Plan Version of the Contract Information Data Extract. Contracting organizations do not have access rights to change the parent organization designation, but rather must report changes to CMS.

While CMS will continue to issue annual requests to contracting organizations to provide updates to CMS concerning the name of the parent organization, effective immediately, we are now requiring contracting organizations to proactively report all parent organization changes to CMS within 30 days of the effective date of such a change. All such change requests must be emailed to drugbenefitimpl@cms.hhs.gov with the subject line of "Parent Organization Update." Contracting organizations should include with the email supporting documentation, such as one or more of the items listed above. CMS may request additional supporting documentation, if necessary. Of note, due to character limitations, CMS will not necessarily agree to all minor changes, such as requests to expand abbreviations.

Prescriber Identifiers

This section provides guidance regarding how Part D sponsors handle prescriber identifiers on Part D claims and PDE records; the first section responds to questions we have received on how sponsors should currently handle identifiers for prescribers from jurisdictions other than U.S states and territories, where allowed under state law; the remaining sections concern permissible prescriber identifiers on Part D claims and PDE records in 2012 and 2013.

Foreign Prescriber Identifers: In an August 13, 2010 memorandum on the use of prescriber identifiers on Medicare Part D drug claims, we reiterated the CMS guidance that specifies that the NPI is intended to uniquely identify a health care provider in standard transactions, such as health care claims. The Health Insurance Portability and Accountability Act of 1996 (HIPAA) requires that covered entities use NPIs in standard transactions by the specified compliance dates. The NPI is the only health care provider identifier that covered entities may use to identify health care providers. Although HIPAA requires pharmacies to use the NPI on HIPPA standard transactions, we recognize that pharmacies cannot always obtain the prescriber NPI at the time of dispensing. Therefore, to ensure Part D enrollees do not experience service interruptions, CMS guidance permits Part D sponsors to accept alternative prescriber identifiers, such as DEA registration numbers or state license numbers. However, we clarified that it is our intention that whatever type of prescriber identifier (i.e., NPI, DEA number, unique provider identification number (UPIN) or state license number) is used, it must be a valid number.

After this guidance was issued, we received comments indicating that a number of States permit pharmacies to fill prescriptions written by foreign (i.e., non-U.S. - licensed) prescribers. We have been asked what prescriber identifier should be required on the Part D claim and submitted on the prescription drug event (PDE) record. If a prescription has been written by a foreign prescriber, the sponsor should require the use of the license number assigned by an appropriate licensing board in the foreign jurisdiction in which the prescriber practices/resides on the claim with the State license qualifier. We understand that the use of this qualifier is not inconsistent with the National Council for Prescription Drug Programs (NCPDP) data dictionary, which defines a State license number as a number assigned and required by a State Board or other State regulatory agency. In the absence of a reference to "U.S." in the NCPDP definition and given the Webster's dictionary definition of "state" as one of the territorial and political units constituting a federal government, we believe State license is the most appropriate qualifier to use for foreign prescribers.

Permissible Prescriber Identifiers in 2012: For 2012, CMS will continue to permit Part D sponsors to accept on Part D claims and report on the PDE records any one of the four currently acceptable types of prescriber identifiers; that is NPI, DEA number, UPIN or state license number. Whichever type of identifier is used, however, the identifier must be valid. We will likewise extend to non-standard format claims, such as paper claims submitted by Medicare beneficiaries, the requirement for a valid prescriber identifier to be on the Part D claim and reported on the PDE record. CMS will begin validating the format of all prescriber identifiers on PDEs that are coded as an NPI and will exclude from payment reconciliation PDEs with invalid NPIs. We will also be assessing each sponsor's performance regarding NPI use and validity and will be notifying plan sponsors of their performance level.

In 2012, we will also impose additional requirements on plan sponsors with regard to Part D claims for Schedule II drugs. We believe that resources are currently available to enable sponsors to buy or build appropriate internal controls to enforce the submission of valid prescriber identifiers from their network pharmacies for these drugs. We also believe that sponsors should ensure that their network pharmacies enforce state and federal laws concerning prescriber scope of practice with respect to authority to prescribe controlled substances. As a result, effective January 1, 2012 Part D sponsors will be required to confirm the validity of DEA numbers on Schedule II drug claims or map NPIs on these claims to the prescriber's DEA. In addition, sponsors will be required to confirm that the controlled substance is within the prescriber's scope of practice to prescribe. Plan sponsors may elect to comply with these requirements by engaging a commercial vendor that provides validation/mapping services or by executing a Memorandum of Understanding with the DEA to access the DEA's Controlled Substance Registration File.

Permissible Prescriber Identifiers in 2013: Finally, we are considering proposing a regulatory change that will limit acceptable prescriber identifiers on Part D claims and PDE records in 2013 to only the individual NPI. In other words, a prescription written by an individual prescriber

who did not acquire an individual NPI and disclose it to the pharmacy on the prescription or otherwise would not be filled under the Part D program. Since all practitioners who are authorized to prescribe Part D drugs under applicable state laws can acquire an individual NPI from CMS, we do not believe that this will present a significant barrier to access to Part D drugs for Medicare beneficiaries. Moreover, consistent use of a single validated identifier will enable CMS to provide better oversight over possible fraudulent activities.

Supplemental Formulary File Submission

The regulation at 42 CFR § 423.272(b)(2) requires that CMS review bids to ensure that the plan designs are not likely to substantially discourage enrollment by certain Part D eligible individuals. Part D sponsors offering partial tier gap coverage, free first fill coverage, home infusion bundling under Part C, coverage of excluded drugs, or coverage of over-the-counter (OTC) drugs under utilization management programs must submit the corresponding required supplemental formulary file(s) as part of their bid submission so that CMS can assess whether or not the plan design meets the non-discrimination requirements as described under 42 CFR § 423.272(b)(2). We are requesting that these supplemental formulary files be submitted no later than June 13, 2011. Given the reduced time frame for review and approval of bids, CMS will not have sufficient information to fully evaluate whether a plan's benefit design meets the non-discrimination requirements if sponsors do not submit these supplemental files in a timely manner. Therefore CMS will assume that if a sponsor does not submit the appropriate supplemental files by the June 13th deadline, then the sponsor does not intend to offer these supplemental benefits and will be asked to revise their bids accordingly. In addition these plans will be subject to a compliance action and will be at risk of having their bids disapproved.

Preventing Part D Payment for Hospice Drugs

Hospice programs, as specified in section 1861(dd) of the Social Security Act and in Federal regulations at Part 418, must provide individuals under hospice care with drugs and biologicals related to the palliation and symptom management of the terminal illness as defined in the hospice plan of care. The only drugs covered by the hospice program are those used primarily for relief of pain and symptom control related to the individual's terminal illness. However, because hospice care is a Medicare Part A benefit, the drugs provided by the hospice and covered under the Medicare per-diem payment to the hospice program are not covered under Part D.

Our October 23, 2010 memorandum entitled, "Preventing Part D Payment for Hospice Drugs," incorrectly stated that all Part D sponsors currently do not have the ability to identify any Medicare enrollees who have elected hospice. In fact, CMS has been sending beneficiary-level hospice data to all Part D sponsors. These data are currently sent on the transaction reply report (TRR) at the time of the beneficiary's enrollment and subsequently whenever the hospice

information changes. As specified in the Plan Communications User Guide, the TRR includes a hospice indicator in position 54 and, in positions 85-96, a hospice start date and, if applicable, hospice termination date. The associated transaction reply codes are 071- Hospice status set and 72- Hospice status terminated. Sponsors need to ensure their claims processor is notified of an enrollee's hospice election and that processes are in place to prevent Part D payment for hospice drugs.

Employer Group Waiver Plans and Application of the Manufacturer Discount

CMS announced in a June 2, 2010 HPMS memorandum to all Part D sponsors that the value of supplemental benefits provided as part of a Part D enhanced benefit, including benefits negotiated between EGWP sponsors and employers, must be calculated prior to the application of the Medicare manufacturer coverage gap discount. Since CMS does not collect supplemental benefits information as part of the EGWP PBP, a Part D sponsor of EGWPs is required to attest, as part of its contract with CMS for CY 2011, that if the sponsor provides supplemental coverage via any of its enhanced benefit plans, it will apply the manufacturer coverage gap discount only after the plan's supplemental benefits have been applied. Sponsors are also required to attest to the accuracy of the discount amounts submitted on the prescription drug event (PDE) data and provide documentation, upon request, to CMS's third party administrator (TPA) when required.

CMS will be developing an information collection effort to ensure Part D EGWP sponsors have correctly applied the manufacturer discounts to covered Part D drugs. This information collection effort would require Part D sponsors submit the Part D supplemental benefits negotiated between employers and EGWPs. The information collected by CMS would be available in the event CMS received other indications that an EGWP was not compliant with the administration of the manufacturer discount. More information will be communicated to Part D sponsors regarding the information collection process, including any modifications to existing EGWP waivers, in upcoming memoranda.

Quality Reporting Requirements for Employer/Union-Only Direct Contracts

Currently, Medicare Advantage (MA) contracts are required to collect and report to CMS quality measurement data from the Healthcare Effectiveness Data and Information Set (HEDIS), Medicare Health Outcome Survey (HOS), and Consumer Assessment of Healthcare Providers and Systems (CAHPS). All stand-alone Prescription Drug Plans (PDPs) are required to collect and report CAHPS data to CMS. To date, the Employer/Union Only Direct contracts have been excluded from the quality reporting requirements. Beginning in 2012 all Employer/Union Only Direct contracts will be required to meet the same reporting requirements as MA or PDP contracts. For example, the Employer/Union Only Direct Private Fee-for-Service (PFFS) contracts will be required to collect and report HEDIS, HOS and CAHPS data to CMS. Employer/Union Only Direct MA contracts can see the HPMS memo "2011 HEDIS, HOS and

CAHPS Measures for Reporting on Medicare Advantage Organizations" dated November 4, 2010 as an example of the MA reporting requirements for 2011. Employer/Union Only Direct PDPs can view the CAHPS reporting requirements at www.ma-pdpcahps.org.

Improvements to Plan Ratings

CMS is committed to continuing to improve the Part C and D quality performance measurement system to increase focus on improving beneficiary outcomes, beneficiary satisfaction, population health, and efficiency of health care delivery. To that end, CMS has been working on developing a more robust system to measure quality and performance of Part C and D contracts. As new measures are developed and adopted, they will be incorporated into the Plan Ratings published each year on the Medicare Plan Finder website and used to determine star ratings for quality bonus payments.

CMS views the MA quality bonuses also referred to as value-based payments as an important step to revamping how care and services are paid for, moving increasingly toward rewarding better value, outcomes, and innovations. As we add measures to the Plan Ratings over time, we will consider the following principles:

- Public reporting and value-based payment systems should rely on a mix of standards, process, outcomes, and patient experience measures, including measures of care transitions and changes in patient functional status. Across all programs, CMS seeks to move as quickly as possible to the use of primarily outcome and patient experience measures. To the extent practicable and appropriate, outcomes and patient experience measures should be adjusted for risk or other appropriate patient population or provider characteristics.

- To the extent possible and recognizing differences in payment system maturity and statutory authorities, measures should be aligned across Medicare's and Medicaid's public reporting and payment systems. CMS seeks to evolve to a focused core-set of measures appropriate to the specific provider category that reflects the level of care and the most important areas of service and measures for that provider.

- The collection of information should minimize the burden on providers to the extent possible. As part of that effort, CMS will continuously seek to align its measures with the adoption of meaningful use standards for health information technology (HIT), so the collection of performance information is part of care delivery.

- To the extent practicable, measures used by CMS should be nationally endorsed by a multi-stakeholder organization. Measures should be aligned with best practices among other payers and the needs of the end users of the measures. Our strategy is to continue to adopt measures that are nationally endorsed and are in alignment with the private sector as we do today through the use of measures developed by the National Committee for Quality Assurance (NCQA) and the Pharmacy Quality Alliance (PQA), and the use of measures that are endorsed by the National Quality Forum (NQF).

As we modify the calculation approaches for the Plan Ratings, we are incorporating the following principles:

- Plans should be scored on their overall achievement relative to national or other appropriate benchmarks. In addition, scoring methodologies should consider improvement as an independent goal.

- Measures or measurement domains need not be given equal weight, but over time, scoring methodologies should be more weighted towards outcome, patient experience and functional status measures.

- Scoring methodologies should be reliable, as straightforward as possible, and stable over time and enable consumers, providers, and payers to make meaningful distinctions among providers' performance.

Using the principles discussed above, CMS has identified a set of enhancements for the 2012 and 2013 Plan Ratings. For the 2012 Plan Ratings we are proposing to add the following measures to the existing set used in the 2011 Plan Ratings:

- All-Cause Readmission rates. (For more information about this measure, please see HEDIS® 2011 Technical Specifications, Volume 2.)
- Advising Smoker and Tobacco Users to Quit. This information is collected through the CAHPS survey. (For more information about this measure, please see HEDIS® 2011 Technical Specifications, Volume 2.)
- Body Mass Index. (For more information about this measure, please see HEDIS® 2011 Technical Specifications, Volume 2.)
- Special Needs Plan (SNP)-specific measures. This would include the four rates included as part of the Care for Older Adults measure. These would only apply to contracts that have a SNP plan. (For more information about this measure, please see HEDIS® 2011 Technical Specifications, Volume 2.)
- Voluntary Disenrollment Rates. www.cms.gov/PrescriptionDrugCovGenIn/06_PerformanceData.asp (see 2011 Display Measures – Technical Notes)
- One or more measures from the Hospital Inpatient Quality Reporting program (formerly known as Reporting Hospital Quality Data for Annual Payment Update). (See http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1138900298473 for a list of measures.) CMS is exploring whether the individual-level hospital data can be associated with individual MA contracts.
- Appropriate implementation of Part D transition processes by plans to ensure continuity of care for beneficiaries. Additional information on this measure will be provided as it becomes available.

- Part D Medication Adherence. This measure would use the proportion of days covered methodology as endorsed by the Pharmacy Quality Alliance. (Several potential adherence measures are currently posted on the display measures page at http://www.cms.gov/PrescriptionDrugCovGenIn/06_PerformanceData.asp#TopOfPage.)

For SNP-specific measures, CMS is seeking comment on the feasibility of creating a methodology to incorporate SNP-specific measures into plan ratings, particularly in cases where CMS applies differential weighting to individual measures.

For all of the measures, CMS will be examining the quality of the data, variation among plans, and the measure's accuracy and validity. For example, for the all-cause readmission rate we will look at the quality of the data reported in June 2011 to make a final decision about whether this measure is incorporated into the 2012 plan ratings or the 2013 plan ratings. For those measures that are not proven to be reliable and valid, CMS will determine whether such measures may be appropriate "display measures", which would not be used in the plans' star ratings.

CMS is also considering using the same 4-star thresholds that were set for the 2011 Part C and D plan ratings. (See http://www.cms.gov/PrescriptionDrugCovGenIn/06_PerformanceData.asp for the current thresholds.) For the 2011 plan ratings, measures that were new or were not part of the plan ratings for at least two years did not receive a 4-star threshold. For 2012 and beyond, CMS will be setting 4-star thresholds for measures with at least a two year data history. For example, (through an HPMS memo) we will be providing sponsors with the 4-star thresholds for the following measure: availability of TTY/TDD services and foreign language interpretation and accuracy of information members get when they call the health plan.

Additional enhancements under consideration for the 2012 Part C and D plan ratings include:

- weighting of the measures to provide greater weight to clinical outcomes and lesser weight to process measures such as call center measures,
- controlling for the concentration of providers in a geographic area, such as a Health Professional Shortage Areas (HPSA),
- rewarding contracts for quality improvement, and
- reducing the overall and/or summary plan ratings for contracts with serious compliance issues.

For the 2013 Plan Ratings we are considering adding the following measures:

- Survey measures of care coordination, care transitions and patient activation. We are considering adding a set of survey items to the CAHPS survey that will be administered in 2012. We will let sponsors know the set of items through an HPMS memo once they are finalized.

- Case-mix adjusted mortality rates.
- Preventable hospitalizations.
- Serious Reportable Adverse Events, including Hospital Acquired Conditions. (See the Part C Reporting Requirements posted at www.cms.gov/HealthPlansGenInfo/16_ReportingRequirements.asp.)
- Grievances. (See the Part C Requirements posted at www.cms.gov/HealthPlansGenInfo/16_ReportingRequirements.asp and Part D Reporting Requirements posted at http://www.cms.gov/PrescriptionDrugCovContra/08_RxContracting_ReportingOversight.asp#TopOfPage.
- Use of highly rated hospitals by plan members. This will combine information about the use of hospitals by plan members with the total performance score that will be calculated for each hospital as part of Hospital Value-based Purchasing. The total performance score is proposed as part of the Notice of Proposed Rulemaking, "Medicare Program; Hospital Inpatient Value-Based Purchasing Program", published on January 7, 2011.
- Medication therapy management (MTM) measures related to comprehensive medication reviews.
- Evaluation of a contract's Chronic Care Improvement Program (CCIP) and Quality Improvement Project (QIP).

We will provide as much advance notice of these changes as possible, but sponsors are encouraged to take proactive steps to put in place quality assurance efforts in these areas in order to have a head start in effecting improved outcomes.

Section 3 – improving beneficiary protections

I. General

Contracting Organizations with Ratings of Less Than Three Stars in Three Consecutive Years

CMS has previously stated publicly that we consider contracting organizations (i.e., MA organizations and PDP sponsors) with less than an "average" or three-star summary plan rating to be out of compliance with the requirements of the Part C or D programs. For example, in the preamble to our notice of proposed rulemaking published in the Federal Register on October 22, 2009, we stated that, "organizations and sponsors with less than 'good' ratings should expect to be the subject of our monitoring and compliance actions." We also made a similar statement in the 2009 Call Letter.

CMS cannot continue to contract with organizations whose performance is consistently out of compliance with Medicare requirements. Contracting organizations should interpret a less than

"average" (or three-star) summary rating on either their Part C or D performance to be a notice from CMS that they are to take corrective action to come into compliance with program requirements. CMS considers organizations that fail for three straight years to achieve at least a three-star summary rating on Part C or D to have ignored over a significant period of time their obligation to meet program requirements and to be substantially out of compliance with their Medicare contracts. These organizations should expect CMS to initiate action to terminate their contracts following 1) our publication of the set of annual plan ratings that assigns the organization its third consecutive summary rating of less than three stars and 2) our confirmation that the data used to calculate the star ratings reflect the sponsor's substantial non-compliance with Part C or Part D requirements.

Special Election Period for Enrollment in 5-Star MA plans

On November 19, 2010, in an HPMS memorandum entitled "Establishing a Special Election Period (SEP) to Enroll in 5-star Medicare Advantage Plans in Plan Year 2012," CMS announced the establishment of an SEP that will allow Medicare beneficiaries eligible for MA plans to enroll in 5-star MA plans at any point during the year. As indicated in the November 19 memorandum, we are providing additional guidance about the new SEP through this call letter, based on questions we have received since publication of the memorandum on the SEP. The general parameters of the SEP are as follows:

- For purposes of the SEP, an MA plan must have 5 stars as of the 2011 Annual Enrollment Period (AEP), regardless of the rating used for purposes of 2012 quality bonus payments.
- As currently constituted, the new SEP will apply only for purposes of enrolling in a 5-star MA plan; it will not permit an individual to enroll in 5-star stand-alone Part D, 1876, 1833 or any other Medicare health plan other than an MA plan. (See below for further information on this point.)
- Individuals will be eligible for this SEP only if they are either enrolled in MA plans with a star rating of 4.5 or less, or enrolled in Original Medicare and meet the MA eligibility requirements. Individuals already enrolled in 5-star MA plans are not eligible for the SEP.
- The SEP will begin on December 8, 2011, that is, the day after the end of the Fall 2011 AEP, which will be December 7. Enrollment requests made using this SEP will be effective the first of the month following the month the enrollment request is received. Once an individual enrolls in a 5-star MA plan, the individual's SEP ends for that plan year, and the individual will be limited to making changes only during other applicable election periods (e.g., annual enrollment period or another valid SEP). Individuals will be able to enroll in 5-star MA plans directly through the plan, or through 1-800-MEDICARE or Medicare.gov.

- MA plans that have received an overall 5-star rating will be required to accept these SEP requests, similar to any other SEP or initial enrollment for a newly eligible individual, unless the plan is closed per a CMS-approved capacity limit.
- The SEP is applicable only to those MA plans with an **overall** 5-star rating. The SEP is not available to enroll in a plan that does not have an overall 5-star rating, even if the plan receives 5 stars in some rating categories. While the SEP can be used by an individual who is enrolled in a plan with fewer than 5 stars to join a 5-star plan offered by the same organization, it cannot be used to enroll in other MA plans in the organization with less than a 5 star rating.
- Individuals enrolled in an MA-PD plan enrolling in a 5-star MA-only plan will be provided an SEP to join a stand-alone PDP, only if the MA-only plan is a Private Fee-for-Service (PFFS) plan. If the MA-only plan is not PFFS, the individual will forgo Part D coverage and may elect to enroll in a stand-alone PDP during a valid enrollment period. Individuals enrolled in Original Medicare will not be provided an additional SEP to enroll in Part D since enrollment in an MA-only plan will not affect their current stand-alone Part D drug coverage.
- CMS plans to create a new SEP indicator to be used for plan submitted enrollment transactions and to track the utilization of this SEP. Details on the new indicator will be included in a future CMS system release announcement later in 2011.

As noted above, the 5-star SEP at this point is designed to apply only to MA plans; however, we are considering whether the SEP should be expanded to also allow enrollment at any time into a 5-star PDP. We have already received some comments indicating that the SEP would provide added incentive for improved PDP performance and thus should be expanded to include PDPs. We welcome additional feedback on this issue. We anticipate releasing further guidance on the new SEP later this year in advance of the 2011 AEP.

II. Part C

Benefit Design

The guidance in this memorandum advances CMS' goals of establishing a more transparent and predictable process so that beneficiaries can select a plan that best meets their health care needs, while also being protected from high unexpected or discriminatory cost sharing. This memorandum provides policy guidance and sets forth cost sharing standards for CY 2012 for MAOs to use to evaluate their bids prior to submission in order to ensure that their plan offerings in the same area are meaningfully different from one another, are not significantly more costly to enrolled beneficiaries than they were in CY 2011 and have sufficient enrollment. Finally, the guidance includes clarifications of our benefits and cost sharing policies and instructions for proper CY 2012 Plan Benefits Package (PBP) preparation.

This guidance references our recently updated Chapter 4 of the Medicare Managed Care Manual (Benefits and Beneficiary Protections). Therefore, we recommend that MAOs and other Medicare health plans review Chapter 4 while designing their plans for CY 2012. Chapter 4 clarifies current Part C benefits policy and incorporates new policy topics in order to address issues that arose in prior bid seasons. Examples include: clarification of items and services that can be classified as supplemental benefits and multi-year benefits. The link to Chapter 4 is: http://www.cms.hhs.gov/manuals/downloads/mc86c04.pdf

Duplicative Plans and Plans with Low Enrollment

The large number of MA plan options that have been offered in many areas has made it difficult and confusing for beneficiaries to distinguish between these plans and to choose the best option to meet their needs. MAOs should not submit CY 2012 bids for plans that have insufficient enrollment and/or are not meaningfully different from their other plan offerings in the area. CMS discussed this issue in our CY 2010 Call Letter, worked with MAOs to improve beneficiary choice for CY 2010 and CY 2011 bid submissions, and addressed this in our April 15, 2010 final rule.

In 42 CFR § 422.254(a)(5) and 422.256(b)(4)(i), we specify that CMS reviews bids to ensure that an MAO's plans in a given service area are meaningfully different from one another in terms of key benefits or plan characteristics such as cost sharing, benefits offered, or plan type. Using our authority under section 1857(c)(2)(B) of the Act and 42 CFR §422.506(b)(1)(iv), CMS may non-renew plans that do not have sufficient enrollment after a specified length of time. CMS will address low enrollment and duplicative plans for CY 2012 with two separate processes, as described below.

The following guidance applies to non-employer MA plans, including Special Needs Plans (SNPs). Note: We reserve the right to review employer plans for low enrollment and/or meaningful difference in future years.

A. Plans With Low Enrollment

During April or May 2011, CMS will send each MAO a list of low enrollment plans that have been in existence for three or more years but, as of April 2011, have fewer than 500 enrollees for non-SNP plans and 100 enrollees for SNP plans. The lists will not include low enrollment plans that CMS determines are located in service areas that do not have a sufficient number of competing options of the same plan type.

For each identified plan, MAOs must provide justification for low enrollment under the standards in the final rule or confirm through return email that the plan will be eliminated or consolidated with another of the organization's plans for CY 2012. If CMS does not find that

there is a unique or compelling reason for maintaining a plan with low enrollment, CMS will non-renew the plan. Instructions for how to submit business cases, the timeframe for submissions, and what information is required in those submissions will be included with the list of low enrollment plans sent to the MAO.

CMS recognizes there may be reasonable factors, such as specific populations served and geographic location, which lead to a plan's low enrollment. SNPs, for example, may legitimately have low enrollments because of their focus on a subset of enrollees with certain medical conditions. We will consider all such information when evaluating whether specific plans should be non-renewed based on insufficient enrollment. MAOs are to follow the CY 2012 renewal/non-renewal guidance in this Call Letter to determine whether a low enrollment plan may be consolidated with another plan(s).

B. Duplicative Plan Offerings

MAOs offering more than one plan in a given service area should ensure that beneficiaries can easily identify the differences between the plans and determine which plan provides the highest value at the lowest cost based on their needs. For CY 2012, CMS will use plan-specific out-of-pocket cost (OOPC) estimates to identify meaningful differences among similar plan types. OOPC estimates are based on a nationally representative cohort of more than 13,000 Medicare beneficiaries represented in the 2004 and 2005 Medicare Current Beneficiary Survey data and are used to provide estimated plan cost information to beneficiaries on Medicare Options Compare. Estimated out-of-pocket costs for each plan benefit package are calculated on the basis of utilization patterns for that cohort. The calculation includes Parts A, B, and D services and certain mandatory supplemental benefits, but not optional supplemental benefits. For purposes of evaluating meaningful differences among MA plans, CMS will exclude premiums from the OOPC calculation. Current enrollment and risk scores will not affect the OOPC calculation. A summary of the OOPC estimates is available at: http://www.medicare.gov/MPPF/Include/DataSection/OOPC/OOPCCalculations.asp?language=English.

MAOs will have access to CY 2011 OOPC estimates for each of their current plans and an OOPC model available in SAS from the CMS website. Instructions on how to download the files and a User Guide for the model will also be made available to MAOs. Organizations can use this information to develop CY 2012 plan bids that comply with CMS requirements. CMS will evaluate meaningful differences among non-employer plans offered by the same MAO, in the same county, as follows:

1. Non-SNP plan offerings will be separated into five plan-type groups on a county basis: (1) HMO (2) HMOPOS; (3) Local PPO; (4) Regional PPO; and (5) PFFS. SNP plans will be further separated into groups representing the specific target populations served by the SNP. Chronic Care SNPS will be separated by the chronic disease served,

Institutional SNPs will be separated into institutional-based SNPsand community-based SNPs, and Dual-Eligible SNPs will be separated by enrollment category: all dual, full dual, zero cost share, Medicaid subset, and fully integrated types. Please note that using different providers or serving different ethnic populations are not considered meaningfully different characteristics between two plans.

2. Plans within each plan-type group will be further divided into MA-only and MA-PD sub-groups for evaluation. That is, the presence or absence of a Part D benefit is considered a meaningful difference.
3. The combined Part C and Part D OOPC estimate will be calculated for each plan within the plan-type groups and sorted from high to low. There must be a total OOPC difference of at least $22.00 per member per month between each plan to be considered meaningfully different.

(Note: Employer plans are not included in this evaluation for CY 2012.)

CMS expects MAOs to submit CY 2012 plan bids that meet the meaningful difference requirements but will not prescribe how the MAOs should redesign benefits packages to achieve the differences. Since MAOs will have access to the necessary tools to calculate OOPC estimates for each plan prior to bid submission, CMS may not permit revised submissions if a plan's initial bid does not comply with meaningful difference requirements. Ultimately, plan bids that do not meet these requirements will not be approved by CMS. MAOs are to follow the CY 2012 renewal/non-renewal guidance in this Call Letter to determine if their plans may be consolidated with other plans.

CY 2012 Cost Sharing Standards

A. Maximum Out-of-Pocket (MOOP) Limits

CMS strives to ensure that MAOs develop more transparent plan benefit designs so that beneficiaries are better able to predict their out-of-pocket costs and also are protected from excessively high or unexpected cost sharing. As provided at 42 CFR § 422.100(f)(4), all local MA plans (employer and non-employer), including HMOs, HMOPOS, local PPO (LPPO) plans, special needs plans (SNPs) (including Dual-eligible SNPs), and PFFS plans must establish an annual MOOP limit on total enrollee cost sharing liability for Parts A and B services, the dollar amount of which will be set annually by CMS.

In addition, as provided at 42 CFR § 422.100(f)(5), LPPO plans were required to have a "catastrophic" limit inclusive of both in- and out-of-network cost sharing for all Parts A and B services, the dollar amount of which also will be set annually by CMS. All cost sharing (i.e., deductibles, coinsurance, and copayments) for Parts A and B services must be included in plans' MOOPs. The "catastrophic" maximum out-of-pocket limit is the term used in regulation (§

422.100(f)(5)) and is synonymous with "combined" maximum out-of-pocket limit used in the PBP and beneficiary marketing materials.

For CY 2012, we do not want to eliminate incentives for organizations to establish lower voluntary MOOP thresholds. Therefore, we will continue to allow MAOs the option of adopting lower, voluntary MOOP limits. MAOs that adopt voluntary MOOP amounts will have more flexibility in establishing cost-sharing amounts for Parts A and B services than those that do not elect the voluntary MOOP.

Like all other local MA plans, D-SNPs must establish a MOOP limit to provide this enrollee protection even though the State Medicaid program is usually paying those costs on the enrollee's behalf. Enrollees' eligibility for Medicaid may change during the year, leaving the enrollee liable for cost sharing. We strongly encourage D-SNPs to establish MOOP amounts that are greater than $0 to protect the plan from full liability for the cost sharing amounts in the event that an enrollee's Medicaid coverage is discontinued for some period of time. However, adoption of a $0 MOOP is permitted.

Second, although it may be rare that an enrollee of a D-SNP would be responsible for paying any cost sharing because the State Medicaid program is making those payments on his behalf, the PBPs for D-SNPs must reflect the plan's actual out-of-pocket cost sharing charges for covered services as well as a valid MOOP amount. Additionally, the plan must track each enrollee's cost sharing expenditures. The PBP will not be acceptable without entry of a valid MOOP amount.

For purposes of tracking out-of-pocket spending relative to its MOOP limit, a D-SNP must count only the enrollee's actual out-of-pocket spending. Thus, for any D-SNP enrollee, MA plans must count only those amounts the individual enrollee is responsible for paying net of any State responsibility or exemption from cost sharing toward the MOOP limit rather than the cost-sharing amounts for services the plan has established in its plan benefit package. Effectively, this means that D-SNP enrollees who are not responsible for paying the Medicare Parts A and B cost sharing will rarely reach the MOOP limit.

Since implementation of the Medicare Modernization Act of 2003, RPPOs have been required to establish a MOOP for in-network cost sharing and a catastrophic limit inclusive of both in- and out-of-network cost sharing for Parts A and B services; however, those amounts are at the discretion of MAOs offering RPPO plans. For CY 2011, RPPOs were permitted to establish their own in-network MOOP and catastrophic limits, but we encouraged them to adopt either the mandatory or voluntary MOOPs established by CMS.

We proposed in our November 22, 2010 Notice of Proposed Rulemaking (75 FR 71233) to require RPPOs to establish MOOP amounts that are consistent with the limits established each year by CMS. If this proposal is finalized, RPPOs would be required to establish both in-

network and catastrophic MOOP limits like LPPOs for CY 2012 consistent with the voluntary and mandatory MOOP levels established by CMS for all Parts A and B covered services.

The dollar amounts for the **mandatory, voluntary** and **catastrophic** MOOPs will be set annually by CMS.

> **Mandatory MOOP** The amount CMS sets as the highest limit for enrolled beneficiary in-network cost sharing for Parts A and B services for the contract year.
>
> **Voluntary MOOP** An amount lower than the CMS established mandatory MOOP. Plans may voluntarily adopt this lower limit in exchange for increased flexibility in establishing cost sharing amounts for Parts A and B services.
>
> **Catastrophic MOOP** The amount CMS sets as the highest limit charged by LPPOs and if the proposal to extend the MOOP requirements to RPPOs in our November 22, 2010 proposed rule is finalized for RPPOs, for the combined in-and out-of-network cost sharing for Parts A and B services for the contract year. The catastrophic MOOP amount is calculated as 1.5 times the mandatory or voluntary MOOP amount, as applicable to the plan.

Plans are responsible for tracking enrolled beneficiaries' out-of-pocket spending and to alert them and plan providers when the spending limit is reached. As stated above, D-SNPs also must track enrollee cost sharing but should include only those amounts the enrollee is responsible for paying net of any State responsibility or exemption from cost sharing.

The chart below provides the CY 2012 mandatory MOOP amount that MA plans may not exceed, the voluntary MOOP amount that, if adopted, would result in less scrutiny of individual service category cost sharing, and the catastrophic MOOP amounts applicable to LPPOs and proposed for RPPOs (if the proposal to extend the MOOP requirements to RPPOs in our November 22, 2010 proposed rule is finalized).

CY 2012 Voluntary and Mandatory MOOP Amounts By Plan Type

Plan Type	Voluntary	Mandatory
HMO	$3,400	$6,700
HMO POS	$3,400 In-network	$6,700 In-network
Local PPO	$3,400 In-network and $5,100 Catastrophic*	$6,700 In-network and $10,000 Catastrophic*
Regional PPO	$3,400 In-network and $5,100 Catastrophic*	$6,700 In-network and $10,000 Catastrophic*
PFFS (full network)	$3,400 In- and out-of-network	$6,700 In- and out-of-network
PFFS (partial network)	$3,400 In- and out-of-network	$6,700 In- and out-of-network
PFFS (non-network)	$3,400	$6,700

*Catastrophic MOOP is inclusive of in- and out-of-network Parts A and B services.

The MA MOOP amounts are based on a beneficiary-level distribution of Parts A and B cost sharing for individuals enrolled in Original Medicare. The mandatory MOOP amount represents approximately the 95th percentile of projected beneficiary out-of-pocket spending for CY 2012. Stated differently, 5 percent of Original Medicare beneficiaries are expected to incur $6,700 or more in Parts A and B deductibles, copayments and coinsurance in CY 2012. The CY 2012 voluntary MOOP amount will be $3,400. This level was established for CY 2012 because, consistent with established methodology, it represents approximately the 85th percentile of projected Original Medicare out-of-pocket costs.

We determined the catastrophic MOOP amounts applicable to LPPOs and proposed for RPPOs, by multiplying the respective MOOP amounts by 1.5 for the relevant year. Thus, the voluntary catastrophic MOOP amount for CY 2012 is calculated as $3,400 x 1.5 = $5,100. Similarly, the mandatory catastrophic MOOP amount for CY 2012 is calculated as $6,700 x 1.5 = $10,000 (with rounding).

For further discussion on MOOP and how it is shown in D-SNPs' Summary of Benefits (SB), please refer to the section entitled "Changes to 2012 Summary of Benefits Regarding Dual Eligible SNP Cost Sharing" on page 105 of this Call Letter.

B. Total Beneficiary Cost (TBC)

CMS will exercise its authority under section 1854(a)(5)(C)(ii) of the Affordable Care Act to deny bids that propose significant increases in cost sharing or decreases in benefits from one plan

year to the next. We note that we proposed to codify this authority in our November 22, 2010 proposed rule (75 FR 71200-71201) and may provide further guidance following the finalization of that rule.

For CY 2011, CMS established the Total Beneficiary Cost (TBC) metric as a means of evaluating changes in plan benefits from one year to the next, and whether such changes imposed significant increases in cost-sharing or decreases in benefits. TBC is the sum of plan-specific premium and estimated beneficiary out-of-pocket costs; the change in TBC from one year to the next captures the combined financial impact of premium changes and benefit design changes (i.e., cost-sharing changes) on plan enrollees; an increase in TBC is indicative of a reduction in benefits. (See Section II; Duplicative Plans; B. Duplicative Plan Offerings of this draft call letter for additional information regarding estimated beneficiary out-of-pocket costs). By limiting the change in the TBC from one year to the next, CMS is able to ensure that beneficiaries are not exposed to significant cost increases from one plan year to the next. In CY 2012, for plans that include a Part B premium buy-down as part of their benefit package, the TBC calculation for that plan will include a factor to account for this additional benefit.

For CY 2011, CMS established TBC requirements for all non-employer plans that existed in CY 2010 and CY 2011 based on an outlier analysis that was conducted after bids were submitted, and negotiated with those plans that were identified as outliers. From CY 2010 to CY 2011, plan payment rates were frozen. Therefore, all plans were on a "level playing field" with respect to TBC.

For CY 2012, CMS will establish TBC requirements that will again apply to all non-employer MA plans that existed in 2011 and 2012, but also apply to plan consolidations into existing and new CY 2012 plans. CMS believes that the MA program is best served when MAOs provide their best package of benefits and premiums in their initial bid submission, and recognizes that MAOs need as much information about CMS' requirements in advance as possible in order to prepare their best initial bid. Therefore, CMS is considering two approaches with regard to establishing the TBC requirement for CY 2012. The first approach would be similar to the CY 2011 process, and include analyzing the distribution of TBC changes after bid submission and identifying outliers. CMS would notify those MAOs with outlier plans that they would need to re-submit an acceptable bid within a limited period of time for that bid to be considered for CY 2012.

Alternatively, CMS would establish an adjusted TBC change amount, based on historical data, and plan bids whose TBC was at or below this amount would not be subject to further scrutiny with respect to TBC. Bids with a TBC above the established amount would be subject to further scrutiny by CMS and MAOs might be required to resubmit these bids within a very limited time period. Under this approach, CMS would set the TBC change amount at approximately $36 PMPM from CY 2011 to CY 2012. CMS believes this amount, which is an increase of about

10% in TBC between CY 2011 and CY 2012, represents a reasonable increase in TBC based on MA program changes for CY 2012, such as benchmarks and quality bonus payments. CMS would reserve the ability to adjust this amount following bid submission if the distribution of all bids increase program costs more than anticipated.

We note that, under either approach, plans would be required to apply a plan specific adjustment factor to account for geographic and quality bonus payment related changes in each plan's payment rates. For CY 2012, effective plan payment rates will change and quality bonus payments will be introduced; this was not the case for CY 2011. Therefore, an adjustment is needed to return the TBC to the "level playing field" that existed in CY 2011, when plan payment rates were frozen. CMS has determined that the projected change in rebate amount from CY 2011 to CY 2012 for a plan's CY 2011 service area will serve as this adjustment amount. CMS will calculate and provide to each plan the rebate adjustment amount that applies to that plan shortly after release of the final call letter. This adjustment factor will be applied to the plan's TBC calculation and then compared to the CMS requirement amount for TBC. We note that the adjustment factor will reflect changes in both MA payment rates and quality bonus payments.

CMS is soliciting comments regarding the two approaches discussed above, as well as the proposed TBC change amount discussed under the second option above. CMS may choose the first approach or the second approach using either the proposed adjusted TBC change amount or a different adjusted TBC change amount. CMS will provide guidance regarding the TBC analysis in the final Call Letter after consideration of public comments. CMS may also consider further rulemaking regarding the evaluation of significant increases in cost sharing or decreases in benefits.

As CMS has previously communicated, the amount of time available for review of CY 2012 bids and any required MAOs corrections has been reduced significantly due to the change in the dates for the Annual Coordinated Election Period. In an effort to ensure that plan bids comply with all applicable requirements, CMS intends to make as much data and information about bid requirements available in advance as possible in order to assist MAOs in calculating an acceptable bid. This material is expected to be available in mid-April.

C. Discriminatory Cost Sharing Assessments

For CY 2012, CMS has established three benefit discrimination assessments for all MA plans (employer and non-employer):

1. Per Member Per Month (PMPM) Actuarially Equivalent (AE) Cost Sharing Maximums;
2. Service Category Cost Sharing Standards; and
3. Discriminatory Pattern Analysis.

The PMPM actuarial equivalent cost sharing maximums and service category cost sharing standards described below are provided in advance of the bid submission deadline with the expectation that all CY 2012 plan bids will conform to these standards when submitted on or before June 6, 2011. CMS will perform a discriminatory pattern analysis following bid submission to identify and resolve discriminatory benefit design elements not anticipated by the standards.

Also note that benefit design and cost sharing amounts approved for CY 2011 will not be automatically acceptable for CY 2012 because a separate and distinct review is conducted each contract year.

1. Per Member Per Month (PMPM) Actuarial Equivalent (AE) Cost Sharing Maximums

Total MA cost sharing for Parts A and B services must not exceed cost sharing for those services in Original Medicare on an actuarially equivalent basis. CMS will also apply this requirement separately to the following service categories for CY 2012: Inpatient Facility, Skilled Nursing Facility (SNF), Home Health; Durable Medical Equipment (DME), and Part B drugs.

Whether in the aggregate, or on a service-specific basis, excess cost sharing is identified by comparing two values found in Worksheet 4 of the Bid Pricing Tool (BPT).

Specifically, a plan's PMPM cost sharing for Medicare covered services (BPT Worksheet 4, Section IIA, column l) is compared to Original Medicare actuarially equivalent cost sharing (BPT Worksheet 4, Section IIA, column n). For inpatient facility and SNF services, the AE Original Medicare cost sharing values, unlike plan cost sharing values, do not include Part B cost sharing; therefore, an adjustment factor is applied to these AE Original Medicare values to incorporate Part B cost sharing and to make the comparison valid.

Once the comparison amounts have been determined, excess cost sharing can be identified. Excess cost sharing is the difference (if positive) between the plan cost sharing amount (column #1) and the comparison amount (column #5). The chart below uses illustrative values to demonstrate the mechanics of this determination.

Illustrative Comparison of Service-Level Actuarial Equivalent Costs to Identify Excessive Cost Sharing

	#1	#2	#3	#4	#5	#6	#7
BPT Benefit Category	PMPM Plan Cost Sharing (Parts A&B) *(BPT Col. l)*	Original Medicare Allowed *(BPT Col. m)*	Original Medicare AE Cost sharing (Part A only) *(BPT Col. n)*	Part B Adjustment. Factor to Incorporate Part B Cost Sharing (Based on FFS data)	Comparison Amount *(#3 × #4)*	Excess Cost Sharing (#1 − #5)	Pass /Fail
Inpatient	$33.49	$331.06	$25.30	1.366	$34.56	$0.00	Pass
SNF	$10.83	$58.19	$9.89	1.073	$10.61	$0.22	Fail
Home Health	TBD	TBD	TBD	TBD	TBD	TBD	TBD
DME	$3.00	$11.37	$2.65	1.000	$2.65	$0.35	Fail
Part B-Rx	$0.06	$1.42	$0.33	1.000	$0.33	$0.00	Pass

2. Service Category Cost Sharing Standards

As provided under 42 CFR § 422.100(f)(6), we may specify service categories for which the cost sharing charged by MA plans may not exceed levels annually determined by CMS to be discriminatory. For purposes of setting cost sharing thresholds for Parts A and B services, CMS reviews the prior year's bid data, as well as actuarial equivalency relative to Original Medicare, in order to identify cost sharing requirements.

Similar to last year, CMS is focusing these standards on those Parts A and B services that are more likely to have a discriminatory impact on sicker beneficiaries. The standards are based on a combination of patient utilization scenarios and Original Medicare. The scenarios reflect factors such as hospital lengths of stay and the number of physician office visits generated by average-to-sicker patients. Some service categories have multiple utilization scenarios in an effort to ensure that plans will consistently distribute cost sharing amounts in a manner that does not discriminate.

We are continuing our current policy of offering MA plans the option to have greater flexibility in establishing Parts A and B cost sharing than is available for plans that adopt the mandatory MOOP by adopting a lower voluntary MOOP limit.

The chart below summarizes the standards and cost sharing amounts by MOOP type (e.g., mandatory or voluntary) for local MA plans. CY 2012 plan bids must reflect enrollee cost sharing for in-network services that is not greater than the amounts displayed below. For LPPOs and RPPOs, these standards will be applied only to in-network services. All standards are inclusive of applicable service category deductibles, copayments and coinsurance, but do not include plan level deductibles.

CY 2012 In-Network Service Category Cost Sharing Requirements

		Voluntary MOOP	Mandatory MOOP
Service Category	**PBP Section B data entry field**	**Cost Sharing Limits**	**Cost Sharing Limits**
Inpatient - 60 days	1a	N/A	$3,935
Inpatient - 10 days	1a	$2,231	$1,785
Inpatient - 6 days	1a	$2,016	$1,613
Mental Health Inpatient - 60 days	1b	$2,471	$1,977
Mental Health Inpatient - 15 days	1b	$1,796	$1,437
Skilled Nursing Facility – First 20 Days[1]	2a	$100/day	$50/day
Skilled Nursing Facility – Days 21 through 100[1]	2a	$146/day	$146/day
Home Health	6a	TBD	TBD
Primary Care Physician	7a	$35 co-pay	$35 co-pay
Chiropractic Care	7b	$20 co-pay	$20 co-pay
Physician Specialist	7d	$50 co-pay	$50 co-pay
Psychiatric Services	7h	$40 co-pay	$40 co-pay
Therapeutic Radiological Services	8b	20% or $60 co-pay	20% or $60 co-pay
DME-Equipment	11a	N/A	20%
DME-Prosthetics	11b	N/A	20%
DME-Medical Supplies	11b	N/A	20%
DME-Diabetes Monitoring Supplies	11c	N/A	20% or $10 co-pay
DME-Diabetic Shoes or Inserts	11c	N/A	20% or $10 copay
Renal Dialysis	12	20% or $30 co-pay	20% or $30 co-pay
Part B Drugs-Chemotherapy[2]	15	20% or $75 co-pay	20% or $75 co-pay
Part B Drugs-Other	15	20% or $50 co-pay	20% or $50 co-pay

1. MA plans may have cost sharing for the first 20 days of a SNF stay, consistent with cost sharing guidance. The per-day cost sharing for days 21 through 100 must not be greater than the Original Medicare SNF amount. Total cost sharing for the overall SNF benefit must be actuarially equivalent with Original Medicare.
2. Home health cost sharing policy for CY 2012 will be determined in the current notice and comment rulemaking process (75 FR 71190)
3. Chemotherapy includes administration services. Chemotherapy drugs and administration services in an inpatient setting are covered under the MA plan's inpatient benefit coverage.

3. Discriminatory Pattern Analysis

Following CY 2012 plan bid submissions, CMS will ensure that MA plans conform to the cost sharing requirements. In addition, CMS will analyze bids to ensure that discriminatory benefit designs are identified and corrected. This could include bids that meet standards but have cost sharing amounts that are distributed in a manner that may discriminate against sicker, higher-cost patients. This analysis may also evaluate the impact of benefit design on patient health status and/or certain disease states. CMS will contact plans to discuss and correct any issues that are identified as a result these analyses.

Other Cost Sharing Policy Issues

A. Multi-Year Benefits

CMS is concerned that allowing MA plans and section 1876 cost contract plans to offer benefits and cost sharing that span multiple contract years, multi-year benefits, is inconsistent with its goal to provide beneficiaries with plan choices that are easy to understand. We believe that abenefit that spans multiple contract years is confusing to many enrolled beneficiaries because it requires them to keep track of which services have been received and which are unused, across years. In addition, we believe that multi-year benefits complicate the comparison of plans by beneficiaries during the open enrollment periods.

To address these concerns, beginning with CY 2012, we strongly encourage plans to limit benefits to one contract year rather than a longer period and are contemplating future rulemaking to limit plans' flexibility to offer benefits over more than one contract year. We understand that plans have become accustomed to pricing some benefits across multiple years and cannot be expected to make immediate changes to those practices, but to the extent possible, we encourage plans to limit or discontinue offering benefits over a period that spans more than one contract year.

B. Copayment and Coinsurance for the Same Service

We have found that, as is allowed for PBP data entry, a small number of plans enter both coinsurance and copayment amounts for the same service categories, presumably to capture variation in the plan's contracting agreements. We want to enable plans to accurately reflect their benefit packages in the PBP but also are committed to ensuring that plan benefits and cost sharing are easily understood by beneficiaries and that an enrollee is not charged both a coinsurance and a copayment for the same service. In our work to revise the PBP for CY 2012, we performed analyses to see how often plans were entering both coinsurance and copayment amounts for the same service categories. We were pleased to find that very few plans entered both types of cost sharing values for any service category in the CY 2011 bids and determined that we would be interested in simplifying the PBP by enabling plans to enter only one type of cost sharing for each of the service categories.

For CY 2012, we discourage plans from entering both types of cost sharing for any service category, but will not disallow those entries. For future contract years, we are considering rulemaking to revise the PBP to limit plans' ability to enter both copayment and coinsurance.

C. PBP Notes

CMS' longstanding policy requires that the Notes sections in the PBP may be used to provide additional information about the benefit that is being offered. The information in the note must not contain any cost sharing for the benefit/service that is not reflected in the PBP data entry field for the benefit/service. Any information in a note must be consistent with the benefit/service as it is reflected in the PBP data entry fields. The Notes must not be used to enter additional benefits, conditions for coverage or cost sharing charges.

D. Supplemental Benefits for Section 1876 Cost Plans

Although cost contracts are prohibited from offering mandatory supplemental benefits, CMS has permitted cost contracts to include collections of optional supplemental benefits in addition to their basic Parts A and B benefits as separate plan benefit package (PBPs) in order to indicate to potential enrollees in Medicare Plan Finder and Medicare & You that optional supplemental benefits are available. CMS does not, however, consider such collections of optional supplemental benefits as separate plan benefit packages, and cost contracts cannot require that potential enrollees choose one of the collections of supplemental benefits in order to enroll. If a cost contract wishes to discontinue a package of optional supplemental benefits for a subsequent contract year, CMS does not consider this a termination of a PBP. Any cost optional supplemental package marked as "terminated" for Contract Year (CY) 2012 will be required to be crosswalked via the plan crosswalk to another supplemental package offered by the cost contract. Cost contracts in this situation must transition enrollees to the cost contract's basic Parts A and B package – with or without Part D depending on the enrollee's original election – via the HPMS Plan Crosswalk. Additional detail on this issue is provided in the renewal/non-renewal guidance in this Call Letter.

As outlined in the Medicare Managed Care Manual (MMCM) Chapter 17, Subchapter F, all benefits that are part of the 1876 Cost Plan must be offered uniformly to all enrollees. Because of this, CMS is also adding a new edit rule to the Health Plan Management System (HPMS) requiring that all Cost plan benefit packages must cover the entire cost contract's service area. This may mean that some cost plan benefit packages will have to expand their service area for CY 2012.

Changes to 2012 Summary of Benefits Regarding Dual Eligible SNP Cost Sharing

CMS is changing the structure of the Summary of Benefits (SB) to address an issue related to how the Maximum Out-of-Pocket (MOOP) limit is reflected for DE SNP enrollees. For contract year 2010, CMS added a new requirement in the bid submission, whereby plans were required to have a MOOP limit in their bids, resulting in a MOOP value appearing in the SB (in column 3 under the plan benefit information).

For contract year 2011, CMS provided a temporary solution by allowing plans to submit a hard copy change to add qualifying language via an asterisk, indicating that the amount beneficiaries may have to pay is based on their level of state Medicaid assistance.

For contract year 2012, CMS is making programming changes to the SB sentences to ensure that cost sharing amounts are displayed accurately.

Renewal Material Timelines Given AEP Changes

Due to the statutory changes to the Annual Enrollment Period (AEP) the CY 2012 standardized, combined Annual Notice of Change (ANOC)/Evidence of Coverage (EOC) documents are due to current members of all MA plans, MA-PD plans, PDPs, and cost-based plans offering Part D by September 30, 2011. Organizations are not required to mail the Summary of Benefits (SB) to existing members when using the combined, standardized ANOC/EOC; however the SB must be available upon request.

In addition to the ANOC/EOC documents, organizations must provide the LIS rider and formulary, if applicable, to enrollees for receipt by September 30, 2011. Plan sponsors should note that no other materials regarding 2011 plan offerings may be sent prior to the beginning of marketing activities on October 1, 2011.

III. Part D

Generic Samples Paid for Through Part D Sponsors' Administrative Costs

As described in section 60.2 of Chapter 7 of the Prescription Drug Benefit Manual, CMS allows Part D sponsors the option to provide OTCs as part of their administrative cost structure when a component of a cost-effective drug utilization management program and without any cost sharing on the part of the beneficiary at the point-of-sale. We have been asked whether the provision of generic samples in physician offices could be similarly treated under Part D and are now providing this guidance, effective immediately. Sponsors may incur expenses related to distribution of and reporting on generic drug samples, provided to members within a physician's office setting, under the plan's administrative cost structure if doing so is consistent with a cost effective drug utilization management program. Any provision of generic samples must be conducted consistent with the requirements of the Prescription Drug Marketing Act, 21 USC §353 and the Food and Drug Administration's implementing regulations at 21 CFR part 203. A drug sample, as defined by 21 CFR § 203.3(i), means a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug. To clarify, for purposes of this analysis, a generic drug sample is a "unit of a prescription drug, limited to a drug subject to an application approved under section 505(j) of the Federal Food, Drug, and Cosmetic Act, which is not intended to be sold and is intended to promote the sale of the drug." A brand drug

sample is "a unit of a prescription drug, limited to a drug subject to an application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act, which is not intended to be sold and is intended to promote the sale of the drug." Drug samples do not meet the definition of a covered Part D drug under 42 CFR § 423.100 because they are not dispensed at a network pharmacy nor are they consistent with our out-of-network pharmacy coverage requirements stated at 42 CFR § 423.124. In other words, drug samples do not meet the emergency definition (42 CFR § 124 (a)(1)) and do not represent Part D drugs, unlike vaccines, which are appropriately dispensed and administered by physicians (42 CFR § 124 (a)(2)).

Given that generic samples do not meet the definition of a Part D drug, Part D sponsors cannot include the provision of samples as part of their benefit structure. Thus, such samples would not be placed on formulary tiers, and like similarly treated OTC products, such samples must be provided to enrollees without cost sharing requirements. However, in contrast to our related policy on the use of OTC products as part of a ulitilzation management program (See Prescription Drug Manual, Chapter 7, Section 60.2), generic samples may not be incorporated into step-therapy protocols because all enrollees would not have equal access to such samples. More broadly, Part D sponsors may not require beneficiares to use generic samples under any conditions. CMS recognizes that generic drug samples may be an effective utilization management tool used to promote compliance with a new drug therapy. By facilitating access to trial supplies of less costly generic versions of Part D drugs, plan sponsors can enhance their enrollees' experience in Part D by reducing their current and future cost sharing expenses. In the case of low income subsidy entitled beneficiaries, facilitating medication starts on generic versions of drugs also helps to limit federal low income cost sharing subsidy reimbursements and overall program costs to the Trust Fund. Therefore, we believe that Part D sponsors may contract with vendors to provide access to and reporting on generic drug samples as part of their drug utilization management program as an incentive to reduce drug costs by promoting the use of lower cost generic medications (We expect that Part D sponsors will have the appropriate business associate agreements with the vendors providing generic sample to Part D beneficiaries. The business associate agreement should require that a beneficiary's protected health information only be used for transactions directly related to providing a generic sample to the Part D beneficiary and reporting the beneficiary's receipt of a generic sample to the Part D sponsor).
If desirable, Part D sponsors should account for such costs when developing their 2012 bids, but may also contract for such services in 2011 if they determine that doing so under their utilization management programs would be an offset to their prescription drug costs. CMS currently has no plans to require reporting on generic samples provided to Part D beneficiaries through PDE reporting, or otherwise.

In making this clarification, we specifically distinguish generic samples from brand samples. We believe that the provision of brand name drug samples would not be an appropriate use of administrative costs and would not be consistent with the requirements relating to drug

utilization management at 42 CFR § 423.153(b), which direct Part D sponsors to establish a drug utilization management program that includes incentives to reduce costs when medically appropriate.

Applying Best Available Evidence Policy to Beneficiaries of Home and Community Based Waiver Services

Section 3309 of the Affordable Care Act extended the elimination of Part D cost sharing to full benefit dual eligibles who would be institutionalized individuals (or an institutionalized couple) if the individuals were not receiving home and community-based services under Title XIX of the Act. The effective date for this requirement will be no earlier than January 1, 2012. We have proposed an implementation date of January 1, 2012 in our November 15, 2010 proposed rule.

With the elimination of cost sharing for full benefit dual eligible individuals that receive home and community-based waiver services, we remind sponsors that once this requirement takes effect, they will need to have systems that can reflect zero cost sharing for these individuals when evidence is presented to the sponsor that the individual receives home and community-based waiver services, and the individual's cost-sharing is more than zero. Sponsors will be required to follow our Best Available Evidence policy as outlined in Chapter 13 of the Medicare Prescription Drug Benefit Manual. That is, on the date that this requirement takes effect (no earlier than January 1, 2012), a copy of a state document confirming full benefit dual eligible status and receipt of home and community-based waiver services is evidence that the beneficiary qualifies for zero cost-sharing.

Monitoring the Implementation of Transition Policy

In CY 2011 CMS required Part D sponsors to complete transition attestations in HPMS and submit a transition policy and implementation statements through the CMS Part D transition mailbox. The CY 2011 review revealed many polices were deficient and did not adequately address all attestations. CMS spent a significant amount of time reviewing updated policies and providing technical assistance and guidance to Part D sponsors to bring the policies into compliance with the regulatory requirements. Despite CMS' efforts to work with plans to achieve approvable transition policies, subsequent audits revealed that Part D sponsors were not implementing the transition policies appropriately in their claims adjudication systems. Therefore, beneficiaries were not receiving their required transition supplies, which is a basic protection of the Part D program to ensure continuity of care. On August 27, 2010, CMS issued an HPMS memo to provide additional clarification to Part D sponsors on the transition benefit.

As a result of the audit findings, CMS remains concerned with whether Part D sponsors are appropriately implementing the transition policy. CMS is exploring several methods to determine if Part D sponsors are implementing their transition policy consistent with CMS'

guidance and applicable regulations. CMS will require that Part D sponsors provide documentation that their transition policy is correctly implemented in their claims system and that beneficiaries are receiving their required transition supplies. This documentation may require the sponsor to submit any or all of the following: (1) up to one quarter's worth of denied claims for 2012; (2) test claims for new beneficiaries; (3) identification of new beneficiaries and documentation of paid claims for transition supplies; or (4) evidence of transition supplies provided across contract years.

Medication Therapy Management (MTM) Services and Racial Disparities

In August 2010, Health Services Research (HSR), an organization that publishes findings from investigations in the field of health care to help improve the health of individuals and communities, published findings from a research study under the title "Disparity Implications of Medicare Eligibility Criteria for Medication Therapy Management Services." (Wang et al. 2010. "Disparity Implications of Medicare Eligibility Criteria for Medication Therapy Management Services." *Health Services Research 45 (4*): 1061-1082.) The objective of the research study was to determine if there were racial and ethnic disparities in meeting eligibility criteria for MTM services provided for Medicare Part D beneficiaries. The report findings suggest that Hispanic and African American beneficiaries could have a lower likelihood of meeting the MTM eligibility criteria when compared to whites based on the original MTM eligibility thresholds in 2006 and the new thresholds beginning in 2010. The study also found that there was disparity among beneficiaries with severe health problems. There are important implications for the Part D program considering these findings are consistent with other literature which suggests that minorities have lower utilization of drugs and health services in general, and the MTM eligibility criteria are based on utilization. The Part D benefit requires prescription drug sponsors to establish a MTM program to optimize therapeutic outcomes for targeted beneficiaries who meet high risk criteria, but currently a potentially vulnerable segment of the population may not be targeted accurately to receive MTM services.

CMS is conducting an analysis to verify the report's findings. As a first step of the analysis, CMS is replicating the analysis conducted in the HSR study using a larger sample of beneficiaries and will also investigate potential racial disparities using the plan-reported MTM data which reflects actual experience. If the report findings are validated, CMS may consider changes to the MTM eligibility thresholds in future rulemaking. Sponsors have had flexibility to determine the first two elements that make up the definition of MTM targeted beneficiaries, and CMS has put in place additional restrictions to define these elements beginning in 2010. CMS would like sponsors to provide comments on MTM eligibility criteria that could be used to target individuals who would otherwise receive a disparate level of care. Furthermore, CMS strongly encourages sponsors to examine their defined MTM targeting criteria and implement or pilot any changes to the criteria as needed to minimize racial disparities in MTM eligibility.

Reassignment Policy for 2012

In the fall of 2011, CMS will again reassign auto-enrolled low income subsidy (LIS) beneficiaries who are in a PDP that has a premium at or below the LIS benchmark in 2011, but above the LIS benchmark in 2012, as well as all LIS beneficiaries whose PDP is terminating for 2012. CMS will also reassign beneficiaries who remain LIS-eligible as of January 1, 2012, and are in Medicare Advantage plans that are terminating in 2012. Consistent with section 3303 of the Affordable Care Act (ACA), PDPs that volunteer to waive a de minimis amount of the premium will no longer lose LIS beneficiaries to reassignment based on the fact that their monthly premium exceeds the low-income benchmark; however, such PDPs will not receive reassignments and auto-enrollments. We anticipate establishing the de minimis amount in August 2011. Details of the reassignment process may be found in section 40.1.5 of the PDP Eligibility, Enrollment, and Disenrollment Guidance, available on our website at: http://www.cms.gov/MedicarePresDrugEligEnrol/Downloads/FINALPDPEnrollmentandDisenrollmentGuidanceUpdateforCY2011.pdf.

Consistent with section 40.1.5 of the enrollment guidance, CMS will first reassign beneficiaries within the same organization if the organization offers another qualified PDP in the same region, either under the same contract number, or if that is not available, under a different contract number sponsored by the same parent organization. If the organization does not offer another qualifying PDP, CMS will randomly reassign affected beneficiaries to other PDP sponsors that have at least one qualifying PDP in that region. CMS will follow the two-step process used for auto-enrollment, i.e., random distribution first at the organization level, then randomly among qualifying PDPs within the organization (see section 40.1.4.C).

Note that organizations under an enrollment sanction will not receive reassignments, either from within their organization or through the random reassignment process. Thus, if a sanctioned organization offers a PDP with a 2011 premium below the low-income benchmark amount and that PDP's premium will be above this threshold for 2012—resulting in premium liability for LIS beneficiaries—affected enrollees in that PDP will be randomly reassigned to other PDPs in the region with a premium at or below the LIS benchmark amount.

Low Enrollment Plans (Stand-alone PDPs only)

CMS has the authority under to 42 CFR §423.507(b)(1)(iii) to non-renew plans (at the benefit package level) that do not have sufficient number of enrollees to establish that they are viable plan options. Consistent with that authority, we will again be scrutinizing low-enrollment plans during the bid review period and will expect that sponsors will have withdrawn or consolidated low-enrollment plans prior to submitting bids for CY 2012. This guidance applies to non-employer stand-alone Part D plans since CMS previously granted a waiver of 42 CFR

§423.512(a) (minimum enrollment requirements) for sponsors of employer group plans. We reserve the right to reconsider this waiver in the future.

We expect to particularly examine plans that constitute the lowest quintile (20%) per region of 2011 plans ranked by enrollment. As of February 2011, the lowest quintile was comprised of 173 plans, with an average of 5 plans per each of the 34 PDP regions. These plans had a total enrollment of 79,953 beneficiaries, with an average of 462 enrollees and a median enrollment of 273 per plan. The actual plan enrollments ranged from a low of 4 to a high of 2,490 beneficiaries. While we are particularly concerned about the smallest plans, we urge sponsors to consider withdrawing or consolidating any stand-alone plan with less than 1,000 enrollees. Sponsors are strongly encouraged to view data on plan enrollment count at: www.cms.hhs.gov/MCRAdvPartDenrolData/ to determine if any of their plans fall into the lowest quintile.

Before CMS would take any action to non-renew a plan pursuant to 42 CFR §423.507(b)(1)(iii), CMS would take into account all relevant factors, including, but not limited to: (1) whether the plan is a basic plan offered to meet the regulatory requirement in 42 CFR § 423.104(f)(2) that a PDP sponsor may not offer enhanced alternative coverage in a service area unless the sponsor also offers a basic drug plan in the area, in which case CMS would renew the basic plan;(2) whether the plan was a new plan and if it has been in existence for three or more years; (3) whether the plan is offered nationally; (4) the total number of plan offerings in the applicable region; and (5) if the plan's premium currently falls at or below the low income benchmark premium amount.

Benefit Design

Cost-Sharing Out-of-Pocket (OOPC) Differential Analysis

For the CY 2011 bid submission, CMS used the cost-sharing OOPC amounts in establishing differences between basic and enhanced plans and between low and high value enhanced. Since then, CMS has received questions about our Cost-Sharing OOPC differential analysis. We employ this analysis to establish meaningful differences among basic and enhanced plans across the Part D program, not just between contract offerings. The purpose of the analysis and the setting of the target differential dollar amounts is to ensure that beneficiaries will receive a minimum additional value over basic coverage, and between enhanced coverage offerings, when they select and pay premiums for any enhanced plan. The analysis is not used to evaluate relative levels of all out-of-pocket costs that a beneficiary may incur, but rather, to establish the difference in cost-sharing incurred among plans as a measure of additional benefits available to the average consumer. For this reason, premiums are not included in the calculation because in the case of enhanced plans (as opposed to basic plans), any additional premium exactly offsets the additional benefits, by law. Thus, supplemental premiums cancel out the additional value of

the enhanced benefits and do not leave a comparable amount to be compared to the value of basic benefits.

In order to set a value for meaningful differences, CMS must be able to evaluate plan benefit packages (PBPs) on the same yardstick. This is accomplished by running the identical Medicare Current Beneficiary Survey (MCBS) data through each PBP. More specifically, CMS established the targets for differentiation by evaluating expected Cost-Sharing OOPC amounts under each 2011 plan offering by the same sponsor in a service area. For this relative analysis, CMS utilized a uniform market basket of drugs from a representative population of Medicare beneficiaries run through each plan's benefit design. Cost-sharing OOPC estimates were originally calculated using PBP and formulary data available during the 2011 bid review period, but were reevaluated using more recent PBP, formulary, and MCBS data (2005/6) as well as more precise calculations related to additional gap coverage for a subset of drugs on a particular tier or tiers (i.e. partial tier additional gap coverage). The latter calculation includes the MCBS data that will be used for the 2012 OOPC estimates. The chart below depicts a summary of the results of our analysis based on CY 2011 data:

2011 Cost-Sharing OOPC Differential Analysis

August Bid/Formulary Data, 2004/5 MCBS Data						
Plan Comparison	**# of Plans**	**Mean**	**25th**	**50th**	**75th**	**95th**
1st Enhanced Plan vs. Basic Plan	886	-$23.55	-$23.48	-$22.58	-$22.16	-$20.88
2nd Enhanced Plan vs. 1st Enhanced Plan	146	-$15.41	-$16.17	-$16.17	-$13.68	-$13.35
December Bid/Formulary Data, 2005/6 MCBS Data						
Plan Comparison	**# of Plans**	**Mean**	**25th**	**50th**	**75th**	**95th**
1st Enhanced Plan vs. Basic Plan	886	-$27.96	-$32.36	-$28.14	-$25.63	-$17.60
2nd Enhanced Plan vs. 1st Enhanced Plan	146	-$12.29	-$16.25	-$15.93	-$5.78	-$5.78

Using the updated OOPC model with the most current formulary, PBP and MCBS data and a more precise calculation for partial gap coverage, the median monthly difference between basic and enhanced plan offerings increased to nearly $28. However, to maintain consistency in this meaningful differences test while sponsors continue to gain experience calculating OOPC estimates, the minimum monthly threshold value between basic and enhanced plan offerings will remain at $22 for CY 2012. Because the 2011 OOPCs considered partial gap coverage to be the same as full gap, the impact on the partial gap plans was greater as the OOPC differentials

decreased further away from the median. This was especially evident in the comparison between enhanced plan offerings (with adjusted OOPC differentials) that were not meaningfully different for these plans. Therefore, for CY 2012, CMS is also proposing using the median monthly cost-sharing OOPC difference of $16 between 2 enhanced plans in the same service area.

Cost-Sharing Out-of-Pocket Cost (OOPC) Software

For CY 2012, CMS will make the Cost-Sharing Out-of-Pocket Cost model (Cost-Sharing OOPC) available in SAS via the CMS website which will allow plans to calculate Cost-Sharing OOPC estimates for each of their benefit offerings to prepare for meaningful difference negotiations with CMS (see below). Standalone Prescription Drug Plans (PDP), and Medicare Advantage Plans with Prescription Drug coverage (MA-PD) will be encouraged to run their plan benefit structures through the SAS Cost-Sharing OOPC model to ensure meaningful differences between their plan offerings as required by CMS regulations (see 42 CFR §§ 423.272(b)(3)(i) and 423.265(b)(2)). The SAS Cost-Sharing OOPC model will be available in the spring of 2011. Instructions for downloading the model and a User Guide will also be published via the CMS website.

CMS expects PDPs and MA-PDs to prepare CY 2012 plan bids that meet the meaningful difference requirements with their initial submissions, since there will be access to the necessary tools to consistently calculate Cost-Sharing OOPC estimates for each plan prior to bid submission. CMS might not permit revised submissions if a plan's initial bid does not comply with meaningful difference requirements. Ultimately, plan bids that do not meet these requirements will not be approved by CMS. Thus, plans should complete this analysis prior to submitting their bids for the 2012 contract year.

Meaningful Differences in Part D Coverage

As part of the bid negotiation process, CMS seeks to ensure a proper balance between affording beneficiaries a wide range of plan choices and avoiding undue beneficiary confusion in making coverage selections. Part D regulations require that plan offerings by sponsors represent meaningful differences to beneficiaries with respect to benefit packages and plan cost structures. Pursuant to § 423.272(b)(3)(i), CMS will only approve a bid submitted by a Part D sponsor if its plan benefit package or plan cost structure is substantially different from those of other plan offerings by the sponsor in the service area with respect to key characteristics such as premiums, cost-sharing, formulary structure, or benefits offered. Section 423.265(b)(2) also requires that Part D sponsors' bid submissions in the same service area reflect differences in benefit packages or plan costs that we determine to represent substantial differences from each other.

Again for 2012, CMS will be waiving the meaningful differences requirements of sections 42 CFR 423.272(b)(3)(i) and 423.265(b)(2) to allow sponsors of employer group plans (800 series

and direct contract plans) to submit, and seek approval of, employer plan benefit packages that do not meet the meaningful differences requirements. We reserve the right to reconsider this waiver in the future.

As noted last year in the 2011 Part D Plan Benefit Package (PBP) Submission and Review Instructions, CMS does not believe that sponsors can demonstrate meaningful differences based on expected Cost-Sharing OOPCs between two stand-alone basic Part D benefit designs and maintain both the statutory actuarial equivalence requirements and fulfill the requirement in §423.153(b) to maintain cost-effective drug utilization review programs. Therefore, sponsors again for the 2012 contract year should submit only 1 basic offering (where basic offering includes defined standard, actuarial equivalent and basic alternative drug benefit types) for a stand-alone prescription drug plan in a service area. As in prior years, CMS will negotiate with Part D sponsors to offer no more than 3 stand-alone prescription drug plan offerings in a service area, resulting in a mix of 1 basic and at most, 2 enhanced plans—subject to the following qualifications.

Cost-Sharing OOPC Differential Thresholds

To determine if cost sharing and formulary and benefit differences result in meaningful differences for the 2012 Contract Year, CMS expects the Cost-Sharing OOPC differential (exclusive of premium amounts) between a basic benefit offering and an enhanced offering of the same Part D sponsor in the same service area to be at least $22 monthly ($264 annually). In other words, the expected Cost-Sharing OOPCs of the basic plan should be higher by at least $22 monthly than the enhanced offering. This amount has not changed from last year.

CMS will also continue its expectation that where 2 enhanced stand-alone drug plans are offered within the same service area, the second enhanced plan will have a higher value than the first and include coverage of at least some brand drugs in the gap (where "some" is defined as ≥ 10% - 65% of formulary drug entities labeled as brands). In addition, CMS expects that the Cost-Sharing OOPC differential between the two enhanced offerings will be at least $16. In other words, the expected Cost-Sharing OOPCs of the first enhanced offering will be $16 higher than the second enhanced offering. Assigning a value to the Cost-Sharing OOPC differential between two enhanced offerings is new this year.

Co-pay Thresholds for Cost Shares

According to 1860D-11(e) of the Medicare Modernization Act, the Secretary can only approve a plan if the design of the plan and its benefits are not likely to substantially discourage enrollment by certain Part D eligible individuals. Pursuant to 42 CFR 423.104(d)(2)(iii), tiered cost sharing for non-defined standard benefit designs may not exceed levels annually determined by CMS to be discriminatory.

To implement these requirements, CMS will examine PDP and MA-PD bid (benefit package) data for 2012 to determine acceptable cost sharing thresholds. Consistent with prior years' review, we plan to conduct an analysis to identify drug tier cost sharing outliers relative to other sponsors' competing benefit packages submitted using the copay cost-sharing associated with the 95th percentile across all initially submitted bids consisting of three or more tiers. CMS believes that cost-sharing at the 95th percentile would reflect the level at which a beneficiary could easily identify outliers they would consider to be discriminatory based on other plan offerings. As part of this analysis, we will also take into consideration plan type (basic versus enhanced), the number of drug tiers within a PBP, cost structure (copayment versus coinsurance), tier content and differences between MA-PDs (including cost plans) as well as differences between MA-PDs and PDPs. The table below shows the results of the threshold analysis for the initial 2011 bid submissions.

Copay Cost-Sharing Distribution for 2011 Bid Submissions with Three or More Tiers

2011 Copay Distribution (Percentiles)					
Tier ID	**Plan Count**	**20th**	**50th**	**70th**	**95th**
1	2846	$2	$5	$6	$10
2	2696	$15	$35	$40	$45
3	2570	$40	$70	$80	$95

Assuming similar benefit designs are submitted for 2012 as they were for 2011, sponsors can expect that CMS will establish 2012 thresholds that are reasonably consistent with the prior year's experience. Therefore, in constructing PBPs, Part D sponsors should consider the following thresholds that were used as part of the 2011 discrimination review for drug plans with three or more tiers:

Tier 1 over $10
Tier 2 over $45
Tier 3 over $95

Based on the most common tier designs submitted by plans, tier 1 represents preferred generic cost-sharing, tier 2 represents preferred brand cost-sharing and tier 3 represents non-preferred brand cost-sharing. As in 2011, the established threshold for preferred generic, preferred brand and non-preferred brand cost-sharing still apply when the tier level for these categories are shifted based on variations in tier design. In addition, CMS will evaluate tier structures that include multiple generic and/or brand tiers to determine whether the weighted average of the retail cost-sharing for these tiers meets the established thresholds. It is important to note that in identifying drug tier outliers, CMS will consider specific benefit design aspects that could justify an exception for the purpose of our discrimination review. For instance, we may allow cost

sharing thresholds for plan benefit designs in which a particular tier represents the specialty tier such that if a plan has a 3 tier formulary which includes a specialty tier, the specialty tier will be held to the specialty tier thresholds, not the thresholds established by the 95th percentile. Atypical tiering structures, such as a two-tier formulary, will also be considered and with the additional standardization in tier design required for 2012, the benefits offered will have a distribution that is unique to each tier structures, thereby allowing CMS to refine the target cost-sharing thresholds. Therefore, we may also consider establishing alternative thresholds for 2012 plans with 4 and 5 tier formularies that follow the standardized models described in the next section.

During 2011, CMS will increase scrutiny of the expected cost sharing amounts incurred by beneficiaries under coinsurance tiers, in order to more consistently compare copay and coinsurance cost sharing impacts. We expect to derive average expected cost sharing amounts for a sponsor's 2012 coinsurance tiers using 2010 PDE drug cost data mapped to 2012 formulary tiers. If a sponsor submits coinsurance values (instead of copayment values) for its non-specialty formulary tiers that are greater than the standard benefit of 25% for non-specialty tiers, CMS may also request documentation from the sponsor on the average expected price for medications on the coinsurance tier(s) in order to better translate the coinsurance value into an average cost sharing amount for the purpose of our discrimination review.

Consistent with the meaningful difference review, CMS will notify plan sponsors whose benefit structures include drug tiers that exceed our discriminatory cost sharing threshold limits and conduct negotiation calls as applicable prior to bid approval. Sponsors not meeting our targets will be asked to amend or withdraw their PBPs.

Tier Labeling and Hierarchy

Over the last few years CMS has heard from various beneficiary and advocacy stakeholders and Part D sponsors that a large number of drug tiers, non-standardized labeling of those tiers and formularies using duplicative tier names or tier names that include multiple drug types in the label (e.g. Brand and Generic Drugs are confusing to beneficiaries especially when trying to compare plans. In order to improve the clarity and consistency of tier designs, CMS revised the PBP and formulary upload software in 2011 to accept a maximum of six drug tiers and established a uniform set of tier label description options based upon the most common tier names used by Part D sponsors. However, CMS believes that additional standardization of the tier structure and number could further improve the comparability of plan offerings by beneficiaries and will simplify the discriminatory cost-sharing analysis performed by CMS.

First, in order to keep drug benefits meaningful to beneficiaries while allowing sponsors adequate flexibility in the Part D benefit design, the 2012 PBP and formulary upload will continue to accept 6 formulary tiers. CMS continues to observe that the vast majority of Part D

plan benefit packages reflect benefit designs using five tiers or less, and those plans with six tier designs are similar to those submitted by five tier plans, but typically include an extra non-preferred cost-sharing tier that does not provide a clear additional value to the beneficiary. Therefore, CMS will only allow a 6th tier if it is an excluded- drug- only tier or a tier that provides a meaningful benefit offering such as a $0 vaccine-only tier, a low or $0 cost-sharing tier for special needs plans (SNP) targeting specific conditions (e.g., $0 diabetic drug tier), or an injectable drug tier with cost-sharing that is at or below the cost sharing for specialty tier drugs in the other five tiers. Plans offering supplemental benefits for excluded drug coverage are not required to have this optional excluded-drug-only tier and may continue to offer excluded drugs on tiers that are shared by Part D covered drugs.

Second, CMS is establishing tier labels and hierarchy to reflect standards established by industry and assist in our analysis of discriminatory benefit practices. CMS updated its regulations at §423.104(d)(2) by adding paragraph (iii) to specify that tiered cost-sharing for non-defined standard benefit designs may not exceed levels (or cost sharing thresholds) annually determined by CMS to be discriminatory. In order to accurately evaluate whether tiered cost-sharing is discriminatory, there needs to be a consistency between the tier labels adopted by the plan sponsors and the cost-sharing thresholds CMS established as part of its discriminatory analyses. Some of the variation in tier labeling that currently exists in Part D presents challenges for the discriminatory cost-sharing analyses, and does not lend itself to a common understanding of how competing plans compare in terms of tier offerings. As a result, beginning with the 2012 bid submissions, CMS is strongly encouraging sponsors to utilize certain tier labels and tiering hierarchy consistent with the industry standards already established in the market place. These standard tier labels and hierarchy reflect the common tier patterns utilized by the majority of sponsors in 2011 and will provide for a more comprehensible description of the overall tier offering as it relates to the drug content and assigned cost-sharing.

Below is a chart depicting the tier labels and hierarchy as observed currently in the industry. CMS will have difficulty determining whether a plan's tier cost-sharing structure is discriminatory if Part D sponsors submit plan benefit packages that do not reflect these industry standards. In addition because of the ACA provision that moved the annual enrollment period from November to October, CMS will have a shortened time frame for review and approval of 2012 Part D bids and may not have enough time to approve bids that are incomplete or otherwise challenging to evaluate. CMS strongly encourages Part D sponsors to ensure that their initial submissions due on June 7, 2011 are complete and consistent with CMS policy and guidance, to avoid the risk of being denied participation in the program. In addition, sponsors must ensure that the formularies submitted in advance of the bids only include a 6th tier that provides a meaningful offering. We further note that the tier labels submitted on the formularies should match those labels submitted in the PBP, with the exception of free text field names in the formulary submission module that are not available in the PBP. As in previous years, excluded-drug-only tiers will not be reflected on formulary submissions.

2012 Tier Labels and Hierarchy

		2012 Tier Label					
2012 Tier Structure	**2012 Option**	**Tier 1**	**Tier 2**	**Tier 3**	**Tier 4**	**Tier 5**	**Optional Tier 6***
2 Tier	A	Generic or Preferred Generic	Brand or Preferred Brand	---	---	---	---
3 Tier	A	Generic or Preferred Generic	Brand or Preferred Brand	Specialty Tier	---	---	---
	B	Generic or Preferred Generic	Preferred Brand	Non-Preferred Brand	---	---	---
4 Tier	A	Generic or Preferred Generic	Preferred Brand	Non-Preferred Brand	Specialty Tier	---	---
	B	Preferred Generic	Non-Preferred Generic	Preferred Brand	Non-Preferred Brand	---	---
5 Tier	A	Preferred Generic	Non-Preferred Generic	Preferred Brand	Non-Preferred Brand	Specialty Tier	optional
	B	Preferred Generic	Non-Preferred Generic	Preferred Brand	Non-Preferred Brand	Injectables	optional
	C	Preferred Generic	Non-Preferred Generic	Preferred Brand	Injectables	Specialty Tier	optional
	D	Generic or Preferred Generic	Preferred Brand	Non-Preferred Brand	Injectables	Specialty Tier	optional

*The optional 6th tier can be used as an excluded-drug-only tier or for other meaningful offerings such as a $0 vaccine-only tier.

Gap Coverage

Consistent with our bid submission requirements provided at 42 CFR 423.265, a Part D sponsor's bid submission must reflect differences in benefit packages or plan costs that CMS determines to represent substantial differences relative to a sponsors other bid submissions. This being the case, CMS expects that the additional gap coverage of generic (non-applicable) drugs offered by plans to reflect meaningful enhancements over the standard prescription drug benefit, which provides 14% generic drug cost coverage in the gap for CY 2012.

To determine how much additional coverage in the coverage gap over the basic benefit would be recognized as substantially different, CMS considered the amount of additional coverage provided by the Part D sponsors in their plan benefit packages for CY 2011. CMS found that the majority of plans offering coverage in the gap had cost sharing levels for generics equal to 50%

coinsurance or less, and brand cost sharing at 60% coinsurance or less. Since the majority of plans reflect additional coverage of at least 50% in the gap for generics and 40% coverage of brands in the gap, CMS intends to scrutinize any 2012 plans that provide gap coverage at or below 30% of the cost of generic or brand drugs. In other words, the plan's benefit has beneficiary cost sharing during the coverage gap that is equal to or more than 70% coinsurance. For example, if a plan submits a basic benefit package which reflects the defined-standard benefit structure of 86% coinsurance for generics during the coverage gap and submits another enhanced plan that reflects more than 70% coinsurance for generics during the coverage gap, CMS will evaluate whether the enhanced plan is substantially different from what is offered under the sponsor's basic plan in accordance with our meaningfully different policies.

Plan Corrections

The plan correction module will be available in HPMS for 2012 PBPs for a limited period, from mid-September until October 1, 2011. Organizations may request a plan correction only after their contract has been approved. This limited timeframe will ensure that correct bid information will be available for review on the Medicare Prescription Drug Plan Finder in time for the open enrollment start date. Only changes to the PBP that are supported by the BPT are allowed during the plan correction period.

CMS expects that sponsors' requests for plan corrections will be very rare. A request for a plan correction indicates the presence of inaccuracies and/or the incompleteness of a bid and calls into question an organization's ability to submit correct bids and the validity of the final actuarial certification and bid attestation. Please be advised that an organization requesting a plan correction will receive a compliance notice.

Specialty Tier Threshold

For contract year 2012, we will maintain the $600 threshold for drugs on the specialty tier. Thus, only Part D drugs with negotiated prices that exceed $600 per month may be placed in the specialty tier, and the specialty tiers will be evaluated and approved in accordance with section 30.2.4 of Chapter 6 of the Medicare Prescription Drug Benefit Manual. In addition to cost calculations, CMS considers claims history in reviewing the placement of drugs on Part D sponsors' specialty tiers. Except for newly approved drugs for which Part D sponsors would have little or no claims data, CMS will approve specialty tiers that only include drugs on specialty tiers when their claims data demonstrates that the majority of fills exceed the specialty tier cost criteria. Part D sponsors should be prepared to provide CMS the applicable claims data during the formulary review process.

Appendix A-1 – Contract Year 2012 Guidance for Medicare Advantage, Medicare Advantage Prescription Drug, and Section 1876 Cost Contract Plan Renewals

I. MA PBP Renewal and Non-Renewal Guidance

Each renewal/non-renewal option available to MAOs for CY 2012 is outlined in Appendix A-2 and summarized below. Some of these actions can be effectuated by MAOs in the HPMS Plan Crosswalk, while others require explicit prior approval from CMS. Note that CMS will not permit plan renewals across product types. For example, we will not permit MA-only plans to renew as, or consolidate into, MA-PD plans (and vice versa), Health Maintenance Organization (HMO) plans to renew as, or consolidate into, Preferred Provider Organization (PPO) plans (and vice versa); HMO plans or PPO plans to renew as, or consolidate into, Private-Fee-for-Service (PFFS) plans (and vice versa); Special Needs Plans (SNPs) to renew as, or consolidate into, non-SNP MA plans (and vice versa); and section 1876 cost contract plans to renew as, or consolidate into, MA plans (and vice versa). With limited exceptions (outlined below) CMS will not permit consolidation of PBPs, regardless of plan type, across contracts.

*1. **New Plan Added***

An MAO may create a new PBP for the following contract year with no link to a PBP it offers in the current contract year in the HPMS Plan Crosswalk. In this situation, beneficiaries electing to enroll in the new PBP must complete enrollment requests, and the MAO offering the MA plan must submit enrollment transactions to MARx.

*2. **Renewal Plan***

An MAO may continue to offer a current PBP that retains all of the same service area for the following year. The renewing plan must retain the same PBP ID number as in the previous contract year in the HPMS Plan Crosswalk. Current enrollees are not required to make an enrollment election to remain enrolled in the renewal PBP, and the MAO will not submit enrollment transactions to MARx for current enrollees. New enrollees must complete enrollment requests, and the MAO will submit enrollment transactions to MARx for those new enrollees. Current enrollees of a renewed PBP must receive a standard Annual Notice of Change (ANOC) notifying them of any changes to the renewing plan.

*3. **Consolidated Renewal Plan***

MAOs are permitted to combine two or more entire PBPs offered in the current contract year into a single renewal plan in the HPMS Plan Crosswalk so that all enrollees in the combined

plans are under one PBP with the same benefits in the following contract year. However, an MAO may not split a current PBP among more than one PBP for the following contract year. An MAO consolidating one or more entire PBPs with another PBP must designate which of the renewal PBP IDs will be retained following the consolidation. The renewal PBP ID will be used to transition current enrollees of the plans being consolidated into the designated renewal plan. This is particularly important with respect to minimizing beneficiary confusion when a plan consolidation affects a large number of enrollees.

Current enrollees of a plan or plans being consolidated into a single renewal plan will not be required to take any enrollment action, and the organization will not submit enrollment transactions to MARx for those current members. However, the MAO may need to submit updated 4Rx data to CMS for the current enrollees affected by the consolidation. New enrollees must complete enrollment requests, and the MAO will submit enrollment transactions to MARx for those new enrollees. Current enrollees of a consolidated renewal plan must receive a standard ANOC.

4. ***Renewal Plan with a Service Area Expansion (SAE)***

An MAO may continue to offer the same local MA PBP but add one or more new service areas (i.e., counties) to the plan's service area in the following contract year. This is known as a service area expansion, or SAE. Organizations that include any new service area additions to a PBP should have submitted an SAE application to CMS for review and approval. An MAO renewing a plan with a SAE in the HPMS Plan Crosswalk must retain the renewed PBP's ID number in order for all current enrollees to remain enrolled in the same plan in the following contract year.

Current enrollees of a PBP that is renewed with a SAE will not be required to take any enrollment action, and the MAO will not submit enrollment transactions to MARx for those current enrollees. New enrollees must complete enrollment requests, and the MAO will submit enrollment transactions to MARx for those new enrollees. Current enrollees of a renewed PBP with a SAE must receive a standard ANOC notifying them of any changes to the renewing plan.

5a. ***Renewal Plan with a Service Area Reduction (SAR) and No Other MA Options Available***

An MAO offering a local MA plan may reduce the service area of a current contract year's PBP. This is known as a service area reduction, or SAR. An MAO renewing a plan with a SAR must retain the renewed PBP's ID number in the HPMS Plan Crosswalk so that current enrollees in the renewal portion of the service area remain enrolled in the same plan in the following contract year. Current enrollees in the renewal portion of the service area will not be required to take any enrollment action, and the MAO will not submit enrollment transactions in MARx for these

current members. Current enrollees in the renewal portion of the service area must receive a standard ANOC notifying them of any changes to the renewing plan.

For the CY 2012 contract year, current plan enrollees in reduced service areas will be disenrolled at the end of 2011, regardless of whether the MAO has other plans available in the reduced area. These individuals affected by the SAR will need to elect another plan regardless of whether the MAO has other options available. The MAO will submit disenrollment transactions pursuant to instructions that CMS will release later this year.

The MAO will send a termination notice to enrollees in the reduced portion of the service area that includes notification of special election period (SEP) and Medigap guaranteed issue rights. Where there are no other MA options in the reduced service area, the MAO may offer current enrollees in the reduced portion of the service area the option of remaining enrolled in the renewal plan consistent with CMS continuation area policy as provided under 42 CFR § 422.74(b)(3)(ii). If an MAO elects to offer current enrollees in the reduced service area the option of remaining enrolled in the renewal plan, the MAO may provide additional information in the termination notice about the option to remain enrolled in the plan for CY 2012. However no specific CY 2012 plan information can be shared with any beneficiaries prior to October 1, 2011. Any current enrollees in the reduced portion of the service area who wish to continue their enrollment must complete an enrollment request, and the organization must submit enrollment transactions to MARx for those members.

5b. ***Renewal Plan with a Service Area Reduction (SAR) When the MAO Will Offer Another PBP in the Reduced Portion of the Service Area***

An MAO offering a local MA plan may elect to reduce the service area of a current contract year's PBP and make the reduced area part of a new or renewal MA PBP service area in the following contract year. An MAO renewing a plan with a SAR must retain the renewed PBP's ID number in the HPMS Plan Crosswalk so that current enrollees in the renewal portion of the service area remain enrolled in the same plan in the following contract year. Current enrollees in the renewal portion of the service area will not be required to take any enrollment action, and the MAO will not submit enrollment transactions to MARx for these current members. These individuals must receive a standard ANOC notifying them of any changes to the renewing plan.

Current enrollees in the reduced portion of the service area must be disenrolled, and the MAO must submit disenrollment transactions to MARx for these individuals, pursuant to instructions that CMS will release later this year. The MAO will send a termination notice to current enrollees in the reduced portion of the service area that includes notification of special election period (SEP) and Medigap guaranteed issue rights. If the MAO offers one or more MA plans in the reduced portion of the service area, it may offer current enrollees in the reduced portion of the service area the option of enrolling in that plan (or those plans). However, no specific CY

2012 plan information can be shared with any beneficiaries prior to October 1, 2011. Any current enrollees in the reduced portion of the service area who wish to enroll in another MA plan offered by the same organization in the reduced service area must complete an enrollment request, and the organization must submit enrollment transactions to MARx for those members.

6. ***Terminated Plan (Non-Renewal)***

An MAO may elect to terminate a current PBP for the following contract year. In this situation, the MAO will not submit disenrollment transactions to MARx for affected enrollees. CMS will disenroll these individuals from the MA plan at the end of the current contract year. These individuals must make a new election for their Medicare coverage for the following contract year. Regardless of whether these individuals elect to enroll in another plan offered by the same or another MAO, or to revert to Original Medicare and enroll in a PDP, they must complete an enrollment request, and the enrolling organization or sponsor must submit enrollment transactions to MARx. If these individuals do not make a new MA plan election prior to the beginning of the following contracting year, they will have Original Medicare coverage as of January 1st of the following contract year.

Enrollees in terminated PBPs will be sent a termination notice by the terminating plan that includes notification of a special election period and Medigap guaranteed issue rights. For more information about non-renewal processes and beneficiary notification requirements, refer to our forthcoming HPMS memorandum providing non-renewal and service area reduction guidance and model notices, to be released this summer.

7a, 7b, 8a, 8b, 9a, and 9c. ***Non-Network and Partial Network PFFS Plans Transitioning to Partial or Full Network PFFS Plans***

As provided under 42 CFR § 422.114(a)(3), PFFS plans in certain counties ("network counties" with two network plans available) must operate with networks. We have historically required organizations to establish separate contracts for PFFS non-network, partial network, and network plans. CMS has not typically allowed plans to move members from one contract to another, and contract-to-contract moves are currently not possible in the HPMS Plan Crosswalk. However, CMS created an exception to this rule for CYs 2010 and 2011, which we will continue for CY 2012, in anticipation of a large number of transitions from non- or partial network PFFS plans to partial or full network PFFS plans due to the PFFS network requirements. The permissible PFFS transitions are outlined below. We note that some of these scenarios involve consolidations of whole PFFS PBPs and others involve transitions of some, but not all, counties of current non-network and partial network PFFS PBPs.

MAOs cannot complete the outlined PFFS renewal options in the HPMS Plan Crosswalk. An MAO must complete and submit a request to Sara Silver at sara.silver@cms.hhs.gov by June 6,

2011. She will coordinate the review of the request and, if approved, complete the renewal on behalf of the requesting MAO. In addition, for those transitions that will involve some, but not all, counties of current non-network and partial network PFFS PBPs, MAOs must submit enrollment transactions to MARx for individuals residing in consolidating counties (i.e., where the contract and PBP number will be different in 2012) following the instructions that CMS will release later this year. To request any of the PFFS exceptions outlined below, organizations must indicate in the subject line of the email "HPMS PFFS crosswalk exceptions request for <Organization Name>" and include the following information in the request.

2011 Contract Number	2011 Contract Name	2011 Plan ID	Whole or Partial 2011 PBP Affected?	2012 Contract Number	2012 Contract Name	2012 Plan ID

NOTE: If a partial 2011 PBP is affected and you wish to submit enrollment transactions to move members to more than one 2012 plan, please list all 2012 plans in your request.

7a. ***Non-Network PFFS Plan Transitioning to a Partial Network PFFS Plan***

An MAO with a PFFS non-network contract may consolidate one or more current non-network PFFS PBPs into a new or renewal partial network PFFS PBP under a separate contract held by the same legal entity. HPMS will record the consolidation of one or more PBPs following the submission and approval of an exceptions request (per the instructions outlined above).

Current enrollees of a PFFS non-network plan or plans being consolidated into a new or renewal PFFS partial network plan will not be required to take any enrollment action, and the organization will not submit enrollment transactions to MARx for those current members, although it may need to submit updated 4Rx data to CMS for the current enrollees affected by the consolidation. New enrollees must complete enrollment requests, and the MAO will submit enrollment transactions to MARx for those new enrollees. Current enrollees of the consolidated PFFS partial network plan must receive a standard ANOC.

7b. ***Some Counties of a Non-Network PFFS Plan Transitioning to a Partial Network PFFS Plan***

An MAO with a PFFS non-network contract may consolidate some counties in the service area of a current non-network PFFS PBP into a single new or renewal partial network PFFS PBP under a separate contract held by the same legal entity. Current enrollees in the remaining counties in the non-network PFFS PBP may remain in that non-network PBP in the following

contract year provided the MAO follows the rules for a renewal plan with a SAR described elsewhere in this guidance.

Following the submission of an exceptions request (per the instructions outlined above) and its approval, the MAO must submit enrollment transactions to MARx for current enrollees in the counties affected by the SAR who will be transitioned to a new or renewing partial network PBP under a separate contract held by the same legal entity. CMS will provide specific instructions for the submission of these transactions later in the year. New enrollees must complete enrollment requests, and the MAO will submit enrollment transactions to MARx for those new enrollees as usual. Current enrollees transitioned to the PFFS partial network plan must receive a standard ANOC.

8a. ***Non-Network PFFS Plan Transitioning to a Full Network PFFS Plan***

An MAO with a PFFS non-network contract may consolidate one or more current entire non-network PFFS PBPs into a new or renewal full network PFFS PBP under a separate contract held by the same legal entity. HPMS will record the consolidation of one or more PBPs following the submission and approval of an exceptions request (per the instructions outlined above).

Current enrollees of a PFFS non-network plan or plans being consolidated into a new or renewal PFFS full network plan will not be required to take any enrollment action, and the organization will not submit enrollment transactions to MARx for those current members, although it may need to submit updated 4Rx data to CMS for the current enrollees affected by the consolidation. New enrollees must complete enrollment requests, and the MAO will submit enrollment transactions to MARx for those new enrollees. Current enrollees of the consolidated PFFS full network plan must receive a standard ANOC.

8b. ***Some Counties of a Non-Network PFFS Plan Transitioning to a Full Network PFFS Plan***

An MAO with a PFFS non-network contract may consolidate some counties in the service area of a current non-network PFFS PBP into a single new or renewal full network PFFS PBP under a separate contract held by the same legal entity. Current enrollees in the remaining counties in the non-network PFFS PBP may remain in that non-network PBP in the following contract year provided the MAO follows the rules for a renewal plan with a SAR described elsewhere in this guidance.

Following the submission of an exceptions request (per the instructions outlined above) and its approval, the MAO must submit enrollment transactions to MARx for current enrollees in the counties affected by the SAR who will be transitioned to a new or renewing full network PBP under a separate contract held by the same legal entity. CMS will provide specific instructions for the submission of these transactions later in the year. New enrollees must complete

enrollment requests, and the MAO will submit enrollment transactions to MARx for those new enrollees. Current enrollees transitioned to the PFFS full network plan must receive a standard ANOC.

9a. ***Partial Network PFFS Plan Transitioning to a Full Network PFFS Plan***

An MAO with a PFFS partial network contract may consolidate one or more current partial network PFFS PBPs into a new or renewal full network PFFS PBP under a separate contract held by the same legal entity. HPMS will record the consolidation of one or more PBPs following the submission and approval of an exceptions request (per the instructions outlined above).

Current enrollees of a PFFS partial network plan or plans being consolidated into a new or renewal PFFS full network plan will not be required to take any enrollment action, and the organization will not submit enrollment transactions to MARx for those current members. New enrollees must complete enrollment requests, and the MAO will submit enrollment transactions to MARx for those new enrollees. Current enrollees of the consolidated PFFS full network plan must receive a standard ANOC.

9b. ***Some Counties of a Partial Network PFFS Plan Transitioning to a Full Network PFFS Plan***

An MAO with a PFFS partial network contract may consolidate some counties in the service area of a current partial network PFFS PBP into a single new or renewal full network PFFS PBP under a separate contract held by the same legal entity. Current enrollees in the remaining counties in the partial network PFFS PBP may remain in that partial network PBP in the following contract year provided the MAO follows the rules for a renewal plan with a SAR described elsewhere in this guidance.

Following the submission of an exceptions request (per the instructions outlined above) and its approval, the MAO must submit enrollment transactions to MARx for current enrollees in the counties affected by the SAR who will be transitioned to a new or renewing full network PBP under a separate contract held by the same legal entity. CMS will provide specific instructions for the submission of these transactions later in the year. New enrollees must complete enrollment requests, and the MAO will submit enrollment transactions to MARx for those new enrollees. Current enrollees transitioned to the PFFS full network plan must receive a standard ANOC.

10a. ***Renewal Dual Eligible SNP (D-SNP) with No State Contract that Converts to a New D-SNP with a Different Designation and a State Contract***

An MAO currently offering a D-SNP PBP with no State contract that has requested conversion to a different D-SNP type under the same MAO contract may retain current eligible enrollees in the renewal D-SNP PBP. The renewing plan must retain the same PBP ID number as in the previous contract year.

Current enrollees who are eligible for the renewing D-SNP with the new designation and a State contract are not required to make an enrollment election to remain enrolled in the renewal PBP, and the MAO will not submit enrollment transactions to MARx for these current eligible enrollees. The MAO must submit disenrollment transactions to MARx for current enrollees who are no longer eligible for the new D-SNP's designation, pursuant to instructions that CMS will release later this year.

Current eligible enrollees remaining in the D-SNP must receive an ANOC. Current enrollees whose enrollment is terminated because they are no longer eligible for the renewal D-SNP's designation must be sent a disenrollment notice that includes notification of plan options, a special election period, and, if appropriate, Medigap guaranteed issue rights. (CMS anticipates providing a model for this special disenrollment notice in the final Call Letter)

10b. ***Consolidation of a Renewal Dual Eligible SNP (D-SNP) with a D-SNP with a State Contract***

An MAO currently offering one or more D-SNP PBPs with no State contracts may consolidate those PBPs into a single renewal PBP that is a D-SNP with a State contract (offered by the same MAO under the same contract and containing the applicable service area of all consolidating PBPs). The organization must retain one of the current year plan IDs as the renewal plan ID for the following contract year.

Current eligible enrollees are not required to make an enrollment election to remain enrolled in the consolidated renewal PBP, and the MAO will not submit enrollment transactions to MARx for those current eligible enrollees. However, the MAO must submit disenrollment transactions for current enrollees who are no longer eligible for the renewing D-SNP's designation, pursuant to instructions CMS will release later this year.

Current eligible enrollees of the consolidated PBP (including newly transitioned enrollees) must receive an ANOC. Current enrollees whose enrollment is terminated because they are no longer eligible for the new State contracted D-SNP's designation must be sent a disenrollment notice that includes notification of plan options, a special election period, and, if appropriate, Medigap

guaranteed issue rights. (CMS anticipates providing a model for this special disenrollment notice in the final Call Letter,)

11. MAO with a Renewing D-SNP that Also Creates a New Medicaid Subset D-SNP and Transitions Eligible Enrollees into the New Medicaid Subset D-SNP

An MAO that renews a current D-SNP that retains the same service area for CY 2012 and also creates a new Medicaid subset D-SNP PBP for the following contract year may transition the subset of current enrollees who are eligible for the new Medicaid subset into the new Medicaid subset D-SNP PBP and may retain current enrollees who are not eligible for the new Medicaid subset D-SNP in the renewing D-SNP. The renewing plan must retain the same PBP ID number as in the previous contract year. MAOs that meet the criteria for this renewal option must complete and submit a request to Sara Silver at sara.silver@cms.hhs.gov by June 6, 2011. She will coordinate the review of the request and, if approved, the MAO will be permitted to submit enrollment transactions to transition eligible current enrollees into the new Medicaid subset D-SNP. To request the exception, organizations must indicate in the subject line of the email "HPMS Medicaid Subset MARx enrollment exception for <Organization Name>" and include the following information in the request:

2011 Contract Number	2011 Contract Name	2011 Plan ID	2012 Contract Number	2012 Contract Name	2012 Plan ID of New Medicaid Subset D-SNP

Current enrollees not eligible for the new Medicaid subset D-SNP are not required to make an enrollment election to remain enrolled in the renewal PBP, and the MAO will not submit enrollment transactions to MARx for these current enrollees not eligible for the new Medicaid subset D-SNP. The MAO must submit enrollment transactions for current enrollees eligible for the new Medicaid subset D-SNP in order to enroll them in the new Medicaid subset D-SNP pursuant to instructions that CMS will release later this year. New enrollees in either the renewing or new Medicaid subset D-SNP must complete enrollment requests, and the MAO will submit enrollment transactions to MARx for those new enrollees.

Current enrollees not eligible for the new Medicaid subset D-SNP and who remain in the renewal D-SNP PBP must receive a standard ANOC. Current enrollees transitioned to the new Medicaid subset D-SNP must also receive a standard ANOC.

*12. **Renewing D-SNP in a Multi-State Service Area with a SAR to Accommodate State Contracting Efforts in Portions of that Service Area***

As MAOs make efforts to comply with State contracting requirements for CY 2013, we are aware that the nature of negotiations with States may particularly impact MAOs with D-SNPs that operate across State lines. CMS will therefore allow a narrow renewal exception described below.

An MAO that renews a current D-SNP PBP operating in a multi-State service area (a service area that covers counties in more than one state) may reduce the service area of the current contract year's PBP to accommodate State contracting in portions of the service area. The MAO may then transition enrollees in the reduced area, who are thus no longer eligible for the renewed D-SNP PBP, into a new or renewal SNP service area in the following contract year.

The renewing plan must retain the same PBP ID number as in the previous contract year so that current enrollees in the renewal portion of the service area remain enrolled in the same plan in the following contract year. MAOs cannot complete this renewal option in the HPMS Plan Crosswalk. An MAO that meets the criteria for this renewal option must complete and submit a request to Sara Silver at sara.silver@cms.hhs.gov by June 6, 2011. She will coordinate the review of the request and, if approved, the MAO will be permitted to submit enrollment transactions to transition eligible current enrollees into a new or renewal D-SNP. To request the exception, organizations must indicate in the subject line of the email "HPMS Renewing D-SNP in a Multi-State Service Area with a SAR enrollment exception for <Organization Name>" and include the following information in the request:

2011 Contract Number	2011 Contract Name	2011 Plan ID	2012 Contract Number	2012 Contract Name	2012 SNP Plan ID of New or Renewal Plan

Current enrollees who remain eligible for the renewing D-SNP PBP are not required to make an enrollment election to remain enrolled in the renewal PBP, and the MAO will not submit enrollment transactions to MARx for these current enrollees. The MAO must submit enrollment transactions for current enrollees being transitioned to a new or renewal D-SNP in order to enroll them in the new or renewal SNP pursuant to instructions that CMS will release later this year. New enrollees in any of the plans affected by this transition must complete enrollment requests, and the MAO will submit enrollment transactions to MARx for those new enrollees.

Current enrollees who remain in the renewal D-SNP PBP must receive a standard ANOC.

Current enrollees transitioned to a new or renewal D-SNP must also receive a standard ANOC.

13. ***Renewing SNP with Ineligible or "Disproportionate Share" Members***

As provided under MIPPA and section 3205(c) of the Affordable Care Act, SNPs may only enroll individuals who meet the plan's specific eligibility criteria; they may no longer enroll and serve a "disproportionate share" of individuals who do not meet the targeted criteria or condition. Also pursuant to MIPPA, chronic care SNPs (C-SNPs) may only enroll and serve individuals with certain chronic conditions, as specified by CMS.

Many SNPs currently include members: (1) who enrolled prior to January 1, 2010 under the previous "disproportionate share" policy option (i.e., the members did not meet the special needs criteria at the time of enrollment); or (2) who were enrolled in a C-SNP as of January 1, 2010, but no longer met the special needs criteria as of that date. In both of these circumstances, rather than require the MAO offering these SNPs to involuntarily disenroll these members as of December 31, 2009 because they no longer met the SNP's targeted criteria, CMS required the MAOs to allow these individuals to continue to be enrolled through CY 2011. However, effective CY 2012, SNPs that include members who enrolled under the two circumstances described above will be required to disenroll those individuals if they do not request enrollment in a different plan prior to January 1, 2012. MAOs will not be permitted to transition these current enrollees into other non-SNP MA plans offered by the organization. However, MAOs must retain any of these enrollees whose circumstances change and who attain special needs status prior to CY 2012.

In order to facilitate this process, in our January 11, 2010 HPMS memorandum, we required MAOs offering SNPs to provide their account managers with information regarding the total number of non-special needs individuals enrolled in these SNPs as of January 1, 2010. A similar process should be followed this year and more details will be provided in an upcoming HPMS memorandum. This accounting will assist MAOs with notifying and disenrolling these individuals for CY 2012. Once they have identified these members, MAOs must notify each individual on or before October 1, 2011, that he/she will be disenrolled effective January 1, 2012, and will need to enroll in another plan prior to that date if he/she wants MA coverage for CY 2012.

The MAO must submit disenrollment transactions to MARx for those individuals who do not meet the plan's specific eligibility criteria, pursuant to instructions that CMS will release this year. The MAO will send a disenrollment notice that includes notification of plan options, a special election period, and, if appropriate, Medigap guaranteed issue rights.

Refer to the renewal plan guidance provided in this memorandum for the notification requirements for current SNP enrollees who are not among the non-special needs individuals described above and will remain enrolled in the plan for 2012.

Enrollees whose enrollment is terminated because they lose their special needs status in 2011 must be sent a termination notice that includes notification of plan options, a special election period, and, if appropriate, Medigap guaranteed issue rights.[9]

II. Section 1876 Cost Contract Renewal and Non-Renewal Guidance

In general, the MA renewal and non-renewal guidance above applies to section 1876 cost contracts that submit PBPs.

A section 1876 cost contract may not, like MA plans, offer separate PBPs. Instead, a cost contract may offer supplemental benefits as separate collections of benefits under its contract for purposes of Medicare Plan Finder and Medicare & You. Because such benefit collections are not considered separate PBPs, a cost contract, unlike an MA plan, is not considered to have terminated a PBP. In the HPMS plan crosswalk, cost contracts are required to consolidate any collection of benefits that have been marked as "terminated" with another collection of benefits. Thus, instead of disenrolling the individual as in the transactions identified in the MA renewal and non-renewal guidance above, the cost contract must send an ANOC to enrollees specifying the benefit changes and notifying the beneficiary that he or she will remain enrolled in the cost contract's A and B-only package (with or without Part D depending on the individual's original election), or, if the enrollee so chooses, may receive one of the cost contract's other benefit packages.

[9] Plans should note that the notification policy in this paragraph applies to those SNP enrollees who lost special needs status in 2011 *not* to disproportionate share enrollees who were not eligible for the SNP as of January 1, 2010.

Appendix A-2 – Contract Year 2012 Guidance for Medicare Advantage and Medicare Advantage Prescription Drug Plan Renewals

	Activity	Guidelines	Renewal Effectuation Method	Systems Enrollment Activities	Enrollment Procedures	Beneficiary Notifications
1	New Plan (PBP) Added.	An MAO creates a new plan benefit package (PBP). .	**HPMS Plan Crosswalk Definition:** A new plan added for 2012 that is not linked to a 2011 plan.. **HPMS Plan Crosswalk Designation:** New Plan	The MAO must submit enrollment transactions for 2012.	New enrollees must complete an enrollment request.	None
2	Renewal Plan.	An MAO continues to offer a CY 2011 MA PBP in CY 2012 and retains all of the same service area. **The same PBP ID number must be retained** in order for all current enrollees to remain in the same MA PBP in CY 2012..	**HPMS Plan Crosswalk Definition:** A 2012 plan that links to a 2011 plan and retains all of its plan service area from 2011. The 2012 plan must retain the same plan ID as the 2011 plan. **HPMS Plan Crosswalk Designation:** Renewal Plan	**The renewal PBP ID must remain the same** so that current enrollees will remain in the same PBP ID. . The MAO **does not** submit enrollment transactions for current enrollees.	No enrollment request is required for current enrollees to remain enrolled in the renewal PBP in 2012. . New enrollees must complete enrollment requests.	Current enrollees are sent a standard ANOC.

Appendix A-2

	Activity	Guidelines	Renewal Effectuation Method	Systems Enrollment Activities	Enrollment Procedures	Beneficiary Notifications
3	Consolidated Renewal Plan.	An MAO ***combines one or more whole MA PBPs*** of the same type offered in CY 2011 into a single renewal PBP so that all current enrollees in combined PBP are offered the same benefits in CY 2012.. The MAO must designate which of the renewal PBP IDs will be retained in CY 2012 after consolidation. CMS will not allow for consolidations across contracts (with limited exceptions for some renewal options, as described elsewhere in this guidance). Only whole PBPs may be consolidated; a CY 2011 PBP may not be split among different PBPs in CY 2012.. **Note:** If an MAO reduces a service area when consolidating PBP, it must follow the rules for a renewal plan with SAR described elsewhere in this guidance.	**HPMS Plan Crosswalk Definition:** One or more 2011 plans that consolidate into one 2012 plan. The 2012 plan ID must be the same as one of the consolidating 2011 plan IDs. . **HPMS Plan Crosswalk Designation:** Consolidated Renewal Plan.	**The MAO's designated renewal PBP ID must remain the same** so that CMS can consolidate enrollees into the designated renewal PBP ID in CMS systems. . The MAO **does not** submit enrollment transactions for current enrollees. The MAO may have to submit 4Rx data for individuals whose PBP number changed..	No enrollment request is required for current enrollees to remain enrolled in the renewal PBP in 2012.. New enrollees must complete enrollment request.	Current enrollees are sent a standard ANOC.

Appendix A-2

	Activity	Guidelines	Renewal Effectuation Method	Systems Enrollment Activities	Enrollment Procedures	Beneficiary Notifications
4	Renewal Plan with an SAE.	**This option is available to local MA Plans only.** An MAO continues to offer a CY 2011 local MA PBP in CY 2012 and retains all of the same PBP service area, but also adds one or more new service areas. **The same PBP ID number must be retained** in order for all current enrollees to remain in the same MA PBP in CY 2012..	**HPMS Plan Crosswalk Definition:** A 2012 plan that links to a 2011 plan and retains all of its plan service area from 2011, but also adds one or more new counties. The 2012 plan must retain the same plan ID as the 2011 plan.. **HPMS Plan Crosswalk Designation:** Renewal Plan with an SAE. **Note**: If the 2012 plan has both an SAE and a SAR, the plan must be renewed as a renewal plan with a SAR..	**The renewal PBP ID must remain the same** so that current enrollees in the remaining in the service area will remain in the same PBP ID.. The MAO **does not** submit enrollment transactions for current 2011 enrollees. The MAO submits enrollment transactions for new enrollees.	No enrollment request is required for current enrollees to remain enrolled in the renewal PBP in 2012.. New enrollees must complete enrollment request.	Current enrollees are sent a standard ANOC.

Appendix A-2

	Activity	Guidelines	Renewal Effectuation Method	Systems Enrollment Activities	Enrollment Procedures	Beneficiary Notifications
5a	Renewal Plan with a SAR and no other MA options available	**This option is available to local MA plans only.** An MAO reduces the service area of a CY 2011 MA PBP and the reduced service area is not contained in another MA PBP offered by the same organization or any other MAO.**.** The MAO **may offer** the option to individuals in the reduced portion of the service area for CY 2012 to enroll in its remaining PBP if no other MA plans are available (see 42 CFR § 422.74(b)(3)(ii)).. **Note:** One renewal plan with a SAR may have counties that should follow the guidance provided in 5a, and other counties in the SAR that should follow the guidance provided under 5b (i.e., the guidance provided in 5a and 5b may both apply to a single plan).	**HPMS Plan Crosswalk Definition:** A 2012 plan that links to a 2011 plan and only retains a portion of its plan service area. The 2012 plan must retain the same plan ID as the 2011 plan.. **HPMS Plan Crosswalk Designation:** Renewal Plan with a SAR. **Note**: If the 2012 plan has both an SAE and a SAR, the plan must be renewed as a renewal plan with a SAR	The MAO **must submit disenrollment transactions** for individuals residing in the reduced portion of the service area for whom it does not collect an enrollment request.. The MAO does not submit enrollment transactions for current enrollees in the renewal portion of the service area.	Enrollees impacted by the SAR need to complete an enrollment request if the MAO offers the option of continued enrollment (see 42 CFR § 422.74(b) (3) (ii))..	The MAO sends a termination notice to current enrollees in the reduced service area that includes notification of SEP and guaranteed issue Medigap rights. The MAO may also provide affected enrollees additional information, within or following the termination notice, about the option to remain enrolled in the plan if the MAO elects to offer enrollment to enrollees in the reduced portion of the service area. . Current enrollees in the renewal portion of the service area receive the standard ANOC..

Appendix A-2

	Activity	Guidelines	Renewal Effectuation Method	Systems Enrollment Activities	Enrollment Procedures	Beneficiary Notifications
5b	Renewal Plan with a SAR when the MAO will offer another PBP in the reduced portion of the service area	**This option is available to local MA plans only.** An MAO reduces the service area of a CY 2011 MA PBP and the reduced service area is part of a new or renewal PBP offered by that MAO in 2012. . The MAO **may market** to enrollees in the reduced service area any other PBP offered in the reduced service area for CY 2012. Affected enrollees who elect to enroll in another MA plan offered in the reduced service area must submit an enrollment request.. **Note:** One renewal plan with a SAR may have counties that should follow the guidance provided in 5a and other counties in the SAR that should follow the guidance provided under 5b (i.e., the guidance provided in 5a and 5b may both apply to a single plan**).**	**HPMS Plan Crosswalk Definition:** A 2012 plan that links to a 2011 plan and only retains a portion of its plan service area. The 2012 plan must retain the same plan ID as the 2011 plan.. **HPMS Plan Crosswalk Designation:** Renewal Plan with a SAR. **Note**: If the 2012 plan has both an SAE and a SAR, the plan must be renewed as a renewal plan with a SAR.	The MAO **must submit transactions to disenroll individuals** residing in the reduced portion of the service area. . The MAO submits enrollment transactions to enroll beneficiaries who have requested enrollment in other PBP offered in the reduced service area. .	Enrollees impacted by the SAR **need to complete enrollment requests** if they elect to enroll in another PBP (plan) in the same organization or a different MA plan.	The MAO sends a termination notice to current enrollees in the reduced portion of the service area that includes notification of SEP and guaranteed issue Medigap rights. The MAO may also provide additional information, within or following the termination notice, including instructions on how to complete an enrollment request to switch to another PBP offered by the same organization.. Current enrollees in the renewal portion of the service area receive the standard ANOC.
6	Terminated Plan (Non-Renewal).	An MAO terminates the offering of a CY 2011 PBP..	**HPMS Plan Crosswalk Definition:** A 2011 plan that is no longer offered in 2012. **.** **HPMS Plan Crosswalk Designation:** Terminated Plan..	The MAO **does not** submit disenrollment transactions. If the terminated enrollee elects to enroll in another MA plan with the same or any other MAO, that organization **must submit enrollment transactions** to enroll the beneficiary.	Terminated enrollees must complete an enrollment request if they choose to enroll in another PBP, even in the same organization.	Terminated enrollees are sent a termination notice that includes notification of SEP and guaranteed issue Medigap rights.

Appendix A-2

	Activity	Guidelines	Renewal Effectuation Method	Systems Enrollment Activities	Enrollment Procedures	Beneficiary Notifications
7a	Non-network PFFS plan transitioning to a partial network PFFS plan.	**For PFFS only:** An MAO **consolidates** one or more CY 2011 non-network PFFS PBPs into a single new or renewing CY 2012 partial PFFS PBP under a separate contract held by the same legal entity. Only consolidation of whole PBPs is allowed under this option; PBPs may not be split.	**Exceptions Renewal Request:** Organizations cannot complete this transition via the HPMS Plan Crosswalk. Organizations must submit an exceptions request to CMS staff, who will complete the transition on behalf of the organization. . **HPMS Plan Crosswalk Designation:** The non-network plan being transitioned must be marked as a terminated plan in the HPMS Plan Crosswalk. The 2012 partial network plan must be active and contain the applicable service area from the terminated plan being renewed.	HPMS will record the consolidation of one or more whole PBPs. The MAO **does not** submit enrollment transactions for current enrollees.. MAOs may need to submit updated 4RX data for enrollees affected by the consolidation.	No enrollment request is required for current enrollees to remain enrolled in the renewal PBP in 2012.. New enrollees must complete enrollment request..	Current enrollees are sent a standard ANOC.

Appendix A-2

	Activity	Guidelines	Renewal Effectuation Method	Systems Enrollment Activities	Enrollment Procedures	Beneficiary Notifications
7b.	Some counties of a non-network PFFS plan transitioning to a partial network PFFS plan.	**For PFFS only:** For the counties in the 2011 non-network PFFS PBP that will remain non-network, the MAO must follow the rules for a renewal plan with SAR described elsewhere in this guidance.. For current enrollees residing in the counties in the 2011 non-network PFFS PBP that will be consolidated into a single new or renewing partial network PBP under a separate contract held by the same legal entity, the MAO must submit enrollment transactions.	**Exceptions Crosswalk Request: .** Organizations cannot complete the transition of current enrollees to the partial network PFFS plan via the HPMS Plan Crosswalk. Organizations must submit an exceptions request to CMS. If approved, the MAO will be permitted to submit enrollment transactions. . **HPMS Plan Crosswalk Definition:** A 2012 non-network plan that links to a 2011 non-network plan and only retains the available non-network counties in its plan service area. The 2012 plan must retain the same plan ID as the 2011 plan.. **HPMS Plan Crosswalk Designation:** Renewal Plan with a SAR	The MAO **must** submit enrollment transactions to transition current enrollees to the new or renewing partial network PBP under a separate contract held by the same legal entity. . For current enrollees that remain in the renewed non-network PFFS plan, the MAO does not submit enrollment transactions.	No enrollment request is required for current enrollees.. New enrollees must complete enrollment requests.	Current enrollees are sent a standard ANOC.

Appendix A-2

	Activity	Guidelines	Renewal Effectuation Method	Systems Enrollment Activities	Enrollment Procedures	Beneficiary Notifications
8a.	Non-network PFFS plan transitioning to a full network PFFS plan.	**For PFFS only:** An MAO consolidates one or more whole CY 2011 non-network PFFS PBPs into a single new or renewing CY 2012 full network PFFS PBP under a separate contract held by the same legal entity. Under this option, only consolidation of whole PBPs is allowed; PBPs may not be split.	**Exceptions Crosswalk Request:** Organizations cannot complete this transition via the HPMS Plan Crosswalk. Organizations must submit an exceptions request to CMS staff, who will complete the transition on behalf of the organization.. **HPMS Plan Crosswalk Designation:** The non-network plan being transitioned must be marked as a terminated plan in the HPMS Plan Crosswalk. . The 2012 full network plan must be active and contain the applicable service area from the terminated plan being transitioned.	HPMS will record the consolidation of one or more whole PBPs. The MAO **does not** submit enrollment transactions for current enrollees.. MAOs may need to submit updated 4RX data for enrollees affected by the consolidation.	No enrollment request is required for current enrollees to remain enrolled in the renewal PBP in 2012.. New enrollees must complete enrollment requests.	Current enrollees are sent a standard ANOC.

Appendix A-2

	Activity	Guidelines	Renewal Effectuation Method	Systems Enrollment Activities	Enrollment Procedures	Beneficiary Notifications
8b.	Some counties of a non-network PFFS plan transitioning to a full network PFFS plan.	**For PFFS only:** For the counties in the 2011 non-network PFFS PBP that will remain non-network, the MAO must follow the rules for a renewal plan with SAR described elsewhere in this guidance.. For current enrollees residing in the counties in the 2011 non-network PFFS PBP that will be consolidated into a single new or renewing full network PBP under a separate contract held by the same legal entity, the MAO must submit enrollment transactions.	**Exceptions Crosswalk Request:** Organizations cannot complete the transition of current enrollees to the full network PFFS plan via the HPMS Plan Crosswalk. Organizations must submit an exceptions request to CMS. If approved, the MAO will be permitted to submit enrollment transactions. **HPMS Plan Crosswalk Definition:** A 2012 non-network plan that links to a 2011 non-network plan and only retains the available non-network counties in its plan service area. The 2012 plan must retain the same plan ID as the 2011 plan.. **HPMS Plan Crosswalk Designation:** Renewal Plan with a SAR.	The MAO **must** submit enrollment transactions to transition current enrollees to the new or renewing full network PBP under a separate contract held by the same legal entity. . For current enrollees that remain in the renewed non-network PFFS plan the MAO does not submit enrollment transactions.	No enrollment request is required for current enrollees.. New enrollees must complete enrollment requests.	Current enrollees are sent a standard ANOC.

Appendix A-2

	Activity	Guidelines	Renewal Effectuation Method	Systems Enrollment Activities	Enrollment Procedures	Beneficiary Notifications
9a	Partial network PFFS plan transitioning to a full network PFFS plan.	**For PFFS only:** An MAO consolidates one or more CY 2011 partial network PFFS PBPs into a single new or renewing CY 2012 full network PFFS PBP under a separate contract held by the same legal entity. Only consolidation of whole PBPs is allowed; PBPs may not be split.	**Exceptions Renewal Request:** Organizations cannot complete this transition via the HPMS Plan Crosswalk. Organizations must submit an exceptions request to CMS staff, who will complete the transition on behalf of the organization. . **HPMS Plan Crosswalk Designation:** The partial network plan being transitioned must be marked as a terminated plan in the HPMS Plan Crosswalk. . The 2012 full network plan must be active and contain the applicable service area from the terminated plan being transitioned..	HPMS will record the consolidation of one or more whole PBPs. The MAO **does not** submit enrollment transactions for current enrollees.. MAOs may need to submit updated 4RX data for enrollees affected by the consolidation, as applicable.	No enrollment request is required for current enrollees to remain enrolled in the renewal PBP in 2012.. New enrollees must complete enrollment requests.	Current enrollees are sent a standard ANOC.

Appendix A-2

	Activity	Guidelines	Renewal Effectuation Method	Systems Enrollment Activities	Enrollment Procedures	Beneficiary Notifications
9b.	Some counties of a partial PFFS plan transitioning to a full network PFFS plan.	**For PFFS only:** For the counties in the 2011 partial network PFFS PBP that will remain partial, the MAO must follow the rules for a renewal plan with SAR described elsewhere in this guidance.. For current enrollees residing in the counties in the 2011 partial network PFFS PBP that will be consolidated into a single new or renewing full network PBP under a separate contract held by the same legal entity, the MAO must submit enrollment transactions.	**Exceptions Crosswalk Request:** Organizations cannot complete the transition of current enrollees to the full network PFFS plan via the HPMS Plan Crosswalk. Organizations must submit an exceptions request to CMS. If approved, the MAO will be permitted to submit enrollment transactions.. **HPMS Plan Crosswalk Definition:** A 2012 partial network plan that links to a 2011 partial network plan and only retains the available partial network counties in its plan service area. The 2012 plan must retain the same plan ID as the 2011 plan. **HPMS Plan Crosswalk Designation:** Renewal Plan with a SAR.	The MAO **must** submit enrollment transactions to transition current enrollees to the new or renewing full network PBP under a separate contract held by the same legal entity. . For current enrollees that remain in the renewed partial-network PFFS plan the MAO does not submit enrollment transactions.	No enrollment request is required for current enrollees.. New enrollees must complete enrollment requests.	Current enrollees are sent a standard ANOC.
10a.	Renewal D-SNP PBP with no State contract that converts to a different D-SNP designation and a State contract such that the same CY 2011 D-SNP PBP with no State contract still exists, but has a State contract and a different title for CY 2012	**For D-SNPs only**: An MAO offering a CY 2011 D-SNP PBP with no State contract that renews and has converted to a different D-SNP type for CY 2012.	**HPMS Plan Crosswalk Definition:** A 2012 plan that links to a 2011 plan and retains all of its plan service area from 2011. The 2012 plan must retain the same plan ID as the 2011 plan. **HPMS Plan Crosswalk Designation:** Renewal Plan	The MAO does not send enrollment transactions for current enrollees who will remain enrolled in the 2012 renewal PBP.. The MAO submits disenrollment transactions for current enrollees who are ineligible for the renewing D-SNP.	No enrollment request is required for current enrollees who are eligible to remain enrolled in the renewal PBP in 2012.. New enrollees must complete enrollment requests.	Current enrollees eligible to remain enrolled in the renewal plan receive a standard ANOC. . The MAO sends a CMS model disenrollment notice to ineligible current enrollees who are disenrolled, which will convey SEP and, if appropriate, guaranteed issue Medigap rights.

Appendix A-2

	Activity	Guidelines	Renewal Effectuation Method	Systems Enrollment Activities	Enrollment Procedures	Beneficiary Notifications
10b.	D-SNP with no State contract consolidating with a D-SNP with a State contract, so that, effectively, an entire D-SNP is transferred into another D-SNP with a state contract and the D-SNP without a State contract no longer exists	**For D-SNPs only**: An MAO offering a CY 2011 D-SNP PBP with no State contract may consolidate with a CY 2012 D-SNP, offered under the same contract, which has a contract with the State.	**HPMS Plan Crosswalk Definition:** Two or more whole 2011 D-SNP plans (PBPs) that consolidate into one 2012 plan. The 2012 plan ID must be D-SNP with the state contract. **HPMS Plan Crosswalk Designation:** Consolidated Renewal Plan.	The MAO does not send enrollment transactions for current enrollees who will remain enrolled in the 2012 PBP.. The MAO must submit disenrollment transactions for current enrollees who are ineligible for the renewal PBP.	No enrollment request is required for current eligible enrollees to remain enrolled in the renewal PBP in 2012.. New enrollees must complete enrollment requests.	Current enrollees eligible to remain enrolled in the renewal plan receive a standard ANOC. . The MAO sends a CMS model disenrollment notice to ineligible current enrollees who are disenrolled, which will convey SEP and, if appropriate, guaranteed issue Medigap rights.
11.	Renewing D-SNPs that also creates new Medicaid subset D-SNP and transitions eligible enrollees into the new Medicaid subset D-SNP	**For D-SNPs only**: An MAO renewing a D-SNP plan for 2012 and also creating a new Medicaid subset D-SNP for 2012. A subset of current enrollees under the renewing D-SNP is eligible to be enrolled in the new Medicaid subset D-SNP. The organization must submit enrollment transactions to move the eligible D-SNP enrollees into the new Medicaid subset D-SNP..	**Exceptions Crosswalk Request:** Organizations **must** submit an exceptions request to CMS to transition eligible enrollees into the new Medicaid subset D-SNP.. **HPMS Plan Crosswalk Definition:** A 2012 D-SNP that links to a 2011 D-SNP and retains all of its plan service area from 2011. The 2012 plan must retain the same plan ID as the 2011 plan.. In addition, a new Medicaid Subset plan is added for 2012 that is not linked to a 2011 plan.. **HPMS Plan Crosswalk Designation:** Renewal Plan Renewal Plan (renewing D-SNP designation) AND New Plan (new Medicaid Subset D-SNP designation).	**The renewal PBP ID must remain the same** so that the HPMS Plan Crosswalk will indicate that beneficiaries remain in the same PBP ID. . The MAO **must** submit enrollment transactions to transition eligible current enrollees into the new Medicaid subset D-SNP. . Individual enrollees not transitioned by the submission of enrollment transactions will remain enrolled in the renewing PBP..	No enrollment request is required for current enrollees to remain enrolled in the renewal PBP in 2012. . New enrollees must complete enrollment request.	Current enrollees transitioned to the renewal plan receive a standard ANOC. Current enrollees who are transitioned to the new Medicaid subset PBP receive a standard ANOC.

Appendix A-2

	Activity	Guidelines	Renewal Effectuation Method	Systems Enrollment Activities	Enrollment Procedures	Beneficiary Notifications
12.	Renewing D-SNP in a multi-state service area with a SAR to accommodate State contracting efforts in portions of that service area	**For D-SNPs only:** An MAO reduces the service area of a CY 2011 D-SNP PBP to accommodate State contracting efforts in a multi-State service area. Current enrollees in the reduced portion of the service area are transitioned to one or more new or renewing CY 2012 D-SNP PBPs. The organization must submit enrollment transactions to move current enrollees in the reduced portion of the CY 2011 D-SNP PBP into the new or renewing CY 2012 D-SNP PBPs.	**Exceptions Crosswalk Request:** Organizations **must** submit an exceptions request to CMS to disenroll individuals residing in the reduced portion of the service area and to enroll those individuals in more than one PBP. **HPMS Plan Crosswalk Designation:** A 2012 plan that links to a 2011 plan and only retains a portion of its plan service area. The 2012 plan must retain the same plan ID as the 2011 plan.. In addition, a new plan is added for 2012 that is not linked to a 2011 plan, or a 2011 plan is renewed in 2012.. **HPMS Plan Crosswalk Designation:** Renewal Plan with a SAR AND New Plan OR Renewal Plan	**The renewal PBP ID must remain the same** so that the HPMS Plan Crosswalk will indicate that beneficiaries remain in the same PBP ID . The MAO **must** submit enrollment transactions to transition current enrollees in the reduced portion of the service area into a new or renewing D-SNP.. Individual enrollees not transitioned by the submission of enrollment transactions will remain enrolled in the renewing PBP.	No enrollment request is required for current enrollees in the remaining portion of the service area to remain enrolled in the renewal PBP in CY 2012. . New enrollees must complete enrollment request.	Current enrollees in the renewal portion of the service area receive the standard ANOC. . Current enrollees in the reduced portion of the service area who are transitioned to a new or renewal D-SNP PBP receive the standard ANOC.

Appendix A-2

	Activity	Guidelines	Renewal Effectuation Method	Systems Enrollment Activities	Enrollment Procedures	Beneficiary Notifications
13.	Renewing SNP with ineligible, or "disproportionate share," enrollees.	**For D-SNPs only**: An MAO renewing a SNP that includes a subset of current enrollees who do not meet the eligibility criteria for enrollment in the SNP ("disproportionate share" enrollees or enrollees affected by change in scope of C-SNP).	**HPMS Plan Crosswalk Definition:** A 2012 plan that links to a 2011 plan and retains all of its plan service area from 2011. The 2012 plan must retain the same plan ID as the 2011 plan. **HPMS Plan Crosswalk Designation:** Renewal Plan	The MAO does not send enrollment transactions for current enrollees who meet the SNP eligibility criteria for enrollment and will remain enrolled in the 2012 PBP.. Plans must submit disenrollment transactions for current enrollees who do not meet the eligibility criteria for enrollment in the SNP.	No enrollment request is required for enrollees eligible to remain enrolled in the renewal PBP in 2012.. New enrollees must complete enrollment requests.	Enrollees who remain eligible for the renewing plan receive a standard ANOC. . The MAO sends a CMS model disenrollment notice to ineligible current enrollees who are disenrolled, which will convey SEP and, if appropriate, guaranteed issue Medigap rights.

Appendix B-1: CY 2012 PDP PBP Renewal and Non-Renewal Guidance

PDP regions are defined by CMS and consist of one or more entire states (refer to Appendix 3, Chapter 5, of the Prescription Drug Benefit Manual for a map of the 34 PDP regions). Each PDP sponsor's PBPs must be offered in at least one entire region and a PDP sponsor's PBP cannot be offered in only part of a region. Please note that PDP bidding rules require PDP sponsors to submit separate bids for each region to be covered. HPMS only accepts a PDP sponsor's PBPs to cover one region at a time for individual market plans (e.g., a PDP sponsor offering a "national" PDP must submit 34 separate PBP bids in order to cover all PDP regions).

A PDP sponsor may expand the service area of its offerings by submitting additional bids in the PDP regions the sponsor expects to enter in the following contract year, provided the sponsor submits a PDP Service Area Expansion (SAE) application and CMS approves that application and then approves the sponsor's submitted bids for the new region or regions. For more information about the application process, refer to: http://www.cms.hhs.gov/PrescriptionDrugCovContra/04_RxContracting_ApplicationGuidance.asp#TopOfPage.

Conversely, a PDP sponsor may reduce its service area by electing not to submit bids for those regions from which it expects to withdraw. A PDP sponsor must notify CMS in writing (by sending an email to drugbenefitimpl@cms.hhs.gov) of its intent to non-renew one or more plans under a contract by the first Monday in June[10] pursuant to 42 CFR §423.507(a)(2)(i). The same procedure applies to PDPs converting contracts from offering both individual and employer products to employer-only products. However, even absent written notification to CMS, a PDP sponsor's failure to submit a timely bid to CMS constitutes a voluntary non-renewal by the sponsor. (Note that PDP sponsors reducing their service areas must provide notice of their action to affected beneficiaries consistent with regulatory requirements, CMS' PDP Eligibility, Enrollment, and Disenrollment Guidance, Chapter 3 of the Prescription Drug Benefit Manual and CMS non-renewal and service area reduction guidance.)

Each renewal/non-renewal option available to PDP sponsors for CY 2012 is outlined in Appendix B-2 and summarized below. All but one of these actions can be effectuated by PDP sponsors in the HPMS Plan Crosswalk.

1. New Plan Added

A PDP sponsor may create a new PBP for the following contract year with no link to a PBP it offers in the current contract year in the HPMS Plan Crosswalk. In this situation, beneficiaries electing to enroll in the new PBP must complete enrollment requests, and the PDP sponsor

[10] CY 2012 bids are due no later than June 6, 2011

offering the PBP must submit enrollment transactions to MARx. No beneficiary notice is required in this case beyond receipt of the Evidence of Coverage (EOC), and other documents as required by current CMS guidance, following enrollment.

2. Renewal Plan

A PDP sponsor may continue to offer a current PBP that retains all of the same service area for the following year. The renewing plan must retain the same PBP ID number as in the previous contract year in the HPMS Plan Crosswalk. Current enrollees are not required to make an enrollment election to remain enrolled in the renewal PBP, and the sponsor will not submit enrollment transactions to MARx for current enrollees. New enrollees must complete enrollment requests, and the sponsor will submit enrollment transactions to MARx for those new enrollees. Current enrollees of a renewed PBP must receive a standard Annual Notice of Change (ANOC) notifying them of any changes to the renewing plan.

3. Consolidated Renewal Plan

PDP sponsors are permitted to combine two or more entire PBPs offered in the current contract year into a single renewal plan in the HPMS Plan Crosswalk. A PDP sponsor may not split a current PBP among more than one PBP for the following contract year. A PDP sponsor consolidating one or more entire PBPs must designate which of the renewal PBP IDs will be retained following the consolidation; the organization's designated renewal plan ID must remain the same in order for CMS to consolidate the beneficiary's election by moving him or her into the designated renewal plan ID. This is particularly important with respect to minimizing beneficiary confusion when a plan consolidation affects a large number of enrollees. When consolidating two existing PBPs into a single renewal PBP, it is permissible for the single renewal PBP to result in a change from:

(1) A basic benefit design (meaning either defined standard, actuarially equivalent standard, or basic alternative benefit designs) to another basic benefit design;
(2) An enhanced alternative benefit design to a basic benefit design; or
(3) An enhanced alternative benefit design to another enhanced alternative benefit design.

We will not, however, permit consolidation of two existing PBPs into a single renewal PBP through the HPMS Plan Crosswalk when it involves a change from a basic benefit design to an enhanced alternative benefit design, since enrollees previously not subject to a supplemental premium under a basic benefit design will have to pay a combined basic and supplemental premium under an enhanced alternative benefit design that may be higher than a basic premium.

Current enrollees of a plan or plans being consolidated into a single renewal plan will not be required to take any enrollment action, and the sponsor will not submit enrollment transactions to

MARx for those current members, although it may need to submit updated 4Rx data to CMS for the current enrollees affected by the consolidation. New enrollees must complete enrollment requests, and the sponsor will submit enrollment transactions to MARx for those new enrollees. Current enrollees of a consolidated renewal plan must receive a standard ANOC.

4. Renewal Plan with a Service Area Expansion ("800 Series" EGWPs only)

A PDP sponsor offering an 800 series EGWP PBP in the current contract year may expand its EGWP service area to include additional PDP regions for the following contract year through the Part D application process. In order for currently enrolled beneficiaries to remain in the renewed PBP, the sponsor must retain the same PBP identification number for the following contract year.

Current enrollees will not be required to take any enrollment action, and the sponsor will not submit enrollment transactions to MARx for those current enrollees. New enrollees must complete enrollment requests, and the sponsor will submit enrollment transactions to MARx for those new enrollees. Current enrollees of a renewed PBP with a SAE must receive a standard ANOC notifying them of any changes to the renewing plan.

5. Terminated Plan (Non-Renewal)

A PDP sponsor may elect to terminate a current PBP for the following contract year. In this situation, the sponsor will not submit disenrollment transactions to MARx for affected enrollees. When a sponsor terminates a PBP, plan enrollees must make a new election for their Medicare coverage in the following contract year. To the extent that a current enrollee of a terminated PBP elects to enroll in another plan offered by the current or another PDP sponsor – or, alternatively, elects to enroll in an MA plan – he/she must complete an enrollment request, and the enrolling organization or sponsor must submit enrollment transactions to MARx so that those individuals are enrolled. Enrollees of terminated PBPs will be sent a model termination notice that includes notification of a special election period. For more information about non-renewal processes and beneficiary notification requirements, refer to our forthcoming HPMS memorandum providing non-renewal and service area reduction guidance and model notices, to be released this summer.

6. Consolidated Plans under a Parent Organization

For purposes of ensuring compliance with transition requirements following an acquisition or merger under our significant differences policy, or to make plan transitions following a novation, CMS may elect to combine two or more entire PBPs offered under different contracts (the contracts may be offered by the same legal entity or represent different legal entities). PDP sponsors cannot complete this renewal option in the HPMS Plan Crosswalk. A PDP sponsor must complete and submit a request to Sara Silver at sara.silver@cms.hhs.gov by June 6, 2011.

She will coordinate the review of the request and, if approved, complete the renewal on behalf of the requesting PBP. To request the exception, organizations must include in the subject line of the email "HPMS PDP Plan Consolidation across contracts for <Organization Name>" and include the following information in the request:

2011 Contract Number	2011 Contract Name	2011 Plan ID	2012 Contract Number	2012 Contract Name	2012 Plan ID	Reason for Request (Merger, Acquisition, Novation)

Current enrollees of a plan or plans being consolidated across contracts in this manner will not be required to take any enrollment action, and the sponsor will not submit enrollment transactions to MARx for those current members, although it may need to submit updated 4Rx data to CMS for the current enrollees affected by the consolidation. New enrollees must complete enrollment requests, and the sponsor will submit enrollment transactions to MARx for those new enrollees.

Current enrollees of a consolidated renewal plan must receive a special notice along with a standard ANOC. (CMS anticipates providing a model for this special notice in the final Call Letter)

Appendix B-2 – Contract Year 2012 Guidance for Prescription Drug Plan Renewals

	Activity	Guidelines	HPMS Plan Crosswalk	Systems Enrollment Activities	Enrollment Procedures	Beneficiary Notifications
1	New Plan (PBP) Added	PDP sponsor creates a new PBP.	**HPMS Plan Crosswalk Definition:** A new plan added for 2012 that is not linked to a 2011 plan.. **HPMS Plan Crosswalk Designation:** New Plan	The PDP sponsor must submit enrollment transactions.	New enrollees must complete an enrollment request.	None.
2	Renewal Plan	A PDP sponsor continues to offer a CY 2011 PBP in CY 2012. **The same PBP ID number must be retained** in order for all current enrollees to remain in the same PBP in CY 2012.	**HPMS Plan Crosswalk Definition:** A 2012 plan that links to a 2011 plan and retains all of its plan service area from 2011. The 2012 plan must retain the same plan ID as the 2011 plan.. **HPMS Plan Crosswalk Designation:** Renewal Plan	**The renewal PBP ID must remain the same** so that current enrollees will remain in the same PBP ID.. The PBP sponsor **does not** submit enrollment transactions for current enrollees.	No enrollment request for current enrollees to remain enrolled in the renewal PBP in 2012.. New enrollees must complete enrollment request.	Current enrollees are sent a standard ANOC.

Appendix B-2

	Activity	Guidelines	HPMS Plan Crosswalk	Systems Enrollment Activities	Enrollment Procedures	Beneficiary Notifications
3	Consolidated Renewal Plan	A PDP sponsor combines two or more PBPs offered in CY 2011 into a single renewal PBP for CY 2012. The PDP sponsor must designate which of the renewal PBP IDs will be retained in CY 2012 after consolidation.. When a PDP sponsor combines an enhanced PBP with a basic PBP, the HPMS crosswalk only allows a crosswalk to a consolidated PBP that offers a basic benefit design.	**HPMS Plan Crosswalk Definition:** Two or more 2011 plans that consolidate into one 2012 plan. The 2012 plan ID must be the same as one of the consolidating 2011 plan IDs. . **HPMS Plan Crosswalk Designation:** Consolidated Renewal Plan	**The PDP sponsor's designated renewal PBP ID must remain the same** so that CMS can consolidate current enrollees into the designated renewal PBP ID. . The PDP sponsor **does not** submit enrollment transactions for current enrollees. Sponsors may need to submit updated 4RX data for enrollees affected by the consolidation.	No enrollment request for current enrollees to remain enrolled in the renewal PBP in 2012.	Current enrollees are sent a standard ANOC.
4	Renewal Plan with an SAE (**applicable only to employer/union group waiver plans**)	A PDP sponsor continues to offer an 800 series CY 2011 prescription drug PBP in CY 2012 and expands it s EGWP service area to include additional regions. **The PDP sponsor must retain the same PBP ID number** in order for all current enrollees to remain in the same PBP in CY 2012.	**HPMS Plan Crosswalk Definition:** A 2012 800-series plan that links to a 2011 800-series plan and retains all of its plan service area from 2011, but also adds one or more new regions. The 2012 plan must retain the same plan ID as the 2011 plan.. **HPMS Plan Crosswalk Designation:** Renewal Plan with an SAE	**The renewal PBP ID must remain the same** so that current enrollees in the current service area will remain in the same PBP ID.. The PDP sponsor does not submit enrollment transaction for current enrollees.	No enrollment request for current enrollees to remain enrolled in the renewal PBP in 2012. New enrollees must complete enrollment request.	Current enrollees are sent a standard ANOC.

Appendix B-2

	Activity	Guidelines	HPMS Plan Crosswalk	Systems Enrollment Activities	Enrollment Procedures	Beneficiary Notifications
5	Terminated Plan (Non-Renewal)	A PDP sponsor terminated the offering of a 2011 PBP.	**HPMS Plan Crosswalk Definition:** A 2011 plan that is no longer offered in 2012. . **HPMS Plan Crosswalk Designation:** Terminated Plan	The PDP sponsor does not submit disenrollment transactions.. If the terminated enrollee elects to enroll in another PBP with the same or another PDP sponsor or MAO, the enrolling PDP sponsor or organization **must submit enrollment transactions** to enroll the terminated enrollees.	Terminated enrollees must complete an enrollment request if they choose to enroll in another PBP, even a PBP offered by the same PDP sponsor.	Terminated enrollees are sent a CMS model termination notice including SEP information and receive a written description of options for obtaining prescription drug coverage in the service area.

Appendix B-2

	Activity	Guidelines	HPMS Plan Crosswalk	Systems Enrollment Activities	Enrollment Procedures	Beneficiary Notifications
6	Consolidated Plans across Contracts under the Same Parent Organization	A parent organization combines two or more whole PBPs under different contracts (the contracts may be the same legal entity or represent different legal entities) as a result of a merger, acquisition, or novation. A PDP sponsor cannot complete this renewal option in the HPMS Plan Crosswalk.	**Exceptions Crosswalk Request:** Sponsors cannot complete this crosswalk via the HPMS crosswalk. Sponsors must submit an exceptions request to CMS, which will complete the crosswalk on behalf of the sponsor**.** **HPMS Plan Crosswalk Designation:** The plan being crosswalked must be marked as a terminated plan in the HPMS crosswalk.. The remaining 2012 plan must be active and contain the applicable service area from the terminated plan being crosswalked.	PDP sponsors cannot complete this renewal option in the HPMS Plan Crosswalk. CMS will effectuate this renewal option and HPMS will record the consolidation of one or more whole PBPs. The PDP sponsor **does not** submit enrollment transactions for current enrollees.. Sponsors may need to submit updated 4RX data for enrollees affected by the consolidation.	No enrollment election for current enrollees to remain enrolled in the renewal PBP in 2012.. New enrollees must complete enrollment request.	Current enrollees are sent a special notice (based on a model CMS will provide) along with a standard ANOC.

April 4, 2005

NOTE TO: Medicare Advantage Organizations and Other Interested Parties

SUBJECT: Announcement of Calendar Year (CY) 2006 Medicare Advantage Payment Rates

In accordance with section 1853(b)(1) of the Social Security Act (the Act), we are notifying you of the annual Medicare Advantage capitation rate for each Medicare Advantage payment area for 2006, and the risk and other factors to be used in adjusting such rates. Attached is a spreadsheet containing the capitation rate tables for CY 2006, which includes the rescaling factors that will be used with the risk-adjusted portion of payment in 2006. Also included is a spreadsheet which shows the statutory component of the regional benchmarks. The rates are posted on the Centers for Medicare & Medicaid Services (CMS) web site at http://www.cms.hhs.gov/healthplans/rates/default.asp.

Enclosure I shows the final estimates of the increase in the National Per Capita Medicare Advantage Growth Percentage for 2006. As discussed in Enclosure I, the final estimate of the increase in the National Per Capita Medicare Advantage Growth Percentage for aged beneficiaries is 4.8 percent. Since these estimates are all larger than 2 percent, these growth rates will be used as the minimum update percentage in calculating the 2006 rates. The CMS has decided not to rebase the county fee-for-service (FFS) rates for 2006. Therefore, all 2006 demographic capitation rates will be the 2005 rate increased by 4.8 percent.

Enclosure II provides a set of tables that summarizes many of the key Medicare assumptions used in the calculation of the National Per Capita Medicare Advantage Growth Percentage.

Section 1853(b)(4) of the Act (added by Section 514 of the BBRA) requires CMS to release county-specific per capita FFS expenditure information on an annual basis, beginning with March 1, 2001. FFS data for CY 2003 is being posted on the Internet at this time as well.

We received 103 comments from 19 organizations in response to CMS' request for comments on the Advance Notice of Methodological Changes for CY 2006 Medicare Advantage (MA) Payment Rates (Advance Notice), published on February 18, 2005. Enclosure III presents our responses to the issues raised in the comments related to Attachment I of the Advance Notice, entitled Preliminary Estimate of the National Per Capita Growth Percentage for Calendar Year (CY) 2006, and Attachment II, which was entitled Changes in the Payment Methodology for Original Medicare Benefits for CY 2006. Enclosure IV contains comments and responses to issues raised regarding Attachment III of the Advance Notice, entitled Overview of Payment for Medicare

Advantage Prescription Drug Plans (MA-PDs) and Prescription Drug Plans (PDPs). Enclosure V contains the Part D CMS-HCC model risk factors for MA-PDs and PDPs.

Questions can be directed to:
Sol Mussey at (410) 786-6386 for Enclosures I and II
Deondra Moseley at (410) 786-4577 for Enclosure III
Mark Newsom at (410) 786-3198 for Enclosures IV and V

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Enclosures

Enclosure I
Final Estimate of the Increase in the National Per Capita Growth Percentages for 2006

The first table below shows the National Per Capita Medicare Advantage Growth Percentages (NPCMAGP) used to determine the minimum update percentage for 2006. Adjustments of -0.3 percent, -0.2 percent, 0.8 percent and -0.2 percent for aged, disabled, ESRD, and combined aged and disabled, respectively, are included in the NPCMAGP to account for corrections to prior years estimates as required by section 1853(c)(6)(C). The combined aged and disabled increase is used in the development of the risk-adjusted ratebook.

The second table below shows the monthly actuarial value of the Medicare deductible and coinsurance for 2005 and 2006. In addition, for 2006, the actuarial value of deductibles and coinsurance is being shown for non-ESRD only, since the plan bids will not include ESRD benefits in 2006. These data were furnished by the Office of the Actuary.

Increase in the National Per Capita MA Growth Percentages for 2006

	Prior Increases	Current Increases			NPCMAGP for 2006 With Sec.1853(c)(6)(C) adjustment[1]
	2003 to 2005	2003 to 2005	2005 to 2006	2003 to 2006	
Aged	13.30%	13.01%	5.06%	18.73%	4.80%
Disabled	12.49	12.23	4.96	17.80	4.72
ESRD	10.71	11.59	3.95	16.00	4.78
Aged+Disabled	13.08	12.85	5.04	18.53	4.83

[1]Current increases for 2003 to 2006 divided by the prior increases for 2003 to 2005.

Monthly Actuarial Value of Medicare Deductible and Coinsurance for 2005 and 2006

	2005	2006	Change	2006 non-ESRD
Part A Benefits	$30.24	$30.64	1.3%	$29.55
Part B Benefits[2]	89.12	94.31	5.8%	89.26
Total Medicare	119.36	124.95	4.7%	118.81

[2]Includes the amounts for outpatient psychiatric charges.

The maximum deductible for Medical Savings Account (MSA) plans for 2006 is $8,850.

Enclosure II

Key Assumptions and Financial Information

Attached is a table that compares the published United States Per Capita Costs (USPCC) with current estimates for 2000 to 2006. In addition, this table shows the current projections of the USPCCs through 2008. In prior years, information in these tables was presented back to 1997. Since the passage of the MMA, formula changes in the law do not require the use of the USPCCs back to 1997 for the purpose of calculating the 2006 rates (e.g., the area-specific rate is not tabulated for years after 2004 and no adjustments to prior years' estimates are allowed for years before 2004 for calculating the minimum update percentage).

We are also providing an attached set of tables that summarizes many of the key Medicare assumptions used in the calculation of the USPCCs. The USPCCs are the basis for the National Per Capita Medicare Advantage Growth Percentages. Most of the tables include information for the years 2000 through 2008. All of the information provided in this enclosure applies to the Medicare Part A and Part B programs. Caution should be employed in the use of this information. It is based upon nationwide averages, and local conditions can differ substantially from conditions nationwide.

None of the data presented here pertain to the new Medicare prescription drug benefit.

Comparison of Current Estimates of the USPCC with Published Estimates

PART A:

Calendar Year	Aged			Disabled			Aged and Disabled		
	Current Estimate	Published Estimate	Ratio	Current Estimate	Published Estimate	Ratio	Current Estimate	Published Estimate	Ratio
2000	$265.10	$286.18	1.080	$217.11	$230.48	1.062	$258.66	$278.61	1.077
2001[1]	$286.28	$288.62	1.008	$235.57	$235.50	1.000	$279.30	$281.25	1.007
2001[2]	$286.28	$298.43	1.042	$235.57	$242.00	1.027	$279.30	$290.59	1.040
2002	$299.41	$294.46	0.983	$249.30	$242.06	0.971	$292.33	$287.10	0.982
2003	$306.56	$290.50	0.948	$258.07	$234.89	0.910	$299.52	$282.50	0.943
2004	$317.20	$326.78	1.030	$265.10	$271.69	1.025	$309.47	$318.43	1.029
2005	$333.76	$348.28	1.044	$278.56	$291.45	1.046	$325.31	$339.49	1.044
2006	$351.38	$351.38	1.000	$295.15	$295.15	1.000	$342.67	$342.67	1.000
2007	$367.00	--	--	$310.88	--	--	$358.25	--	--
2008	$383.64	--	--	$327.36	--	--	$374.83	--	--

PART B:

Calendar Year	Aged			Disabled			Aged and Disabled		
	Current Estimate	Published Estimate	Ratio	Current Estimate	Published Estimate	Ratio	Current Estimate	Published Estimate	Ratio
2000	$199.93	$218.78	1.094	$194.05	$195.91	1.010	$199.19	$216.03	1.085
2001[1]	$219.99	$217.57	0.989	$214.96	$191.99	0.893	$219.35	$214.32	0.977
2001[2]	$219.99	$223.83	1.017	$214.96	$198.69	0.924	$219.35	$220.63	1.006
2002	$233.57	$244.17	1.045	$236.48	$218.23	0.923	$233.95	$240.76	1.029
2003	$251.54	$232.24	0.923	$261.43	$211.58	0.809	$252.87	$229.47	0.907
2004	$278.89	$263.39	0.944	$286.89	$252.74	0.881	$280.00	$261.89	0.935
2005	$296.97	$281.90	0.949	$304.48	$272.79	0.896	$298.05	$280.58	0.941
2006	$311.28	$311.28	1.000	$316.82	$316.82	1.000	$312.09	$312.09	1.000
2007	$322.54	--	--	$327.93	--	--	$323.33	--	--
2008	$335.29	--	--	$341.16	--	--	$336.15	--	--

PART A & PART B:

Calendar Year	Aged			Disabled			Aged and Disabled		
	Current Estimate	Published Estimate	Ratio	Current Estimate	Published Estimate	Ratio	Current Estimate	Published Estimate	Ratio
2000	$465.03	$504.96	1.086	$411.16	$426.39	1.037	$457.85	$494.64	1.080
2001[1]	$506.27	$506.19	1.000	$450.53	$427.49	0.949	$498.65	$495.57	0.994
2001[2]	$506.27	$522.26	1.032	$450.53	$440.69	0.978	$498.65	$511.22	1.025
2002	$532.98	$538.63	1.011	$485.78	$460.29	0.948	$526.28	$527.86	1.003
2003	$558.10	$522.74	0.937	$519.50	$446.47	0.859	$552.39	$511.97	0.927
2004	$596.09	$590.17	0.990	$551.99	$524.43	0.950	$589.47	$580.32	0.984
2005	$630.73	$630.18	0.999	$583.04	$564.24	0.968	$623.36	$620.07	0.995
2006	$662.66	$662.66	1.000	$611.97	$611.97	1.000	$654.76	$654.76	1.000
2007	$689.54	--	--	$638.81	--	--	$681.58	--	--
2008	$718.93	--	--	$668.52	--	--	$710.98	--	--

[1]Applies to M+C ratebook for January to February, 2001

[2]Applies to M+C ratebook for March to December, 2001

Comparison of Current Estimates of the USPCC with Published Estimates-continued

PART A:

Calendar Year	ESRD Current Estimate	ESRD Published Estimate	Ratio
2000	$1,320.28	$1,443.13	1.093
2001[1]	$1,432.85	$1,541.76	1.076
2001[2]	$1,432.85	$1,597.34	1.115
2002	$1,531.71	$1,435.62	0.937
2003	$1,619.66	$1,596.58	0.986
2004	$1,638.05	$1,685.25	1.029
2005	$1,717.13	$1,759.90	1.025
2006	$1,717.97	$1,717.97	1.000
2007	$1,708.55	--	--
2008	$1,755.24	--	--

PART B:

Calendar Year	ESRD Current Estimate	ESRD Published Estimate	Ratio
2000	$1,582.16	$2,436.13	1.540
2001[1]	$1,806.81	$1,875.57	1.038
2001[2]	$1,806.81	$1,921.53	1.063
2002	$1,916.48	$2,014.79	1.051
2003	$1,977.62	$1,847.53	0.934
2004	$2,189.97	$2,552.18	1.165
2005	$2,297.24	$2,739.99	1.193
2006	$2,454.98	$2,454.98	1.000
2007	$2,582.64	--	--
2008	$2,680.43	--	--

PART A & PART B:

Calendar Year	ESRD Current Estimate	ESRD Published Estimate	Ratio
2000	$2,902.44	$3,879.26	1.337
2001[1]	$3,239.66	$3,417.33	1.055
2001[2]	$3,239.66	$3,518.87	1.086
2002	$3,448.19	$3,450.41	1.001
2003	$3,597.28	$3,444.11	0.957
2004	$3,828.02	$4,237.43	1.107
2005	$4,014.37	$4,499.89	1.121
2006	$4,172.95	$4,172.95	1.000
2007	$4,291.19	--	--
2008	$4,435.67	--	--

[1]Applies to M+C ratebook for January to February, 2001

[2]Applies to M+C ratebook for March to December, 2001

Summary of Key Projections Under Present Law[1]

Part A

Year	Calendar Year CPI Percent Increase	Fiscal Year PPS Update Factor	FY Part A Total Reimbursement (Incurred)
2000	3.5	1.1	-0.9
2001	2.7	3.4	8.6
2002	1.4	2.8	7.8
2003	2.2	3.0	3.8
2004	2.6	3.4	6.4
2005	2.1	3.3	7.0
2006	2.2	3.9	7.1
2007	2.6	4.0	6.4
2008	2.8	4.1	6.6

Part B[2]

Calendar Year	Physician Fee Schedule		Part B Hospital	Total
	Fees	Residual		
2000	5.9	3.6	-0.8	9.8
2001	5.3	4.1	12.5	9.5
2002	-4.2	6.1	-1.4	6.2
2003	1.4	4.9	5.9	7.3
2004	3.8	6.8	11.8	10.3
2005	1.5	4.2	8.2	5.9
2006	-4.6	5.7	8.0	3.5
2007	-5.4	5.4	7.7	2.6
2008	-5.0	5.0	7.7	3.4

[1]Percent change over prior year.
[2]Percent change in charges per Aged Part B enrollee.

Medicare Enrollment Projections Under Present Law (In Millions)

Non-ESRD

Calendar Year	Part A		Part B	
	Aged	Disabled	Aged	Disabled
2000	33.693	5.215	32.419	4.602
2001	33.898	5.406	32.581	4.761
2002	34.074	5.609	32.712	4.931
2003	34.387	5.838	32.904	5.116
2004	34.755	6.057	33.108	5.337
2005	35.102	6.347	33.401	5.573
2006	35.545	6.516	33.750	5.734
2007	36.122	6.676	34.217	5.875
2008	36.802	6.832	34.785	6.013

ESRD Part A

Calendar Year	Part A			
	Aged	Disabled	299I[1]	Total
2000	0.143	0.105	0.101	0.349
2001	0.150	0.110	0.106	0.365
2002	0.158	0.112	0.112	0.382
2003	0.166	0.117	0.117	0.399
2004	0.173	0.124	0.121	0.418
2005	0.179	0.129	0.125	0.433
2006	0.185	0.133	0.129	0.446
2007	0.190	0.136	0.131	0.458
2008	0.196	0.139	0.134	0.468

ESRD Part B

Calendar Year	Part B			
	Aged	Disabled	299I	Total
2000	0.140	0.090	0.083	0.313
2001	0.146	0.094	0.086	0.326
2002	0.153	0.095	0.091	0.338
2003	0.161	0.097	0.094	0.352
2004	0.167	0.100	0.097	0.365
2005	0.173	0.104	0.099	0.376
2006	0.178	0.107	0.102	0.386
2007	0.183	0.109	0.103	0.395
2008	0.188	0.112	0.105	0.404

[1] Individuals who qualify for Medicare based on ESRD only.

Part A Projections Under Present Law [1]

Calendar Year	Inpatient Hospital		SNF		Home Health		Managed Care		Hospice: Total Reimbursement (in Millions)	
	Aged	Disabled	Aged	Disabled	Aged	Disabled	Aged	Disabled	Aged	Disabled
2000	2,241.10	2,373.01	315.41	105.11	91.62	64.01	593.36	270.30	2,831	149
2001	2,431.75	2,581.96	382.26	129.40	120.07	89.98	571.77	256.09	3,541	186
2002	2,606.22	2,767.31	418.21	145.52	126.36	95.26	523.26	228.44	4,614	243
2003	2,682.97	2,877.93	427.49	152.18	133.90	102.49	523.08	222.33	5,908	311
2004	2,732.17	2,927.40	446.36	158.52	150.69	115.20	570.84	241.87	7,200	379
2005	2,858.72	3,063.48	458.64	162.69	164.08	125.47	623.92	264.14	8,460	445
2006	2,861.20	3,155.56	448.89	163.78	169.16	133.24	838.05	358.91	9,546	502
2007	2,851.33	3,241.70	436.15	164.27	172.15	140.11	1,044.67	449.67	10,383	546
2008	2,927.40	3,377.49	434.92	166.87	179.68	148.93	1,164.79	505.18	11,180	588

[1]Average reimbursement per enrollee on an incurred basis, except where noted.

Part B Projections Under Present Law[1]

Calendar Year	Physician Fee Schedule		Part B Hospital		Durable Medical Equipment	
	Aged	Disabled Non-ESRD	Aged	Disabled Non-ESRD	Aged	Disabled Non-ESRD
2000	1,003.19	949.16	238.98	298.42	118.54	183.98
2001	1,131.46	1,061.03	326.91	410.60	137.12	214.59
2002	1,177.30	1,106.00	333.46	434.42	158.98	262.20
2003	1,269.05	1,209.04	379.87	492.55	186.05	313.32
2004	1,412.53	1,336.59	434.96	561.97	190.04	320.34
2005	1,473.55	1,399.64	476.84	606.93	186.09	318.48
2006	1,411.43	1,373.02	513.15	669.15	180.35	316.25
2007	1,337.90	1,336.39	531.78	712.43	178.91	322.06
2008	1,308.43	1,320.27	567.81	768.87	182.90	332.53

Calendar Year	Carrier Lab		Other Carrier		Intermediary Lab	
	Aged	Disabled Non-ESRD	Aged	Disabled Non-ESRD	Aged	Disabled Non-ESRD
2000	58.89	57.87	201.38	194.65	46.25	62.20
2001	64.86	63.52	239.95	231.38	47.73	67.54
2002	70.96	70.94	286.77	287.40	55.32	77.66
2003	76.70	76.89	333.38	365.54	60.33	84.40
2004	82.70	84.57	357.87	428.85	64.71	92.16
2005	88.15	90.65	369.21	448.23	69.47	99.31
2006	87.62	92.15	386.81	475.89	69.32	101.51
2007	86.09	92.84	399.42	498.09	66.62	100.18
2008	86.89	94.58	425.81	531.06	67.51	102.56

Calendar Year	Other Intermediary		Home Health		Managed Care	
	Aged	Disabled Non-ESRD	Aged	Disabled Non-ESRD	Aged	Disabled Non-ESRD
2000	117.89	221.19	139.80	106.45	531.83	220.83
2001	138.53	232.66	130.33	75.13	498.03	189.36
2002	173.55	280.30	140.50	81.49	494.67	204.43
2003	178.45	273.36	143.96	84.99	483.00	202.31
2004	202.31	267.46	162.78	95.06	543.46	219.59
2005	216.85	290.58	177.47	103.90	619.37	258.04
2006	210.90	279.13	183.33	110.10	820.55	345.19
2007	212.45	288.31	187.02	115.78	1,009.60	428.21
2008	219.01	301.67	195.62	123.05	1,116.97	476.84

[1]Average reimbursement per enrollee on an incurred basis.

Claims Processing Costs as a Fraction of Benefits

Calendar Year	Part A	Part B
2000	0.002195	0.014790
2001	0.001862	0.013223
2002	0.001496	0.011708
2003	0.001849	0.011194
2004	0.001676	0.010542
2005	0.001676	0.010542
2006	0.001676	0.010542
2007	0.001676	0.010542
2008	0.001676	0.010542

Approximate Calculation of the USPCC and the National Medicare Advantage Growth Percentage for Aged Beneficiaries

The following procedure will approximate the actual calculation of the USPCCs from the underlying assumptions for the contract year for both Part A and Part B.

Part A:
The Part A USPCC for aged beneficiaries can be approximated by using the assumptions in the tables titled "Part A Projections Under Present Law" and "Claims Processing Costs as a Fraction of Benefits." Information in the "Part A Projections" table is presented on a calendar year per capita basis. First, add the per capita amounts for the aged over all types of providers (excluding hospice). Next, multiply this amount by 1 plus the loading factor for administrative expenses from the "Claims Processing Costs" table. Then, divide by 12 to put this amount on a monthly basis. The last step is to multiply by .97503 to get the USPCC for the aged non-ESRD. This final factor is the relationship between the total and non-ESRD per capita reimbursements in 2006. This factor does not necessarily hold in any other year.

Part B:
The Part B USPCC can be approximated by using the assumptions in the tables titled "Part B Projections Under Present Law" and "Claims Processing Costs as a Fraction of Benefits." Information in the "Part B Projections" table is presented on a calendar year per capita basis. First, add the per capita amounts for the aged over all types of providers. Next, multiply by 1 plus the loading factor for administrative expenses and divide by 12 to put this amount on a monthly basis. Then multiply by .95676 to get the USPCC for the aged non-ESRD.

The National Per Capita Medicare Advantage Growth Percentage:
The National Per Capita Medicare Advantage Growth Percentage for 2006 (before adjustment for prior years' over/under estimates) is calculated by adding the USPCCs for Part A and Part B for 2006 dividing by the sum of the current estimates of the USPCCs for Part A and Part B for 2005.

Enclosure III. CMS' Responses to Public Comments for Medicare Advantage Plans

Summary
We received 61 comments from 19 organizations on the February 18, 2005 Advance Notice of Methodological Changes for CY 2006 Medicare Advantage (MA) Payment Rates. Our responses to the issues raised by the commenters are organized as follows: Section A: Estimate of the National Per Capita Growth Percentage for Calendar Year 2006; Section B: Overview of Bidding for Non-drug Benefits; Section C: Payment Formulas and Other Non-drug Payment Policies; Section D: Changes to Risk Adjustment Method for MA Organizations; and Section E: Budget Neutral Risk Adjustment in Payments for Local and Regional MA Organizations.

Section A: Estimate of the National Per Capita Growth Percentage for Calendar Year 2006

Comment – Decision not to Rebase: Several commenters asked CMS to reconsider the decision not to rebase the 100 percent FFS rates for 2006 and provide the criteria used to reach this decision. The commenters recommended that CMS rebase annually.

Response: Section 1853(c)(1)(D)(ii) of the MMA states that CMS must rebase the rates not less than once every three years as the Secretary may specify. Thus, the law does not require us to rebase each year. We will consider rebasing the rates each year in context with all other priorities.

The MMA has brought many changes to the Medicare Advantage program that must be effective in 2006. Given the volume of changes required for 2006, CMS chose to exercise its discretion not to rebase for 2006.

Comment: One commenter was concerned that FFS rates for 2006 would not accurately reflect the recent changes in FFS reimbursement in rural areas, since CMS decided not to rebase the FFS rates using updated data. The commenter stated that FFS reimbursements have increased at a faster pace in rural areas than non-rural areas due to the accelerated reimbursement increases such as Health Professional Shortage Area (HPSA) bonuses to providers, hospital wage index reclassification, and critical access hospital designation. The commenter recommended that OACT reconsider rebasing the 2006 FFS cost by forecasting expenditures based on upcoming prospective payment system rules, thus using updated Medicare reimbursement rates that vary by area, rather than using out-dated average geographic adjustment factors (AGAs) to estimate FFS cost by county. If the FFS rates will not be rebased, the commenter recommended that CMS consider applying varying growth rates by rural vs. urban counties that reflect the differences in reimbursement trends between rural and urban counties. If this is not possible, the commenter suggested that the CMS consider designating rural counties as urban counties when determining which floor to use if the majority of hospitals (or hospital) in these rural areas have been reclassified to urban wage indexes.

Response: As discussed above, we will not rebase the FFS rates for 2006. The commenter also made several suggestions about how CMS could update FFS rates in the future. First, the commenter suggested that CMS model historical FFS reimbursement data to reflect the payment system rules and provider classifications that will be in effect for the upcoming payment year, instead of historical reimbursement rules and classifications. In the future, during a rebasing year, we expect to look at the feasibility of reflecting structural changes in FFS payment so that the geographic adjustments will reflect the rules and classifications in place for the upcoming payment year.

Second, the commenter suggested that CMS consider varying growth rates by urban versus rural counties. We do not believe it is feasible to use separate growth rates at this time. CMS data tabulations have not been set up to track trends on this basis. Even if we were to track trends on this basis, it would take several years before reasonable trends between urban and rural counties would be available.

Finally, the commenter suggested that, for those rural counties affected by the provision to temporarily redesignate hospitals to higher wage indices, CMS designates these counties as urban counties to assign them the high floor rate. We believe the commenter is referring to the pre-MMA rate-setting method, under which MA organizations were paid the "highest of three rates" - a floor amount reflecting a minimum specified in statute, a minimum percentage increase of 2 percent, or a blended rate combining local and national data. There were two types of floor rates: a "high" floor rate for counties with population of more than 250,000, and a "low" floor rate for counties with populations of 250,000 or less. Under the MMA, 2004 was the last year when floor rates were part of the "higher of" rate-setting methodology. While the 2004 floors are reflected in future rates, they no longer exist in MA rate-setting. MA rates are minimum percentage increase rates except in rebasing years, when a county rate is the higher of the minimum rate or the FFS rate. Based on these changes, the "low floor" and "high floor" rates are no longer applicable.

Comment – National Per Capita MA Growth Percentage: One commenter asked CMS to discuss the components of the estimate of the National Per Capita MA Growth Percentage, including the costs of national coverage determinations.

Response: The assumptions underlying the components of the National Per Capita MA Growth Percentage can be found in the tables in Enclosure II of this Announcement. These assumptions are based on the 2005 Trustees Report baseline. The assumptions and methodologies used in calculating this baseline are discussed in detail in the 2005 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds (Trustee's Report), which can be found at http://www.cms.hhs.gov/publications/trusteesreport/. All new NCDs that we are aware of at the time the rates are published are included in the base rates. All new benefits mandated by the MMA have been included in the estimate.

Comment: One commenter recommends that CMS provide greater detail in the Advance Notice with regard to the revisions to rates based on prior years. The commenter felt the

basis for determining the revisions is unclear and further explanation is needed to permit MA organizations to understand CMS' methodology for this important element of the rate calculation.

Response: The United States Per Capita Costs (USPCCs) are the basis for the National Per Capita MA Growth Percentages, and include managed care payments and FFS payments. Each year, Enclosure II of the Rate Announcement provides tables comparing current estimates of the USPCC with prior published estimates. For information on how these current estimates are developed, see the tables in Enclosure II, and for more detailed information, see the 2005 Trustee's Report mentioned above. For information on prior year's estimates, see the assumptions in prior Announcements and prior years Trustees Reports.

Comment: One commenter asked how a Congressional change in physician payment for 2006 would be reflected in payment rates, and when a permanent change to the Sustainable Growth Rate (SGR) would be reflected in the rates if a change was made.

Response: A change to the SGR for a given year would be reflected in the annual capitation rates for the following year, unless the legislation implementing such a change mandates a recalculation of the rates for the year the change is implemented or if the change for the following year is made before the capitation rates are determined for the following year.

OACT does not normally retabulate the annual MA capitation rates to reflect legislative changes to provider payments that are passed after the rates are published, unless the law prescribes it. MA organizations base their bid submissions on these annual rates, and unless the law required it, we would not require MA organizations to re-price benefit packages mid-year.

Comment: One commenter wanted to know the assumption that was used for the physician update to the conversion factor for the National Per Capita MA Growth Percentage for 2005 and 2006.

Response: The physician update to the conversion factor implicit in the National Per Capita MA Growth Percentage for 2005 was 1.5% and for 2006 is estimated to be -4.6%. This is also discussed in the 2005 Trustees Report, mentioned above.

Comment – VA/DoD Costs: The notice does not discuss CMS' plans for implementation of a mechanism for incorporating into the payment methodology costs associated with Medicare covered services provided to beneficiaries in Veterans' Administration (VA) and Department of Defense (DoD) facilities. The Medicare Modernization Act established a requirement for incorporating these costs into the CY 2004 payment methodology (in the "blended" rates and in the 100 percent of FFS rates), but CMS indicated that the Agency was unable to do this at that time due to a lack of reliable data.

Response: Incorporating costs associated with Medicare-covered services provided to beneficiaries in VA and DoD facilities into the payment methodology is a multi-year project that will involve developing methods for matching coverage determinations, pricing of services, etc. CMS will continue to work on obtaining and sorting through the data. Until that project is complete, we expect the adjustment will be zero.

Section B: Overview of Bidding for Non-drug Benefits

The Advance Notice and Rate Announcement are technical notices concerning the MA payment methodology. Pricing policy is discussed in the annual Call Letter and Instructions for Completing the Medicare Advantage Plan Bid Form. We made an exception this year in the February 18, 2005 Advance Notice by also including an overview of the Part C bidding methodology established by the MMA, because of the new links between pricing and payment. We received public comments on the bidding methodology discussed in the Notice, so again we make an exception for this year by responding to these comments in the Rate Announcement.

Comment – Bid Pricing Tool. One commenter wanted to know where to find the Bid Pricing Tool on the CMS website.

Response: The Medicare Advantage bid form and instructions can be found at http://www.cms.hhs.gov/healthplans/. The prescription drug pricing form and instructions can be found at http://www.cms.hhs.gov/pdps/default.asp.

Comment - Actuarially Equivalent Cost Sharing. One commenter noted that while CMS intends to vary the proportions on a geographic basis, it does not appear that CMS intends to vary the proportions for special populations. The commenter recommended that CMS study this further to determine if unique proportions should apply to some of the demonstration plans and to special needs plans.

Response: The data source we use to determine the service-specific proportions of FFS expenditures and beneficiary cost-sharing is the National Claims History, which combines the claims experience of all Medicare FFS beneficiaries without distinguishing types of beneficiaries such as dually-eligible and institutionalized individuals. In addition, we believe that applying proportions that vary by type of service takes into account variation in the types of services used by certain special populations.

Comment: The commenter states that if the bid forms will automatically complete the proportions for each service category line, it will be important for a bidding organization to assign its allowed costs to service category lines on the same basis. The commenter requests that CMS provide detailed information on how to do this such that the costs and proportions are aligned.

Response: We have developed a mapping that crosswalks costs in the Medicare benefit description report to the bid pricing categories. This mapping is available through CMS' Health Plan Management System (HPMS).

Comment – Trending. The commenter asks how CMS applies credibility issues by geographic area/service category.

Response: As we discussed in the Advance Notice, which can be found at www.cms.hhs.gov/healthplans/rates/, the plan A/B bid must reflect cost sharing as required under original Medicare, or an actuarially equivalent (A.E.) amount. Plan-specific actuarially equivalent cost sharing will be determined based on cost sharing proportions in original Medicare that are applied to projected plan allowed costs for Medicare benefits. Our development of the A.E. factors takes into consideration the validity and credibility of the data at the service-specific and county-specific level. Although we call the proportions "county level proportions," there is relatively low credibility in some counties due to small amounts of beneficiaries and claims dollars. As a result, in general (with some exceptions) the proportions have been developed at the level of Metropolitan Statistical Area (MSA) or non-MSA areas in a State using the aggregate claim experience for each of these areas. The same set of proportions will be assigned to all counties in each MSA or non-MSA area.

Comment – Benchmarks. The commenter states that the weights used to compute the statutory component of the regional plan benchmark should exclude not only Part B-Only enrollees (as announced in the Advance Notice), but also Part A-only enrollees.

Response: The MMA specifies that the weights used to determine the statutory component of the regional plan benchmark must be MA eligibles. We agree that Part A-only enrollees should be excluded, in addition to Part B-only enrollees, since in general beneficiaries must be entitled to benefits under Part A and enrolled in Part B to be eligible for enrolling in an MA plan. In fact, we always have excluded Part A-only beneficiaries from the MA eligible count. However, these weights function as a relative scale in the benchmark calculation, so we do not believe the inclusion or exclusion of Part A enrollees would have a significant impact.

Comment – ESRD enrollees. One commenter noted that CMS will allow bids to be adjusted for the "supplemental cost" of ESRD enrollees and asked whether it be possible to apply the MA rebate to this cost.

Response: For 2006, ESRD enrollee costs are excluded from pricing the A/B basic benefit. MA organizations will have the option to adjust a plan's supplemental benefit premium by an ESRD factor, based on an organization's estimate of higher supplemental benefit costs for ESRD enrollees in the plan. Specifically, section V of Worksheet 6 allows MA organizations to estimate a PMPM loss for ESRD enrollees that is added to the price of the A/B supplemental package at Section IIC in Worksheet 6. This is an optional adjustment factor.

The plan's rebate is based on the relationship of the plan A/B bid for original Medicare benefits and the plan's A/B benchmark. The option of applying an ESRD adjustment factor to the price of the A/B supplemental benefit is available after the rebate has been applied to buy down the cost of the A/B supplemental costs. The rebate cannot be applied to this cost. We recognize that choosing to apply the supplemental ESRD factor could preclude a plan from having a zero supplemental premium.

Comment: One commenter noted that PACE organizations and certain demonstrations are transitioning to risk adjustment on a schedule that is lagged one year behind regular MA plans, so their payments for the 2007 contract year will be 25 percent demographic and 75 percent risk adjustment payments, while in 2007 regular MA plans will be paid 100 percent on the risk adjustment model. The commenter asked whether ESRD enrollee costs will continue to be excluded from the benchmark and bid calculations in the 2006 bid forms for the 2007 contract year for PACE and demonstration plans.

Response: The 2005 Rate Announcement addresses questions concerning the 2006 payment year. In February and April 2006 we will address questions concerning 2007 payment policies.

Comment – Administrative Rate: One commenter asked what is the administrative rate on the MA product. The commenter indicated that Fiscal Intermediaries that handle the standard Medicare program are paid less than the HMO organizations.

Response: Each bid must reflect the projected administrative costs of the plan. The average administrative cost per MA plan enrollee as reported by MA plans in their 2005 ACR submissions was approximately 7.5 percent of total revenue.

Comment – Supplemental Benefits and the Employer Group Product: One commenter asked how supplemental benefits can be offered with regard to employer group products. The commenter asked if they can only be offered as packages, so plans would not be able to charge separately for each benefit, and would therefore need to charge one premium for a combination of supplemental benefits. The commenter also asked if an MA plan would need to complete a version of the optional supplemental benefit worksheet for every combination of benefits desired by different employer groups, resulting in multiple submissions of this worksheet. Finally, the commenter asked whether plans can use the "actuarial swapping" method for the 2006 plan bid for employer group organizations.

Response: Plans can offer multiple optional supplemental benefit packages in the form of groups of services. Plans can also offer optional supplemental benefits individually – on a benefit by benefit basis. Finally, plans can offer both a combination of groups of services and individual services. Please see 42 CFR 422.102(d). Members (or employers on their behalf) may pay different premiums for different optional supplemental benefit combinations. However, the cost of a specific group of services or for a specific optional supplemental benefit may not vary within an MA plan. "Actuarial swapping" and "actuarial equivalence" will continue to be available, pursuant to the Call Letter and

Instructions for Completing the Medicare Advantage Plan Bid Form for 2006, which will be released soon. Employer group organizations also should refer to the Employer Group guidance for more information related to these types of plans.

Section C: Payment Formulas and Other Non-drug Payment Policies

Comment – Payment Formulas. One commenter stated they cannot confirm that the diagram on page 11 of the Advance Notice accurately reflects the three payment formulas on Page 9 of the Notice. Please provide this documentation.

Response: For plans with bids less than benchmarks, the statutory formula on p. 9 says the base payment is the standardized A/B bid, adjusted by the county ISAR factor, plus the net rebate. The diagram says the same, because the combined formula in the diagram also says subtract the beneficiary premium, which is always zero for these plans. For plans with bids equal to benchmarks, the statutory formula on p. 9 says the base payment is the standardized A/B benchmark adjusted by the county ISAR factor, while the diagram says the base payment is the standardized A/B bid adjusted by the county ISAR factor. These statements are equivalent for plans with bids equal to benchmarks. For plans with bids greater than benchmarks, the statutory formula on page 9 says the base payment is the standardized A/B benchmark, adjusted by the county ISAR factor. The diagram says the base payment is the standardized A/B bid, adjusted by the county ISAR factor, minus the standardized A/B premium the beneficiary will pay, which results in the same amount (the ISAR-adjusted benchmark). The combined formula in the diagram also says add the rebate, which is always zero for these plans.

Comment – Regional plan risk sharing. One commenter asked what is the rationale for excluding uncollected premiums from the calculation of target amount and allowed costs for regional plan risk sharing.

Response: An organization sets policy for the management of uncollected premiums, and we believe this is an administrative expense. Thus, this amount should be left out of risk sharing. This is consistent with our guidance for pricing of the Part D benefit.

Comment – Regional plan medical expenses for purposes of risk corridor calculation. One commenter asked whether claims data (with IBNR adjustment) be used to calculate allowed medical expenses, or whether CMS could provide some examples of accepted methodologies.

Response: MA organizations offering regional plans should use actual claims data to calculate allowed medical expenses and may include an adjustment for claims incurred during the contract period that remain unpaid as of the reconciliation date, which is 12 months beyond the end of the contract period. MA organizations may build-in a reasonable level of claim reserves when calculating the allowed medical expenses for purposes of regional plan risk corridor payments. Accompanying the reconciliations shall be exhibits and data (that is, “claim triangles”) that support development of the

claim reserves. The reserves, and supporting data, will be reviewed by CMS' Office of the Actuary (OACT). If these amounts are in question, the reconciliation will be considered to be preliminary and a cash settlement will occur with a final settlement to take place 12 months later. The reconciliation exhibit will be audited by an independent Certified Public Accountant, at the expense of the MA organization.

Comment – Out of Area Enrollees. One commenter stated that the ISAR adjustment for "county 99999" (any county outside of filed service area) will be 1.00, which may be inequitable for plans that have a high "snowbird" enrollment. The commenter recommended that CMS consider the allowing a plan to select one of the following options:

- As proposed (exclude from benchmark calculation, include costs in bid, ISAR = 1.000).
- Exclude from benchmark calculation, exclude costs in bid, but set the ISAR for any county outside the service area based on that county's relationship in the MA ratebooks.
- Same as the bullet above, except that plans will also submit an ISAR factor (with supporting documentation if other than 1.000) for all counties combined that fall outside the filed service area.

Response: In the Advance Notice, we stated that for enrollees who are out of the plan's service area, the base payment will be the standardized A/B bid (the "1.0" bid), with individual-level risk adjustment for demographic and health status factors. Here we are clarifying that statement.

An MA plan enrollee must, with limited exceptions, permanently reside in the plan's service area. Beginning in 2006, CMS will make payment based on the counties in a plan's service area, which is the geographic basis for the estimated revenue requirements in the plan's bid. In the event there are plan enrollees with State/county codes outside the plan's service area – which could happen for limited reasons discussed below – we will pay the standardized A/B bid ("1.0" bid). Therefore, we will not allow the MA organization to select an option from those the commenter recommended. The bid should be determined based on the plan's projected enrollment in the plan's service area.

The MA organization is responsible for determining where an enrollee permanently resides. When an organization sees in the CMS monthly payment reports that the standardized A/B bid is the base payment – because the enrollee's State/county code is 99999 (county unknown) or an out-of-service area State/county code, the organization should seek information from the enrollees as to whether they are still permanent residents of the plan's service area, and confirm the correct State/county code. If the beneficiary continues to be a permanent resident in the plan's service area, the MA organization should use the current process for requesting a State/county code change to return the enrollee code to the correct permanent county of residence, to ensure that the appropriate ISAR-adjusted county rate is used to determine payment for the enrollee.

In the MA plan context, a "snowbird" is still a permanent resident of a county in the plan's service area. We recognize that situations may arise where a beneficiary files a change of address with the Social Security Administration to have the benefit check sent to the temporary address outside the plan's service area, or where a change of address is filed with the US Postal Service. In situations where the SSA sends this change of address to our enrollment database, the MA organization should use the CMS' existing process mentioned above for correcting the State/county code back to the code for the enrollee's permanent county of residence in the plan's service area.

Exceptions. There are limited instances in which the regulations permit an MA plan enrollee to permanently reside outside the plan's service area. (For a summary of the circumstances when an MA plan may have out of area enrollees, see Section 20.3 of Chapter 2 of the Managed Care Manual on the CMS website at http://www.cms.hhs.gov/manuals/116_mmc/mc86toc.asp?.) Two of these instances are: (1) Enrollees that fall under the 422.50(a)(3)(ii) rule, which, generally, is for beneficiaries who were enrolled in a commercial plan and converted to MA plan enrollment upon becoming eligible for Medicare; and (2) the 422.50(a)(4) rule for enrollees in an employer group health plans that is part of an MA plan. This latter type of MA plan enrolls a mixture of individual and group enrollees. If a plan has a significant number of "snowbirds" who fall under these 422.250(a) exceptions, the MA organization may choose to include in its 2006 service area the county or counties where these enrollees live if the organization wishes be paid a plan-specific ISAR-adjusted county rate instead of the standardized A/B bid amount. Also, if a plan has significant number of 422.50(a)(4) group health plan enrollees, the organization may choose instead to offer an 800-series employer group health plan (open only to group plan enrollees) with a service area encompassing these enrollees.

Comment – National Coverage Determinations: One commenter asked whether CMS reviews local coverage decisions as well as national coverage decisions to determine whether they have significant costs impact. Another commenter recommended that CMS include an adjustment in the growth rate to account for new therapies that are covered through local coverage decisions similar to what CMS will be doing for National Coverage Determinations (NCDs). The commenter also recommended that CMS establish a process for MA plans to submit claims for FFS reimbursement for local coverage decisions that are introduced mid-year and are determined to be of significant cost. This FFS payment would apply until an adjustment is included in the payment rate, similar to what occurs now for NCDs. The commenter reasoned that it appears that the emerging business model for some significant new therapies is to not seek or receive an NCD due to speed to market considerations (if labeling is quite clear and the likelihood of favorable local coverage determinations is high). A current example of this is "wet macular degeneration." The company developing this technology did not seek or receive an NCD. However, it is covered under some local coverage decisions and as a result will be quite costly to the MA organizations.

Response: Claims costs related to local coverage determinations (LCDs) are reflected in the 100 percent FFS rate and in the National Per Capita Growth Trend, because claims

paid under an LCD in an area are included in both the FFS USPCCs used to determine the FFS capitation rates and in the USPCCs based on all beneficiaries (FFS and MA) that are used to estimate the national MA growth trend. This growth trend is used to tabulate the minimum update rates in years when the trend is greater than 2 percent.

However, in terms of adjusting payments to MA organizations, §422.109 applies only to NCDs and legislative changes in benefits that meet significant cost thresholds set forth in law. When an NCD or legislative change in benefit is determined to be a "significant cost" new benefit in the middle of an MA contract year, CMS must pay providers for MA enrollee claims under the new benefit on a FFS basis on behalf of the MA organization. The statute addresses only NCDs and legislative changes, not LCDs.

Comment – Late Payment for Non-Contracting Providers: One commenter wondered how issues regarding late payment for non-contracting providers, beneficiary dissatisfaction with MA services, and plan refusal to pay for covered services would be handled.

Response: Providers and beneficiaries should let the appropriate CMS regional office or plan manager know about these types of concerns. Plans are required to abide by CMS policies in these areas. CMS will review concerns and investigate and act on any violations of CMS policy.

Section D: Changes to Risk Adjustment Method for MA Organizations

Delay in Implementing Updated CMS-HCC Risk Adjustment Model. CMS has decided to delay the implementation of the updated and recalibrated CMS-HCC risk adjustment model until calendar year 2007. In the Advance Notice, published February 18, 2005, we announced that a refined CMS-HCC model for Part C payment would be effective for 2006. The Notice stated that all segments of the risk adjustment model (community, long-term institutionalized, and ESRD) would be updated for 2006 to reflect newer treatment and coding patterns in fee-for-service Medicare, to use the additional codes being collected for the Part D model, and to accommodate additional codes that complete a Hierarchical Condition Category (HCC).

However, we recognize that implementing an updated risk adjustment model in 2006 at the same time that the new MMA bidding and payment methodology must be implemented introduces additional uncertainty into the MA program. Given the considerable volume of changes that must be in effect for 2006, we have concluded that a delayed implementation of the updated CMS-HCC model is appropriate. The one-year delay will allow MA organizations additional time to gain experience with the bidding and payment changes effective in 2006.

We are committed to working with MA organizations to implement the updated model in 2007. Through open door forums and contacts with expert actuaries, we will develop and present analyses to demonstrate the anticipated impact of the updated model, and we will

have an opportunity to take additional comments into account prior to finalizing the model.

In light of the delayed implementation date, we are not responding to other comments on the recalibrated CMS-HCC model at this time.

Because we intend to implement the updated model in 2007, MA organizations should continue submitting the additional codes for the updated CMS-HCC model. (Instructions and updated codes were posted on 5/17/2004 on the CMS website at cms.hhs.gov/healthplans/riskadj). In addition, we will continue to reflect changes to the ICD-9 codes made by the National ICD-9-CM Coordination and Maintenance Committee twice a year (April and October), so MA organizations should check this website to learn what codes have been added to the model to reflect Committee changes.

The delayed introduction of the refined CMS-HCC model does not affect the treatment of MSP status, including working aged status, as discussed below.

Medicare as a Secondary Payer for Risk Adjustment in 2006

Comment – Medicare as Secondary Payer for Risk Adjustment: In the Advance Notice, CMS proposed to recalibrate the Part C risk adjustment models (CMS-HCC model and ESRD model) for 2006 to include the costs associated with beneficiaries for whom Medicare is a Secondary Payer (MSP). This means that, on average, risk scores would be appropriately adjusted for MSP status and that no further adjustment would be necessary. We received a number of comments on this proposal. Most commenters asked that CMS not include MSP beneficiary costs in the models, and instead retain the current plan-level working aged adjustment for aged beneficiaries. Commenters asserted that calibrating the risk adjustment models on combined MSP and non-MSP costs will result in less accurate plan payments and more burden for MA plans. Several commenters stated that the loss of revenue for plans will be significant under the combined models. Several commenters also concluded that CMS is weakening the ability of the risk adjustment model to accurately forecast the expected costs of any Medicare population that has a significantly different proportion of working aged or MSP than would be assumed in the calibration of the model.

Furthermore, commenters stated that MA organizations have invested significant resources to improve the accuracy of working aged data (the subset of the MSP status that includes beneficiaries age 65 or older with employer group health coverage through their own or spousal employment). Commenters claimed they have achieved considerable success in accurately establishing the appropriate Working Aged (WA) percentage for our enrolled member population. Finally, many commenters suggested that CMS work with the industry to further analyze the proposed introduction of combined models.

Response: Based on the comments, CMS has decided not to proceed at this time with the proposal to recalibrate the Part C risk adjustment models (CMS-HCC and ESRD) for

2006 to include the costs associated with beneficiaries for whom Medicare is a Secondary Payer.

This decision not to proceed with the MSP inclusive model means, however, that payments must be adjusted to reflect MSP status. Changes to the current methodology to address these issues are described below.

Medicare as a Secondary Payer under the CMS-HCC Model. Currently each MA organization surveys a cohort of its aged members and reports to CMS those with coverage primary to Medicare due to working aged (WA) status. The WA status of non-responders to the survey is determined from the Common Working File. Using this information, CMS then calculates a WA payment adjustment factor by comparing prospective capitated blended payments with no WA adjustment to payments with a WA adjustment for those identified as WA. This factor is then applied to the organization's monthly blended capitated payment. We will continue to apply this methodology for the organization's aged enrollees to their demographic payments (rather than to their blended demographic and risk adjusted payments). Specifically, the current adjuster developed for the working aged will apply only to the prospective demographic payments.

This current method of identifying MSP status is not appropriate for risk adjusted payment because the disabled are not included in the development of the plan-level adjustment for WA. Unlike the demographic model for which the current methodology was developed, risk adjusted payments for the disabled must be adjusted for MSP to ensure accurate payment. Therefore, for risk adjustment, we will revise the 2005 methodology to include the disabled. In our estimate of the proportion of beneficiaries with MSP in the plan, we will expand WA status to include MSP status for disabled individuals, as determined by the Common Working File. We will then calculate the appropriate MSP factor and apply it to the prospective risk adjusted payments.

Medicare as a Secondary Payer under the ESRD Risk Adjustment Model. Currently, in the demographic system, there is no adjustment for the MSP status of MA enrollees with ESRD. The MSP and non-MSP populations are averaged. Given that the ESRD model is calibrated as if Medicare were always primary, such an adjustment is necessary. For 2006, we will use CMS' standard system to identify ESRD beneficiaries for whom Medicare is secondary and adjust payments at the individual level.

Based on the extensive comments, we have decided that further study is needed on the impact of our proposal. Therefore, we plan to continue to work through these issues and are committed to working with the industry to determine the payment impact of our combined model proposal, and to determine how to identify the best estimate of the percentage of MSP in these populations. We may propose the combined model again at a future date.

Comment—Definition of New Enrollee Status for Risk Adjustment. One commenter asked whether beneficiaries with Part B-only coverage will be considered new enrollees for purposes of calculating Part D payments. The commenter noted that consistent with

Part D eligibility requirements, PACE organizations have always enrolled beneficiaries with Part A and/or Part B coverage. Further, as a consequence of PACE requirements under §460.92, PACE organizations are required to provide all Medicare and Medicaid covered services to all PACE enrollees regardless of payment source.

Response: This comment regarding which risk adjustment factors apply to payment was submitted as a Part D PACE comment. We have determined that this comment pertains to all risk adjustment payments under Parts C and D for MA plans, demonstrations, and PACE organizations. Therefore, we include this response here and also in Enclosure IV.

Table II-1. Which Risk Adjustment Factors Apply to Payment*

Time Period Beneficiary Has Been Enrolled in Part B Medicare**	**Time Period Beneficiary Has Been Entitled to Benefits under Part A Medicare****	
	0 - 11 months	**≥ 12 months**
0 – 11 months	new enrollee factors	Plan's option: new enrollee or full risk adjustment factors
≥ 12 months	full risk adjustment factors	full risk adjustment factors

* Applies to Part C and D payments for MA plans, demonstrations, and PACE organizations. Note that MA enrollees must be entitled benefits under Part A and enrolled in Part B.
** During data collection period (previous calendar year).

As indicated in Table II-1 above, beneficiaries with 12 or more months of Medicare Part B enrollment during the data collection period (previous calendar year) are considered full risk enrollees. The new enrollee factors do not apply.

Beneficiaries with less 12 months of entitlement to benefits under Part A and less than 12 months of Part B enrollment during the data collection period will be treated as new enrollees, as they are now.

Currently beneficiaries with than 12 or more months of entitlement to benefits under Part A and less than 12 months of Part B enrollment during the data collection period (referred to as "Part A-only" enrollees in this response) are considered new enrollees for the purpose of risk adjusted payments. Because of concerns expressed by some demonstrations that "Part A only" enrollees are always considered to be new enrollees, CMS is creating an option for how the risk adjustment payments for this category of enrollees are determined. Effective for 2006 payments, organizations may elect to have CMS determine payments for all "Part A-only" enrollees using either new enrollee factors or full risk adjustment factors. The organization's decision will be applied to all "Part A-only" enrollees in the plan. Plans may not elect to move some eligible "Part A-only" enrollees into risk adjustment, while retaining others as new enrollees.

This option elected by the organization will remain turned "on" until CMS is notified otherwise prior to August 31st of any successive year. CMS will apply this option during reconciliation for a payment year only (that is, it will not be applied prospectively). Plans interested in this option must contact: Angela Porter, at Aporterjames@cms.hhs.gov by 8/31/2005 to elect this option.

Comment – Transition Payment Blends and PACE: A commenter requested confirmation of how payments made by CMS on behalf of PACE enrollees will be calculated for Medicare services covered under Parts A and B.

Response: In 2006, 50 percent of PACE payment will be based on the 2003 PACE payment methodology. The remaining 50 percent of payment will be based on the CMS-HCC risk adjustment methodology, including frailty. Because PACE organizations are excluded from the Part A and B bidding process, the individually risk-adjusted portion of the payment will continue to be equal to the rescaled MA county level rate multiplied by the enrollee's individual risk score. ESRD will be paid 100 percent at the appropriate ESRD rate multiplied by the enrollee's risk score.

Comment – Demographic Factors: One commenter noted that for the new MA Parts A&B bidding, plan bids are expected to be at a CMS-HCC risk score of 1.0 for 75 percent of the bid and at 1.0 demographic factor for 25 percent of the bid. The commenter stated that an additional adjustment to the demographic portion of bid is appropriate only in 2006 because, unlike the CMS-HCC risk adjustment scores, the demographic county benchmarks are not currently normalized to 1.0. The commenter noted that the demographic scores average to be less than 1.0, something on the order of 0.993. For this one year of including the demographic portion in the bidding process, the commenter suggested that plans be able to inflate the demographic portion of their bids by 1/ 0.993 (if 0.993 is the right number) to make the bids on par with the demographic county benchmark.

Response: The 2005 FFS rates do take into account that the demographic factors are no longer normalized to 1.0. We were able to standardize the FFS rates to reflect this shift because these were newly created rates, effective in the revised 2004 ratebook. These FFS rates represent the best estimate of what average FFS costs are per county Specifically, a county FFS rate is determined by dividing the USPCC for FFS by the average demographic factor for the country -- which would reflect the fact that the average is less than 1.0, and then multiplying by a county geographic adjustment. The county rates that were floor, blend, or minimum updates rates in the revised 2004 ratebook do not reflect this shift in the demographic factors. These rates are based on formulas set in law. Floor and minimum update rates were rates established by the Congress as the appropriate amounts to pay, first in the 1997 BBA, and later in the BIPA 2000.

Comment – Changes to Frailty Factors for PACE and Certain Demonstrations. One commenter asked whether frailty factors will be applied outside of the PACE program and certain demonstrations.

Response: Because we are delaying the implementation of the updated CMS-HCC risk adjustment model until 2007, the frailty factors for 2006 will not change. In 2006, frailty factors will only be applied to PACE organizations and certain demonstrations. CMS is continuing to conduct analyses to determine the feasibility of implementing the frailty adjuster for the MA program. We are investigating whether and how the ratebook should

be adjusted. We are also considering refinements to the current model, including re-estimation of the frailty adjuster based on a larger sample. Once the technical issues are resolved, we will calculate impact estimates and address policy issues. If CMS determines that the frailty adjuster is appropriate for application to the MA program, the earliest this application would occur is 2007. CMS will announce payment changes for 2007 through the 2006 Advance Notice of Methodological Changes for CY 2007 MA Payment Rates.

Summary of Comments on Reporting of Medicaid Status for Demographic Payment and Part C Risk Adjusted Payment.

Comment: Several commenters supported CMS' efforts to improve the accuracy and efficiency of the system that captures dual eligible status. Comments were very supportive of the creation of a uniform, standard process to obtain the needed information and look forward with cautious optimism to the implementation of this system. However, a number of major concerns were raised, including the accuracy and reliability of the new Medicare/Medicaid files, the ability of MA organizations to report Medicaid status if the CMS system does not accurately reflect the enrollee's status, and the schedule for implementing the change in the system for Medicaid reporting. Several commenters recommended that CMS provide a process for correcting Medicaid status indicators in situations where the Medicare Advantage plan has information that an enrollee or potential enrollee is Medicaid eligible but the CMS system is not reflecting this Medicaid status. Commenters believed that errors in the data are inevitable and that there should be a process in place to address such errors.

Response: CMS agrees that the completeness and accuracy of the States' monthly submission of Medicare/Medicaid files will be extremely important. The implementation of a number of Part D provisions is crucially dependent on the success of this process. These include: determination of low income subsidy status and auto-enrollment of "deemed" low income beneficiaries in Part D plans; determination of the number of enrollees for the phased-down State contribution payment; and reporting of low income subsidy applications and determinations by the States. However, given the known limitations of the current system for the identification of dually-eligible individuals in MA organizations, CMS is sympathetic to plans' concerns about the reporting of Medicaid status. While we believe that the importance of obtaining the appropriate low-income subsidies under Part D for dually-eligible beneficiaries will provide the incentive for vastly improved reporting, we are also aware that the new system will require monitoring and feedback. Therefore, we will implement a process for Part C payments in 2006 whereby CMS will use the new Medicare/Medicaid Dual eligible file to replace the Third Party Buy-In file as our standard source of the Medicaid status indicator. CMS will continue to provide a process for MA organizations to correct Medicaid Status indicators for Part C payment purposes.

CMS will conduct analyses to assess the reliability and accuracy of the data from the Medicare/Medicaid Dual Eligible enrollment files compared to current sources (i.e. the Third Party Buy-In file and plan-reported Medicaid) and make public, at an aggregate

level, the results of these analyses. We expect to base further decisions on the results of this analysis and consultation with the industry.

Comment: One commenter interpreted the Advance Notice as indicating that the MMA Medicaid file will limit the reporting of Medicaid eligibility to the reporting month plus only one prior month.

Response: There is no intention to limit Medicaid eligibility reporting to the current month plus only one prior month. The phrase "in a prior month" should read "in prior months" and should be interpreted to mean all retrospective monthly changes in Medicaid eligibility. As is the current policy, CMS will impose a limit on the time that retrospective Medicaid status adjustments will be accepted for payment purposes.

Comment: One commenter asked CMS to confirm how enrollees will be assigned Medicaid status in 2006. Specifically, the commenter asked CMS to confirm that Medicaid status in the payment year will no longer be based on a minimum of one month's Medicaid eligibility in the prior year; rather, beginning in 2006, Medicaid status will be assigned on a concurrent basis using data in States' MMA Medicare/Medicaid Dual Eligible monthly submission files.

Response: Only the source of the Medicaid indicator is changing. The rules for assignment of Medicaid status will be the same as in 2005 for both demographic and risk adjusted payment. Briefly, under risk adjustment, Medicaid status for full risk enrollees will be assigned based on Medicaid eligibility during the data collection year and Medicaid status for new enrollees will be on a concurrent basis during the payment year. For non-risk adjusted payment, Medicaid status will be assigned on a concurrent monthly basis. Medicaid status will be reconciled for final payment under risk adjustment after the end of the payment year.

Section E: Budget Neutral Risk Adjustment in Payments to Local and Regional MA Organizations

Comment - Modification of the Budget Neutrality Adjustment for Regional Plan Enrollees: One commenter requested that CMS not adjust the budget neutrality estimate for projected regional plan enrollment. The commenter also asked what is the maximum swing in the budget neutrality factor by county resulting from the technical adjustments to the budget neutrality calculation made because regional plans may exist in 2006.

Response: The Advance Notice announced that the budget neutrality adjustment for 2006 will be calculated as the difference between payments to organizations at 100 percent of the demographic rate and payments at 100 percent of the risk rate. For purposes of the calculation, OACT assumed that payments to local plans will be at the

local benchmarks adjusted for each plan's demographic and risk scores. Current data do not show any enrollment in regional plans, since those plans will not start until next year. OACT assumed an estimate of enrollees in regional plans consistent with the assumptions in the President's FY 2006 Budget baseline and the 2005 Trustees Report (which can be found at http://www.cms.hhs.gov/publications/trusteesreport/). The budget neutrality adjustment is the same percentage for all counties and all regions. The budget neutrality calculation was determined as follows:

1) For enrollees in local plans, the adjustment was calculated as in prior years, i.e. 100 percent of demographic payments to plans minus 100 percent of risk adjustment payments to plans expressed as a percent of risk adjusted payments. This resulted in an adjustment of 14.23 percent.
2) For enrollees in regional plans, the estimated adjustment for local plans was adjusted for the expected difference in risk scores relative to demographic scores for the regional enrollees relative to local enrollees. This resulted in an adjustment of 9.61 percent for expected enrollees in regional plans.
3) An enrollment weighted average of local and regional plan factors was calculated, using the estimated local and regional enrollment as weights. We currently estimate about 74.6 percent of enrollees in 2006 to be in local plans and about 25.4 percent in regional plans. This resulted in a weighted average adjustment of 13.05 percent. This is the budget neutrality factor for 2006.
4) The weighted average budget neutrality factor and the FFS normalization adjustment of 5 percent was applied to all local rates and hence in the statutory components of the regional rates through the weighting of the local rates. Both of the adjustments are reflected in the rescaling factors for the determination of the risk ratebook. As explained in the ratebook file, the rescaling factors are adjusted by 1.0767 (1.1305/1.05).

Comment – Budget Neutrality: One commenter recommended that CMS maintain for the 2006 ratebook the current budget neutrality factor of 8.65 percent utilized for 2005. In addition, the commenter recommended that CMS announce this factor as soon as possible and not wait until the release of rates on April 4, 2005. The rationale for this recommendation is to enhance payment stability and to help plans with their bid preparation by announcing the budget neutrality factor in advance of the Final Rate Announcement on April 4.

Response: The budget neutrality factor is always announced in conjunction with the Medicare Advantage Rates because it is based on the upcoming annual rates. Currently, the budget neutrality (BN) estimate is calculated to ensure that risk adjustment does not reduce the aggregate amount of payments to MA organizations. We must determine each year what the aggregate payments are under the demographic and risk adjustment methods in order to arrive at the correct BN estimate. Budget neutrality is not intended to inflate or deflate risk adjusted rates above or below the level that would produce payments equivalent to demographic payments. Unless the BN adjustment for 2006 is exactly equal to the 2005 adjustment (1.0865), the effect of the commenter's suggestion

would be to either overpay or underpay MA organizations. As indicated above, the BN factor for 2006 is different from the 2005 factor.

Comment: In order to fully understand the implications of phasing-out budget neutrality, it would have been helpful if CMS had provided estimates of the percent reduction in capitation payments that will result from this change in policy. Such information would have provided currently operating and prospective PACE organizations as well as other Medicare managed care programs with the ability to estimate the financial consequences of this policy change on their operations. By waiting until late December 2005 to release such estimates as part of the January 2006 MMRs, programs are prevented from utilizing this information in formulating their responses to the Advance Notice.

Response: Budget neutrality is being implemented at 100 percent in 2006 and therefore there are no payment implications. CMS published the budget neutrality phase-out schedule in the Advance Notice, and we believe organizations will have ample time to estimate the impact of this policy prior to 2007.

Enclosure IV. Response to Part D Public Comments

Summary

The following enclosure provides responses to comments and questions submitted for the Part D Section III portion of the "Advance Notice of Methodological Changes for Calendar Year (CY) 2006 Medicare Advantage (MA) Payment Rates" published on February 18, 2005. The comment period closed on March 4, 2005.

We received 42 separate sets of comments and questions. The majority of comments and questions were focused on the Part D risk adjustment model, the reconciliation process, and the special payment methodology for PACE. These comments and questions generally can be categorized as requests for clarification and additional information. Some comments only expressed support and do not need to be addressed, including the following:

- one commenter commended CMS for the establishment of an administratively reasonable method to allow Part D plans to receive interim reinsurance and low-income subsidy payments subject to an end of the year reconciliation;
- another commenter expressed support for the efforts CMS has made to establish low-income and institutional multipliers that are designed to ensure that the payment methodology accurately reflects the cost of care for vulnerable populations; and
- another comment fully supported CMS' effort to implement the MMA conference report language and CMS' demonstration authority to make available a demonstration for PDPs, MA-PD plans, and Cost plans that is designed to address a disincentive under the Part D program for plans to provide coverage in the coverage gap.

We also wish to clarify that as was anticipated in the final Part D rule preamble, we will not be conducting a geographic risk adjustment of the national average bid amount in 2006.

Enclosure V is organized as follows:

- Section A-Part D risk adjustment model
- Section B-Reconciliations and risk sharing
- Section C-Special PACE methodology
- Section D-Implementation issues
- Section E-Reinsurance demonstration
- Section F-Private fee-for-service (PFFS)
- Section G-Dual eligibles and institutional status

A-Part D risk adjustment model

Comment—Relative weights for Part D risk adjustment model. The reason for the relative weights for some RXHCCs is unclear. For example, the weight for RXHCC 30 Other Musculoskeletal and Connective Tissue Disorders is greater than for RXHCC 46 Lung, Upper Digestive Tract and Other Severe Cancers. Even though many of the cancer

drugs may be covered under Part B, it is our understanding that there could be a relatively high use of Part D covered drugs for RXHCC 46. We recommend that CMS reexamine RXHCC weights to ensure that they are correct and release information concerning the underlying data and methodology that has result in these weights.

Response: As an integral part of the development of our Part D model, we submitted it to physicians and pharmacists for review. The consultants argued that prospective drug costs for RXHCC 30 (Other Musculoskeletal and Connective Tissue Disorders) can be high because of long term costs. In their original rankings of drug costs using an ordinal scale, they ranked most of the component diagnoses of RXHCC 30 greater than or equal to the component diagnoses of RXHCC 46.

Comment: 70 new ICD-9 codes in the model. It is our understanding that the recently released list of codes includes seventy ICD-9 codes that were not in the list issued in July, 2004, as the basis for expanded collection of diagnoses intended to lay the foundation for the Part D risk adjustment model. While we and our member organizations are still in the process of evaluating the additional diagnoses, at this time, we do not have an objection to their inclusion. If CMS retains these diagnoses in the model, we recommend that CMS explicitly call attention to these new diagnoses to ensure that affected plans are aware of the addition, clarify whether all of these diagnoses are being added for both MA and Part D risk adjustment purposes, and formally announce as quickly as possible the requirement that these diagnoses must be submitted for the period beginning January 1, 2005. We also recommend that CMS provide more detailed information regarding the rationale for their inclusion in the both risk adjustment models.

Response: The omitted codes are included in the Part D model, but not in the MA model, because their inclusion will lead to more accurate Part D risk scores. These additional diagnoses must be submitted for the period beginning January 1, 2005. They were omitted from the earlier list by mistake. All managed care organizations, PDP applicants and PACE organizations have been notified of the codes and submission requirements via the Health Plan Management System (HPMS). In addition, the omitted codes and submission requirements are posted on the CMS website at http://cms.hhs.gov/pdps .

Comment—Risk scores. Two commenters ask that CMS identify the scores that were used and applied to the Federal Employee Health Benefit Program (FEHB) data in developing the risk methodology.

Response: The question implies the use of HCC risk scores in the modeling, however, risk scores were not **assigned** to the observations in the data files. The FEHB data were used to **statistically develop** factors related to the demographic and diagnostic groupings. Diagnoses from the Medicare files were used along with pharmacy expenditures by the FEHB plan for each enrollee from the next year's pharmacy data.

Comment: Disabled Medicaid in risk adjustment model. One commenter asked us to identify to what extent this subgroup of members were included in the modeling construct.

Response: The Medicaid file used in the modeling was a 5% file of dual eligibles including both those under 65 (disabled) and over 65. Some states were omitted because their data were incomplete. All age/sex groups were weighted up to their proportion in the Medicare population.

Comment—Specialized population variation. One commenter asked that the factors that vary for specialized populations such as dual eligibles and institutionalized beneficiaries be identified.

Response: The factors within the model do not vary. However, the resulting total risk factor is augmented by a multiplier that depends on low-income status or institutional status.

Comment—Denominator. Several commenters asked that the denominator used to convert the dollar amounts to factors be released.

Response: The national mean for the Fee-For-Service (FFS) population is used as the denominator and is $993.33.

Comment: Low spenders. Several commenters noted that the Advance Notice stated that the method tends to over-predict for "low spenders". Since Part D is a voluntary program, it is possible that "low spenders" will choose not to enroll in Part D. The commenters asked CMS to identify if the model was calibrated to take into account this potentially skewed spending pattern.

Response: The model is not adjusted to reflect any particular assumptions concerning the enrollment pattern. Over-prediction of low base amounts of spending has a relatively small impact because the expenditures are a small proportion of the total.

Comment: Uniformity. One commenter asked that we confirm that the same risk adjustment factors will be used for all plan designs.

Response: Yes, this approach was adopted in consultation with independent actuaries in an American Academy of Actuaries' workgroup.

Comment: Base Population. Please identify the population base that will be used to establish the standardized risk score.

Response: The base is the entire FFS population present on July 1, 2004 including full risk-adjustable and new enrollee designated beneficiaries.

Comment: Aggregate Weighted Average of 1.0. Please publish the calculations supporting the establishment of this factor by providing the membership distribution and factors used for each individual county.

Response: The factor is 1.0 for the average prediction from the model for the FFS population. The county factors result from the mean predictions for the FFS beneficiaries who reside in each county as indicated in the Medicare Beneficiary Database. The membership distribution and aggregate risk factors for each individual county will be available on the CMS website.

Comment: Cost Sharing Variation. One commenter noted that the spending of all people in the model calibration data was reduced to compensate for the higher cost sharing (reverse of "induced demand effect") and asked that we provided the factor used in this calculation.

Response: The actuarial estimate of the effect of cost sharing in moving from the reference (FEHB) benefit to the standard Medicare benefit is a reduction in spending of 19.8%. The institutionalized were not subject to this adjustment.

Comment: Factor Information. One commenter requested that CMS share further information and supporting documentation to demonstrate that the additional factors identified in the Notice (1.08 and 1.05 for low income and 1.08 and 1.21 for LTC beneficiaries) are appropriate for these populations. This would include documentation to indicate that these factors are sufficient to cover the adjustment made for the spending of all people in the data.

Response: Low income beneficiaries. The additional factors for low income beneficiaries adjust for the "insurance effect" (induction) of the low income subsidies. That is, beneficiaries respond to these subsidies, which reduce out-of-pocket payments for prescription drugs, by increasing their use of prescription drugs. The induction model is based on a regression of drug expenses as a function of out-of-pocket expenses.

The adjustment factors are the ratios of calculated drug plan liabilities using our induction model and drug expense data in the Medicare Current Beneficiary Survey for beneficiaries in the community to the predicted drug plan liabilities using the risk adjustors without induction. Although we calculated factors for each of the low income groups, we found that the difference in the means for the $1/$3 copay group and the $2/$5 copay group was not significant. Hence, we combined these two groups and recalculated their adjustment factor (1.08). The adjustment factor for those who pay a $50 deductible and 15 percent coinsurance is 1.05.

Long term care beneficiaries. The predicted model was developed on the community population only, excluding the institutionalized. The estimate for the additional long-term institutionalized factors was a direct estimate made by comparing predictions using the model to the actual spending by the institutionalized reported in the data. Data for the institutional were not adjusted downward for the induced demand effect in moving from

the reference FEHB benefit to the standard Medicare benefit. Only the scaling of the Medicaid data to FEHB affected the expenditures of institutionalized Medicaid enrollees.. The ratios of reported expenditures to model predicted expenditures for aged and disabled are the additional multiplicative factors.

Comment—Disabled Medicaid Adjustment. Please identify if there is any adjustment provision established for disabled Medicaid status.

Response: The disabled factors derive from the age/sex specific factors for the under 65 and the common set of condition factors. The low-income factor then applies if the disabled person has Medicaid or other low-income status.

Comment—Trend factors. What trend factors, if any, were used to adjust the data? Were different practice, prescribing, or utilization patterns and Rx market changes assumed for 2006 versus 2000?

Response: The Office of the Actuary made spending projections into 2006. The FEHB spending data were from calendar year 2002. This spending was increased by 55.42 percent. The Medicaid data were from calendar year 2000. This spending was increased by 103.98 percent.

Comment—Low income multiplier. Is the low-income multiplier for dual eligible beneficiaries with incomes greater than 100% of the federal poverty level also 1.08?

Response: Yes, as illustrated in the second column of table III-2 on page 47 of the advance notice, low-income beneficiaries up to 135% of the federal poverty level receive the estimated 1.08 multiplier.

B. Reconciliations and risk sharing

Comment—Timing of reconciliations and induced utilization adjustment. When are low-income subsidy and reinsurance reconciliations done? How are the risk corridors adjusted for induced utilization?

Response: The low-income subsidy and reinsurance reconciliations will begin after the coverage year once final data have been submitted, which is no later than six months after the end of the coverage year. As defined by §423.308 of the final Part D rule, allowable risk corridor costs must exclude costs attributable to induced utilization resulting from enhanced alternative coverage. The induced utilization factor used to adjust the costs will be included and negotiated with the bid. For an example see the draft bid pricing tool available online at: http://www.cms.hhs.gov/pdps/.

Comment: Risk sharing in an enhanced alternative plan. One commenter recommended that CMS add an example in this discussion that would identify how risk

corridor calculations are made when the Part D plan includes supplemental benefits under the enhanced alternative benefit design.

Response: As defined in §423.308 of the final Part D rule, allowable risk corridor costs are the subset of actually paid costs for covered Part D drugs not including administrative costs that are attributable to basic drug coverage and adjusted for an induced utilization effect. The example in the Advance Notice still holds except for the adjustments made so the costs are attributable to basic only and for the induced utilization. The adjustment for basic only will be done at the claims submission level and this process is discussed in detail in the forthcoming PDE guidance. The adjustment for induced utilization will be done through a factor provided with the bid. For an example of the induced utilization effect in the bid see the draft bid pricing tool online at http://www.cms.hhs.gov/pdps/.

Comment: Calculation of reinsurance and risk sharing. The calculation and application of the reinsurance and risk sharing need to be logically and algebraically consistent with the bidding process. CMS should carefully review the methodology for calculating the reinsurance and risk sharing to ensure the results are consistent with the application of the reinsurance, induced utilization factor, etc. in the bidding process.

Response: CMS has attempted to make the payment, reconciliation and risk sharing methodologies consistent with the bidding process and with applicable Part D statute and regulations. We also clarify that because dollars resulting from a negative premium described in 42 CFR §423.329 are applied to a supplemental benefit as directed by 42 CFR §423.272(e) these dollars are not included in the target amount, which defined in 42 CFR §423.308 is the total amount of payments to the plan for the risk adjusted standardized bid amount.

Comment: Adequate claims submission. One commenter asked CMS to define "adequate documentation of LICS amounts on PDE records" and identify the "claims submission deadlines" which were not identified in the Notice. Furthermore, the Agency was asked to clarify the statement "CMS may recoup all interim LICS payments" and whether this applies only to the claims of the records for which sufficient data has not been adequately submitted, or whether this applies to all LICS amounts.

Response: Details on the Prescription Drug Event (PDE) records, including submission deadlines, will be provided in separate guidance that will be available online at www.cms.hhs.gov/pdps/. In cases where insufficient data are submitted for LICS, CMS would recoup those interim LICS payments not supported by the PDE records.

Comment—Claims submission deadline. One commenter requested that CMS provide details regarding this process and include in the policy a process that will afford participating organizations extensions for data submission in the event that plans cannot timely obtain necessary records from entities integrally involved in aggregating PDE record data.

Response: As previously stated, details on the Prescription Drug Event (PDE) records and submission process will be provided in separate guidance that will be available online at www.cms.hhs.gov/pdps/. The Part D rule (42 CFR §423.343) states that submission of cost data must be made "within 6 months of the end of the coverage year". Therefore, no additional extension of the data submission deadline is permissible.

C. Special PACE methodology

Comment—New enrollees. One commenter asked whether beneficiaries with Part B only coverage will be considered new enrollees for purposes of calculating Part D payments. Consistent with Part D eligibility requirements, PACE organizations have always enrolled beneficiaries with Part A and/or Part B coverage. As a consequence of PACE requirements under §460.92, PACE organizations are required to provide all Medicare and Medicaid covered services to all PACE enrollees regardless of payment source.

Response: We have determined that this comment pertains not only to PACE Part D payments but to all risk adjustment payments under Parts C and D for MA plans, demonstrations, and PACE organizations. Therefore, we include this response here and also in Enclosure III.

Table II-1. Which Risk Adjustment Factors Apply to Payment*

Time Period Beneficiary Has Been Enrolled in Part B Medicare**	Time Period Beneficiary Has Been Entitled to Benefits under Part A Medicare**	
	0 - 11 months	≥ 12 months
0 – 11 months	new enrollee factors	Plan's option: new enrollee or full risk adjustment factors
≥ 12 months	full risk adjustment factors	full risk adjustment factors

* Applies to Part C and D payments for MA plans, demonstrations, and PACE organizations. Note that MA enrollees must be entitled benefits under Part A and enrolled in Part B.
** During data collection period (previous calendar year).

As indicated in Table II-1 above, beneficiaries with 12 or more months of Medicare Part B enrollment during the data collection period (previous calendar year) are considered full risk enrollees. The new enrollee factors do not apply.

Beneficiaries with less 12 months of entitlement to benefits under Part A and less than 12 months of Part B enrollment during the data collection period will be treated as new enrollees, as they are now.

Currently beneficiaries with than 12 or more months of entitlement to benefits under Part A and less than 12 months of Part B enrollment during the data collection period (referred to as "Part A-only" enrollees in this response) are considered new enrollees for the purpose of risk adjusted payments. Because of concerns expressed by some demonstrations that "Part A only" enrollees are always considered to be new enrollees, CMS is creating an option for how the risk adjustment payments for this category of enrollees are determined. Effective for 2006 payments, organizations may elect to have

CMS determine payments for all “Part A-only” enrollees using either new enrollee factors or full risk adjustment factors. The organization’s decision will be applied to all “Part A-only” enrollees in the plan. Plans may not elect to move some eligible “Part A-only” enrollees into risk adjustment, while retaining others as new enrollees.

This option elected by the organization will remain turned "on" until CMS is notified otherwise prior to August 31st of any successive year. CMS will apply this option during reconciliation for a payment year only (that is, it will not be applied prospectively). Plans interested in this option must contact: Angela Porter, at Aporterjames@cms.hhs.gov by 8/31/2005 to elect this option.

Comment—Risk adjustment and the frail community-based population. Has CMS evaluated the predictive power of the Part D risk adjustment model for a frail community-based population such as that enrolled in PACE? There is a substantial long term care multiplier applied to Part D payments for beneficiaries residing in long term care institutions. PACE programs serve individuals in the community whose acuity levels are consistent with those of individuals residing in long-term care institutions. One commenter argues that many of the same issues that CMS identifies as the basis for the long term care multiplier would also apply to drug costs for long-term care eligible populations in community settings.

Response: There is no evidence that after adjusting for health status that a community-based population such as those enrolled in PACE have higher prescription drug costs. The long-term care multiplier that CMS has developed is reflective of the increased prescription drug spending observed in institutional settings even after health status is held constant.

Comment—Enrollment changes. Referring to p. 57 of the Part D notice related to Part D enrollees who change plans during the coverage year, a commenter requests that CMS take into account any unique circumstances that might result from involvement of PACE enrollees in these transitions, as necessary.

Response: We clarify that the intention of our comment regarding enrollees changing plans on page 57 of the advance notice was to note the issues that will be resolved through the true out-of-pocket (TrOOP) coordination process. The request for proposal for the TrOOP facilitation contract is available online at www.fedbizopps.gov (search on: "CMS2005TrOOP2") and additional guidance regarding TrOOP coordination is forthcoming.

Comment—PDE data and PACE. Referring to CMS’ discussion of prescription drug event (PDE) data reporting requirements for PACE, a commenter requests clarification of the specific PDE data elements that will not be required of PACE organizations. Referring to the draft Prescription Drug Events Paper posted on CMS’ website, these are interpreted to be data elements including patient pay, low-income cost sharing subsidy, and supplemental cost share amounts; as well as those related to the attachment point, i.e. the catastrophic covered flag and gross drug cost below/above catastrophic cap.

Understanding that the PDE data reporting requirements have not yet been finalized, are these generally the types of data elements to which CMS is referring in the Notice?

Response: The commenter is correct in their interpretation of the draft prescription drug event (PDE) paper released December 14, 2004. A revision of the paper based on public comments is forthcoming.

Comment—Medicare-only PACE enrollees and premium methodology. Referring to the sections entitled "CMS payment methodology applicable to Medicare-only PACE enrollees" and "Premium methodology applicable to Medicare-only PACE enrollees", there is no recognition of the possibility that a Medicare-only enrollee may qualify for low-income premium and cost-sharing subsidies under Part D. Rather, CMS explicitly states that "no costs will be attributed to LICS," and the supplemental premium "will apply to all Medicare-only enrollees, regardless of income level." Under what authority would PACE organizations be allowed to deny low-income subsidies to qualified low-income beneficiaries?

Response. To clarify, Medicare-only PACE beneficiaries will be enrolled in an enhanced alternative plan, whereas the dual eligible PACE beneficiaries will be enrolled in a standard plan. Thus the Medicare-only PACE beneficiaries would have a supplemental benefit with a supplemental premium. The low-income subsidy does not apply to supplemental benefits. However, the commenter has recognized that these Medicare only beneficiaries may be eligible for a partial subsidy of the basic portion of the premium. For these beneficiaries, the rules for low-income benchmark premium and appropriate low-income premium subsidies would apply to these PACE plans as they would any other enhanced alternative plan with low-income eligible enrollees.

Comment—Medicare-only PACE enrollees and premium payment. One commenter seeks clarification of CMS' statement that Medicare-only PACE enrollees will be responsible for paying the full base beneficiary premium amount. Isn't it the case that Medicare-only enrollees will generally be liable for the full monthly beneficiary premium, i.e., the base beneficiary premium adjusted for the difference between the PACE organization's standardized bid amount and the national average monthly bid amount?

Response. The commenter is correct. This was a typographical error in the Advance Notice. The statement should be that the Medicare-only enrollees are liable for the monthly beneficiary premium.

Comment—Supplemental premium for Medicare-only PACE enrollees. Referring to CMS' instructions for calculating the supplemental premium for Medicare-only PACE enrollees on p. 60, CMS explains that the supplemental premium must account for the $250 deductible, 25% cost-sharing between $250 and $2250 and full beneficiary responsibility for all costs above $2250. We are not clear on why the 15% plan liability for costs above the out-of-pocket threshold are not included in the plan's basic bid.

Response. Due to the cost sharing prohibitions in sections 1894(b)(1)(A)(i) and 1934(b)(1)(A)(i) of the Act, PACE beneficiaries never reach the out-of-pocket threshold as defined by 1860D-2(b)(4)(B) of Act and therefore there is no reinsurance payments. The 15% plan liability is factored into the basic bid which will be the basis for payment and risk corridor calculations.

Comment—Medicare-only supplemental premiums. One commenter expressed concern that Part D may have unintended consequences for our Medicare-only enrollees. As a consequence of having to build all Medicare enrollees' cost-sharing responsibility into a supplemental premium thereby precluding reinsurance payments that would otherwise have been made on their behalf, we are concerned that the amount of the combined basic Part D and supplemental premiums may, in some situations, be higher than the amount they were previously paying for comprehensive drug coverage through PACE.

Response. As previously stated due to the cost sharing prohibitions, in place before the creation of Part D, PACE beneficiaries never reach the out-of-pocket threshold as defined by 1860D-2(b)(4)(B) of Act. We do not have the authority to make reinsurance payments unless beneficiaries reach the out-of-pocket threshold.

D. Part D Implementation Issues

Comment—Prescription drug claim submission process guidance. Potential Part D sponsors have not received any further guidance or final standards for the prescription drug claim submission process. We urge the Agency to establish the final standards no later than April 1, 2005 and communicate these processes to organizations prior to the CMS training that has been scheduled for April 4th and 5th. Plans will then be better prepared to engage CMS staff regarding issues that may potentially inhibit data submission. We recommend that CMS establish standards that would clearly demarcate timeframes for the submission of data from participants involved in the coordination of LIS benefits. This process should compliment the final prescription drug claim submission requirements that Part D sponsors must ultimately conform.

Response: CMS is making revisions to the draft "Requirements for Submitting Prescription Drug Event Data" based on public comments. The updated version will be released promptly. The CMS training the commenter refers to is specifically focused on the bidding process and will not include a session on requirements for submitting prescription drug event data.

E. Reinsurance demo

Comment—Negotiating the capitated reinsurance payment. One commenter requested that CMS provide additional details for negotiating the capitated reinsurance payment component during the plan bid approval process and asked for clarification on how the estimates for reductions identified in the options will be applied and how the risk corridors will be applied for plans that are approved for participation in option one.

Response: Additional guidance on the reinsurance demonstration will be provided online at www.cms.gov/pdps.

Comment—Different benefit plans. One commenter asked if a demonstration plan could apply for one benefit plan and not another?

Response: Eligible Part D sponsors may provide plans using either of the two options. They are not expected to do both options, but could do so if they were an eligible MA organization and wanted to have two demonstration plans. More details are available in the February 25, 2005 notice in the Federal Register, Vol. 70, No. 37, page 9360 available online at www.gpoaccess.gov/fr/index.html. Additional guidance on the reinsurance demonstration will be provided online at www.cms.gov/pdps.

F. Private fee-for-service (PFFS) plans

Comment—Reinsurance process. One commenter asked if a Private Fee-For-Service (PFFS) plan uses negotiated discounts, can the reinsurance reconciliation process work the same as for a non-PFFS MA-PD plan?

Response: No, the option to provide negotiated prices in section 1860D-21(d)(1) of the Act and the special PFFS reinsurance directive in 1860D-21(d)(4) of the Act are not linked. Irrespective of other special PFFS rules, CMS must make reinsurance payments to PFFS plans taking "into account the average reinsurance payments made under section 1860D-15(b) for populations of similar risk under MA-PD plans".

G. Dual eligibles and institutional status

Comment—Institutional status data. In the Part D final rule preamble, it says "States will be providing information on a full-benefit dual eligible individual's institutional status on a monthly basis to us. We will provide this information to Part D plans. We will address through operational guidance how plans should address situations in which an enrollee's institutional status is different than the information provided to them from us." Will you require PDPs or cost-PDs to do conduct an institutional census to compare against the state data? This is a time consuming and expensive process, especially if you are a regional plan. It would be a substantial effort to waive and track a $1 or $3 copay.

Response: Institutional status for low-income full dual eligibles for the purpose of the Part D cost sharing and premium subsidy will be ascertained from the Medicare/Medicaid dual eligible files submitted by the States. This dataset is discussed extensively above.

Long term institutional status for the purpose of applying the institutional factor for risk adjustment will be determined using CMS' Minimum Data Set (MDS). CMS has been using the MDS for determining LTI status since 2004 and this process has proven reliable.

Enclosure V. Part D risk adjustment model

Introduction

The Part D risk adjustment models are presented below. The plan liability models (for continuing and new enrollees) are the appropriate models for payment purposes. The multipliers for Low-Income Subsidy Eligible and Long Term Care (institutionalized) are also included. These multipliers are used to account for the additional costs of low income and long term care (institutionalized) individuals.

Because of public interest in the spending model which was used to develop Part D risk adjustment we have presented the spending model (full risk and new enrollee) for informational purposes. The spending model presents coefficients in dollars for projected total expenditures on prescription drugs covered by Part D in 2006 not accounting for cost sharing. Again, the spending model is not for payment purposes.

Risk Model for Plan Liability - The Payment Model

The RXHCCs are the condition categories in the model that are assigned incremental payments. They were developed starting with the taxonomy developed for the HCC model used to risk adjust payments for Part A and B services in MA plans. The HCC groupings were built from smaller groups called DXGs. We used both the high level HCCs and lower level DXGs in creating the new groups for drug risk adjustment. A new nomenclature is used because, although some groups are the same as those in the earlier work, there are also a number of splits, additions and deletions. The diagnoses used in the model are those found in Medicare data in the year prior to the drug payment year.

This table associates a risk factor with each RXHCC. The factors are generally additive. An enrollee may be credited with many conditions. In some circumstances a hierarchy is imposed so some conditions are mutually exclusive. The draft model posted in the Advance Notice associated dollar amounts with the conditions and demographics. Using this model a dollar prediction was made for each person in FFS Medicare and the average prediction was computed. The average was divided into the coefficients for the RXHCCs and the other payment factors to compute relative factors.

Below the RXHCCs are three groups labeled DRXHCC. These are add-on factors for people under 65 (disabled) with particular conditions - schizophrenia, other major psychiatric disorders, and cystic fibrosis. These amounts are added to the amount for the main entry of the diagnosis.

Below these categories are demographic categories for age/sex and for an aged person having entered Medicare originally for reasons of disability. Because one cannot predict all diseases with drug consequences by knowing prior year diagnoses, the demographic coefficients are significant in magnitude.

Plan liability takes into account the plan liability for spending after deductibles and other cost sharing in the Standard Part D benefit. These factors were derived for the noninstitutionalized population and without adjustments for the effects of the low income

subsidy. These factors will be discussed separately.

Part D Continuing Enrollee Risk Adjustment Model, Plan Liability Model

RXHCC Groups	RXHCC Labels	Relative Factors
RXHCC1	HIV/AIDS	2.042
RXHCC2	Opportunistic Infections	0.257
RXHCC3	Infectious Diseases	0.073
RXHCC8	Acute Myeloid Leukemia	0.293
RXHCC9	Metastatic Cancer, Acute Leukemia, and Severe Cancers	0.174
RXHCC10	Lung, Upper Digestive Tract, and Other Severe Cancers	0.050
RXHCC17	Diabetes with Complications	0.258
RXHCC18	Diabetes without Complication	0.190
RXHCC19	Disorders of Lipoid Metabolism	0.163
RXHCC20	Other Significant Endocrine and Metabolic Disorders	0.078
RXHCC21	Other Specified Endocrine/Metabolic/Nutritional Disorders	0.049
RXHCC24	Chronic Viral Hepatitis	0.092
RXHCC31	Chronic Pancreatic Disease	0.048
RXHCC33	Inflammatory Bowel Disease	0.182
RXHCC34	Peptic Ulcer and Gastrointestinal Hemorrhage	0.033
RXHCC37	Esophageal Disease	0.176
RXHCC39	Bone/Joint/Muscle Infections/Necrosis	0.023
RXHCC40	Behçet's Syndrome and Other Connective Tissue Disease	0.066
RXHCC41	Rheumatoid Arthritis and Other Inflammatory Polyarthropathy	0.198
RXHCC42	Inflammatory Spondylopathies	0.075
RXHCC43	Polymyalgia Rheumatica	0.043
RXHCC44	Psoriatic Arthropathy	0.150
RXHCC45	Disorders of the Vertebrae and Spinal Discs	0.141
RXHCC47	Osteoporosis and Vertebral Fractures	0.115
RXHCC48	Other Musculoskeletal and Connective Tissue Disorders	0.077
RXHCC51	Severe Hematological Disorders	0.113
RXHCC52	Disorders of Immunity	0.207
RXHCC54	Polycythemia Vera	0.092
RXHCC55	Coagulation Defects and Other Specified Blood Diseases	0.025
RXHCC57	Delirium and Encephalopathy	0.000*
RXHCC59	Dementia with Depression or Behavioral Disturbance	0.221
RXHCC60	Dementia/Cerebral Degeneration	0.142
RXHCC65	Schizophrenia	0.250
RXHCC66	Other Major Psychiatric Disorders	0.158
RXHCC67	Other Psychiatric Symptoms/Syndromes	0.127
RXHCC75	Attention Deficit Disorder	0.254
RXHCC76	Motor Neuron Disease and Spinal Muscular Atrophy	0.152
RXHCC77	Quadriplegia, Other Extensive Paralysis, and Spinal Cord Injuries	0.048
RXHCC78	Muscular Dystrophy	0.083
RXHCC79	Polyneuropathy, except Diabetic	0.077
RXHCC80	Multiple Sclerosis	0.358
RXHCC81	Parkinson's Disease	0.320
RXHCC82	Huntington's Disease	0.055

RXHCC Groups	RXHCC Labels	Relative Factors
RXHCC83	Seizure Disorders and Convulsions	0.127
RXHCC85	Migraine Headaches	0.106
RXHCC86	Mononeuropathy, Other Abnormal Movement Disorders	0.071
RXHCC87	Other Neurological Conditions/Injuries	0.031
RXHCC91	Congestive Heart Failure	0.251
RXHCC92	Acute Myocardial Infarction and Unstable Angina	0.140
RXHCC98	Hypertensive Heart Disease or Hypertension	0.222
RXHCC99	Specified Heart Arrhythmias	0.093
RXHCC102	Cerebral Hemorrhage and Effects of Stroke	0.063
RXHCC105	Pulmonary Embolism and Deep Vein Thrombosis	0.027
RXHCC106	Vascular Disease	0.035
RXHCC108	Cystic Fibrosis	0.163 [a]
RXHCC109	Asthma and COPD	0.163 [a]
RXHCC110	Fibrosis of Lung and Other Chronic Lung Disorders	0.077
RXHCC111	Aspiration and Specified Bacterial Pneumonias	0.043 [b]
RXHCC112	Empyema, Lung Abscess, and Fungal and Parasitic Lung Infections	0.043 [b]
RXHCC113	Acute Bronchitis and Congenital Lung/Respiratory Anomaly	0.043 [b]
RXHCC120	Vitreous/Retinal Hemorrhage and Vascular Retinopathy except Diabetic	0.056
RXHCC121	Macular Degeneration and Retinal Disorders, Except Detachment and Vascular Retinopathies	0.040
RXHCC122	Open-angle Glaucoma	0.161
RXHCC123	Glaucoma and Keratoconus	0.068
RXHCC126	Larynx/Vocal Cord Diseases	0.024
RXHCC129	Other Diseases of Upper Respiratory System	0.083
RXHCC130	Salivary Gland Diseases	0.050
RXHCC132	Kidney Transplant Status	0.215
RXHCC134	Chronic Renal Failure	0.074
RXHCC135	Nephritis	0.051
RXHCC137	Urinary Obstruction and Retention	0.048 [c]
RXHCC138	Fecal Incontinence	0.048 [c]
RXHCC139	Incontinence	0.102
RXHCC140	Impaired Renal Function and Other Urinary Disorders	0.023
RXHCC144	Vaginal and Cervical Diseases	0.033
RXHCC145	Female Stress Incontinence	0.067
RXHCC157	Chronic Ulcer of Skin, Except Decubitus	0.048 [c]
RXHCC158	Psoriasis	0.077
RXHCC159	Cellulitis and Local Skin Infection	0.048 [c]
RXHCC160	Bullous Dermatoses and Other Specified Erythematous Conditions	0.048 [c]
RXHCC165	Vertebral Fractures without Spinal Cord Injury	0.055
RXHCC166	Pelvic Fracture	0.040
RXHCC186	Major Organ Transplant Status	0.079 [d]
RXHCC187	Other Organ Transplant/Replacement	0.079 [d]
DRXHCC65	age < 65 and RXHCC65	0.375
DRXHCC66	age < 65 and RXHCC66	0.165
DRXHCC108	age < 65 and RXHCC108	0.897

RXHCC Groups	RXHCC Labels	Relative Factors
FEMALE 0 - 34		0.421
FEMALE 35 - 44		0.576
FEMALE 45 - 54		0.611
FEMALE 55 - 59		0.583
FEMALE 60 - 64		0.532
FEMALE 65 - 69		0.459
FEMALE 70 - 74		0.447
FEMALE 75 - 79		0.434
FEMALE 80 - 84		0.416
FEMALE 85 - 89		0.395
FEMALE 90 - 94		0.371
FEMALE 95+		0.317
MALE 0 - 34		0.397
MALE 35 - 44		0.519
MALE 45 - 54		0.541
MALE 55 - 59		0.491
MALE 60 - 64		0.433
MALE 65 - 69		0.355
MALE 70 - 74		0.354
MALE 75 - 79		0.348
MALE 80 - 84		0.334
MALE 85 - 89		0.326
MALE 90 - 94		0.301
MALE 95+		0.266
Age ≥ 65, female, originally entitled to Medicare due to disability		0.089
Age ≥ 65, male, originally entitled to Medicare due to disability		0.078

Notes:

1. a, b, c and d coefficients with same letter are restricted to be equal.
2. These relative factors are for community residents without the low income subsidy.
3. *Plan liability coefficient was set to zero because the coefficient was negative under the plan liability model.
4. The long term care or low-income multiplier applies if valid for the payment month
5. The FFS mean expenditures for normalization of the plan liability model is $993.33.

New Enrollee Model – Plan Liability

Enrollees with less than 12 months of Part B enrollment prior to the payment year, potentially do not have a complete diagnostic record in Medicare files. Most of these people are new enrollees in the Medicare program. For such people a model based solely on demographic characteristics is used. This table is not additive. A person is assigned to one cell by age/sex and whether they are aged and entered Medicare due to disability. The Plan Liability model is used for payment.

These factors were derived for the noninstitutionalized population and without adjustments for the effects of the low-income subsidy.

Part D New enrollee factors, Plan Liability Model

	Age-Sex not originally disabled	Age-Sex originally disabled
	Relative Factors	Relative Factors
Female 0 - 34	0.874	--
Female 35 - 44	1.174	--
Female 45 - 54	1.287	--
Female 55 - 59	1.287	--
Female 60 - 64	1.287	--
Female 65	0.903	1.287
Female 66	0.922	1.287
Female 67	0.942	1.287
Female 68	0.949	1.287
Female 69	0.959	1.287
Female 70 - 74	0.995	1.287
Female 75 - 79	1.028	1.204
Female 80 - 84	1.030	1.204
Female 85 - 89	1.005	1.204
Female 90 - 94	0.946	1.057
Female 95+	0.835	0.947
Male 0 - 34	0.845	--
Male 35 - 44	1.109	--
Male 45 - 54	1.109	--
Male 55 - 59	1.109	--
Male 60 - 64	1.109	--
Male 65	0.753	1.109
Male 66	0.767	1.109
Male 67	0.796	1.109
Male 68	0.817	1.109
Male 69	0.835	1.109
Male 70 - 74	0.877	1.109
Male 75 - 79	0.927	1.022
Male 80 - 84	0.941	1.022
Male 85 - 89	0.934	1.022
Male 90 - 94	0.868	0.956
Male 95+	0.804	0.891

Notes:
1. All cells are mutually exclusive. Specifically, an age 65, male who is originally disabled has a relative factor of 1.109; if he is not originally disabled, the relative factor is .753.
2. These relative factors are for community residents without the low income subsidy.
3. The long term care or low income multiplier applies if valid for the payment month.

Disease Hierarchies - Part D Risk Adjustment Model

As in the CMS-HCC model some of the disease groups are clustered in hierarchies. In clinical review it was found that drug regimens may get more intense and more drugs may be added when a disease has a higher severity. In such a case the highest cost

category of the related diseases is triggered and the lower cost categories zeroed out. Such is the case with diabetes, in which diabetes with complications overrides uncomplicated diabetes. In predicting drugs the codes for particular complications picked up the spending that differentiates diabetes with different complications.

If the drugs for diseases differ from one another, even it the diseases are related, the RXHCCs are not placed in the same hierarchy and remain additive.

Disease Hierarchies - Part D Risk Adjustment Model		
If the Disease Group is Listed in this Column….		**… Then Drop the Associated Disease Group(s) Listed in this Column**
Disease Group (RXHCC)	Disease Group Label	
1	HIV/AIDS	3
2	Opportunistic Infections	3, 112, 113
8	Acute Myeloid Leukemia	9, 10
9	Metastatic Cancer, Acute Leukemia, and Severe Cancers	10
17	Diabetes with Complications	18
37	Esophageal Disease	126
45	Disorders of the Vertebrae and Spinal Discs	48
51	Severe Hematological Disorders	54, 55
54	Polycythemia vera	55
59	Dementia with Depression or Behavioral Disturbance	60, 67
65	Schizophrenia	67
66	Other Major Psychiatric Disorders	67
91	Congestive Heart Failure	98
108	Cystic Fibrosis	109, 110, 113
109	Asthma and COPD	110, 113
110	Fibrosis of Lung and Other Chronic Lung Disorders	113
111	Aspiration and Specified Bacterial Pneumonias	113
112	Empyema, Lung Abscess, and Fungal and Parasitic Lung Infections	113
120	Vitreous/Retinal Hemorrhage and Vascular Retinopathy except Diabetic	121
122	Open-Angle Glaucoma	123
132	Kidney Transplant Status	134, 135, 140, 187
134	Chronic Renal Failure	135, 140
135	Nephritis	140
138	Fecal Incontinence	137
139	Incontinence	137
157	Chronic Ulcer of Skin, Except Decubitus	138, 160
159	Cellulitis and Local Skin Infection	160
186	Major Organ Transplant Status	187

How Payments are Made with a Disease Hierarchy
EXAMPLE: If a beneficiary triggers RXHCC157 (Chronic Ulcer of the Skin) and RXHCC160 (Bullous Dermatoses and Other Specified Erythematous Conditions) then RXHCC160 will be dropped. In other words, payment will always be associated with the RXHCC in column 1, if an RXHCC in column 3 also occurs during the same collection period. Therefore, the Part D plan sponsor's payment will be based on RXHCC157 rather than RXHCC160.

Long Term Care and Low-Income Multipliers for Part D Risk Adjustment Model (Plan Liability)

Long Term Care and Low Income Multipliers for Part D Risk Adjustment (Plan Liability Model)

Long Term Care Multiplier		Low Income Multiplier	
Disabled < 65 years	Aged ≥ 65 years	Group 1	Group 2
1.21	1.08	1.08	1.05

Notes:

1. The enrollee's base Part D risk score generated by the plan liability model is multiplied by the LI or LTC multiplier if they apply for the payment month.
2. The LI and LTC multipliers are mutually exclusive (i.e. only one multiplier can apply in a payment month) and LTC takes precedence over LI for the purposes of risk adjustment.
3. Long Term Care (Institutional) status is defined as residing in a nursing home for more than 90 days prior to the payment month. This is the same definition as in MA risk adjustment.
4. Group 1 for the LI multiplier includes all full low-income subsidy eligible individuals as defined in regulation at §423.773(b) as having income less than 135% of the Federal Poverty Level (FPL) and resources not exceeding three times the Supplemental Security Income (SSI) resource limit. Group 2 includes all partial low-income-subsidy eligible individuals.

Risk Model for Spending - for reference, not payment

This model is similar to the Plan Liability model in structure. The coefficients are in dollars projected for 2006. This model does not account for cost sharing; it is predictive of total expenditures on prescription drugs covered by Part D. This model is not used for payment but is of potential interest to bidders. The dollar values would have to be scaled to match any particular plan's price structure and deviation from average patterns of utilization. This is not a payment model.

These factors were derived for the noninstitutionalized population and without adjustments for the effects of the low income subsidy. These factors will be discussed separately.

Part D Continuing Enrollee Risk Adjustment Model, Spending Model

RXHCC Groups	RXHCC Labels	Dollar Coefficients
RXHCC1	HIV/AIDS	12314.00
RXHCC2	Opportunistic Infections	1647.65
RXHCC3	Infectious Diseases	345.61
RXHCC8	Acute Myeloid Leukemia	1689.53

RXHCC Groups	RXHCC Labels	Dollar Coefficients
RXHCC9	Metastatic Cancer, Acute Leukemia, and Severe Cancers	729.38
RXHCC10	Lung, Upper Digestive Tract, and Other Severe Cancers	111.55
RXHCC17	Diabetes with Complications	1091.45
RXHCC18	Diabetes without Complication	658.61
RXHCC19	Disorders of Lipoid Metabolism	397.06
RXHCC20	Other Significant Endocrine and Metabolic Disorders	400.91
RXHCC21	Other Specified Endocrine/Metabolic/Nutritional Disorders	158.53
RXHCC24	Chronic Viral Hepatitis	516.44
RXHCC31	Chronic Pancreatic Disease	293.08
RXHCC33	Inflammatory Bowel Disease	753.96
RXHCC34	Peptic Ulcer and Gastrointestinal Hemorrhage	141.62
RXHCC37	Esophageal Disease	644.19
RXHCC39	Bone/Joint/Muscle Infections/Necrosis	202.75
RXHCC40	Behçet's Syndrome and Other Connective Tissue Disease	294.36
RXHCC41	Rheumatoid Arthritis and Other Inflammatory Polyarthropathy	931.89
RXHCC42	Inflammatory Spondylopathies	392.74
RXHCC43	Polymyalgia Rheumatica	136.31
RXHCC44	Psoriatic Arthropathy	695.26
RXHCC45	Disorders of the Vertebrae and Spinal Discs	456.69
RXHCC47	Osteoporosis and Vertebral Fractures	292.27
RXHCC48	Other Musculoskeletal and Connective Tissue Disorders	182.63
RXHCC51	Severe Hematological Disorders	624.40
RXHCC52	Disorders of Immunity	1403.95
RXHCC54	Polycythemia Vera	320.79
RXHCC55	Coagulation Defects and Other Specified Blood Diseases	93.35
RXHCC57	Delirium and Encephalopathy	168.96
RXHCC59	Dementia with Depression or Behavioral Disturbance	1103.73
RXHCC60	Dementia/Cerebral Degeneration	558.69
RXHCC65	Schizophrenia	1268.40
RXHCC66	Other Major Psychiatric Disorders	644.59
RXHCC67	Other Psychiatric Symptoms/Syndromes	477.69
RXHCC75	Attention Deficit Disorder	991.13
RXHCC76	Motor Neuron Disease and Spinal Muscular Atrophy	876.70
RXHCC77	Quadriplegia, Other Extensive Paralysis, and Spinal Cord Injuries	261.77
RXHCC78	Muscular Dystrophy	391.39
RXHCC79	Polyneuropathy, except Diabetic	443.15
RXHCC80	Multiple Sclerosis	1926.99
RXHCC81	Parkinson's Disease	1377.19
RXHCC82	Huntington's Disease	269.28
RXHCC83	Seizure Disorders and Convulsions	497.65
RXHCC85	Migraine Headaches	542.02
RXHCC86	Mononeuropathy, Other Abnormal Movement Disorders	323.60
RXHCC87	Other Neurological Conditions/Injuries	147.75
RXHCC91	Congestive Heart Failure	717.49
RXHCC92	Acute Myocardial Infarction and Unstable Angina	436.02
RXHCC98	Hypertensive Heart Disease or Hypertension	469.14
RXHCC99	Specified Heart Arrhythmias	223.95

RXHCC Groups	RXHCC Labels	Dollar Coefficients
RXHCC102	Cerebral Hemorrhage and Effects of Stroke	232.31
RXHCC105	Pulmonary Embolism and Deep Vein Thrombosis	147.95
RXHCC106	Vascular Disease	134.53
RXHCC108	Cystic Fibrosis	637.90 [a]
RXHCC109	Asthma and COPD	637.90 [a]
RXHCC110	Fibrosis of Lung and Other Chronic Lung Disorders	341.15
RXHCC111	Aspiration and Specified Bacterial Pneumonias	158.65
RXHCC112	Empyema, Lung Abscess, and Fungal and Parasitic Lung Infections	222.96
RXHCC113	Acute Bronchitis and Congenital Lung/Respiratory Anomaly	115.26
RXHCC120	Vitreous/Retinal Hemorrhage and Vascular Retinopathy except Diabetic	182.63
RXHCC121	Macular Degeneration and Retinal Disorders, Except Detachment and Vascular Retinopathies	101.03
RXHCC122	Open-angle Glaucoma	446.49
RXHCC123	Glaucoma and Keratoconus	168.39
RXHCC126	Larynx/Vocal Cord Diseases	104.61
RXHCC129	Other Diseases of Upper Respiratory System	243.66
RXHCC130	Salivary Gland Diseases	281.75
RXHCC132	Kidney Transplant Status	882.63
RXHCC134	Chronic Renal Failure	328.48 [b]
RXHCC135	Nephritis	328.48 [b]
RXHCC137	Urinary Obstruction and Retention	156.29 [c]
RXHCC138	Fecal Incontinence	156.29 [c]
RXHCC139	Incontinence	395.50
RXHCC140	Impaired Renal Function and Other Urinary Disorders	72.71
RXHCC144	Vaginal and Cervical Diseases	66.85
RXHCC145	Female Stress Incontinence	228.45
RXHCC157	Chronic Ulcer of Skin, Except Decubitus	156.29 [c]
RXHCC158	Psoriasis	244.58
RXHCC159	Cellulitis and Local Skin Infection	162.37
RXHCC160	Bullous Dermatoses and Other Specified Erythematous Conditions	131.84
RXHCC165	Vertebral Fractures without Spinal Cord Injury	304.88
RXHCC166	Pelvic Fracture	250.06
RXHCC186	Major Organ Transplant Status	433.46
RXHCC187	Other Organ Transplant/Replacement	245.87
DRXHCC65	age < 65 and RXHCC65	1677.91
DRXHCC66	age < 65 and RXHCC66	711.85
DRXHCC108	age < 65 and RXHCC108	5650.38
Female 0 - 34		976.33
Female 35 - 44		1569.12
Female 45 - 54		1659.47
Female 55 - 59		1518.63
Female 60 - 64		1171.04
Female 65 - 69		817.34
Female 70 - 74		736.87

RXHCC Groups	RXHCC Labels	Dollar Coefficients
Female 75 - 79		660.60
Female 80 - 84		576.10
Female 85 - 89		488.31
Female 90 - 94		412.62
Female 95+		263.00
Male 0 - 34		965.44
Male 35 - 44		1485.05
Male 45 - 54		1526.10
Male 55 - 59		1116.51
Male 60 - 64		817.55
Male 65 - 69		561.65
Male 70 - 74		493.61
Male 75 - 79		421.40
Male 80 - 84		336.70
Male 85 - 89		277.13
Male 90 - 94		200.39
Male 95+		97.12
Age ≥ 65, female, originally entitled to Medicare due to disability		473.06
Age ≥ 65, male, originally entitled to Medicare due to disability		361.59

Notes:

1. a, b, and c coefficients with same letter are restricted to be equal.
2. All dollars have been inflated to 2006 and scaled to the Medicare standard Part D benefit.
3. These coefficients are for community residents without the low income subsidy.
4. Neither low-income nor long-term institutionalized multipliers have been computed for the spending model.

New Enrollee Model - Spending

Enrollees with less than 12 months of Part B enrollment prior to the payment year, potentially do not have a complete diagnostic record in Medicare files. Most of these people are new enrollees in the Medicare program. For such people a model based solely on demographic characteristics is used. This table is not additive. A person is assigned to one cell by age/sex and whether they are aged and entered Medicare due to disability.. The Spending model is informational only.

These factors were derived for the noninstitutionalized population and without adjustments for the effects of the low income subsidy.

Part D New enrollee factors, Spending Model

	Age-Sex not originally disabled	Age-Sex originally disabled
	Dollar Coefficients	Dollar Coefficients
Female 0 - 34	2762.77	--
Female 35 - 44	3915.93	--
Female 45 - 54	4159.27	--
Female 55 - 59	4056.48	--
Female 60 - 64	3629.43	--
Female 65	2138.17	3696.27
Female 66	2219.25	3746.65
Female 67	2243.91	3771.31
Female 68	2260.02	3787.42
Female 69	2272.42	3799.82
Female 70 - 74	2367.15	3594.17
Female 75 - 79	2445.51	3181.09
Female 80 - 84	2423.97	3159.55
Female 85 - 89	2333.61	3069.19
Female 90 - 94	2161.52	2897.10
Female 95+	1861.97	2597.55
Male 0 - 34	2852.94	--
Male 35 - 44	4062.05	--
Male 45 - 54	3932.86	--
Male 55 - 59	3354.82	--
Male 60 - 64	2931.37	--
Male 65	1750.51	3091.49
Male 66	1803.73	2974.05
Male 67	1853.76	3024.08
Male 68	1924.60	3094.92
Male 69	1966.66	3136.98
Male 70 - 74	2059.76	2899.48
Male 75 - 79	2173.48	2635.01
Male 80 - 84	2183.40	2644.93
Male 85 - 89	2137.78	2599.31
Male 90 - 94	1950.05	2411.58
Male 95+	1762.15	2223.68

Notes:

1. All dollars have been inflated to 2006 and scaled to the Medicare standard Part D benefit.
2. All cells are mutually exclusive. Specifically, an age 65, male who is originally disabled has spending of $3091.49; if he is not originally disabled, the plan liability is $1750.51.
3. These coefficients are for community residents without the low income subsidy.
4. Neither low-income nor long-term institutionalized multipliers have been computed for the spending model.

April 3, 2006

NOTE TO: All Medicare Advantage Organizations and Other Interested Parties

SUBJECT: Announcement of Calendar Year (CY) 2007 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies

In accordance with section 1853(b)(1) of the Social Security Act (the Act), we are notifying you of the annual Medicare Advantage (MA) capitation rate for each MA payment area for 2007, and the risk and other factors to be used in adjusting such rates. Attached is a spreadsheet containing the capitation rate tables for CY 2007. Also included is a spreadsheet which shows the statutory component of the regional benchmarks. The rates are posted on the Centers for Medicare & Medicaid Services (CMS) web site at http://www.cms.hhs.gov/MedicareAdvtgSpecRateStats/ under Ratebooks and Supporting Data.

Enclosure I shows the final estimates of the increase in the National Per Capita MA Growth Percentage for 2007. As discussed in Enclosure I, the final estimate of the increase in the National Per Capita MA Growth Percentage for combined aged and disabled beneficiaries is 7.13 percent. Since these estimates are all larger than 2 percent, these growth rates will be used as the minimum update percentage in calculating the 2007 rates. Under section 1853(c)(1) of the Act, MA payment rates in 2007 will be based on the higher of the county fee-for-service (FFS) per capita amount or a minimum percent increase over the 2006 rate. Enclosure II provides a set of tables that summarizes many of the key Medicare assumptions used in the calculation of the National Per Capita MA Growth Percentage.

Section 1853(b)(4) of the Act (added by Section 514 of the BBRA) requires CMS to release county-specific per capita FFS expenditure information on an annual basis, beginning with March 1, 2001. In accordance with this requirement, FFS data for CY 2004 is being posted on the Internet at this time as well.

We received 32 comments from 9 organizations in response to CMS' request for comments on the Advance Notice of Methodological Changes for CY 2007 MA Payment Rates and Part D Payment (Advance Notice), published on February 17, 2006. Enclosure III presents our responses to the issues raised in the comments related to the Advance Notice. Enclosure IV contains the updated CMS-HCC risk adjustment factors effective CY 2007.

Questions can be directed to:
Sol Mussey at (410) 786-6386 for Enclosures I and II
Deondra Moseley at (410) 786-4577 for Enclosure III
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Enclosures

Enclosure I
Final Estimate of the Increase in the National Per Capita Growth Percentages for 2007

The first table below shows the National Per Capita MA Growth Percentages (NPCMAGP) used to determine the minimum update percentages for 2007. Adjustments of 3.13 percent, 5.28 percent, 4.40 percent and 3.41 percent for aged, disabled, ESRD, and combined aged and disabled, respectively, are included in the NPCMAGP to account for corrections to prior years estimates as required by section 1853(c)(6)(C). The combined aged and disabled increase is used in the development of the risk-adjusted ratebook.

The second table below shows the monthly actuarial value of the Medicare deductible and coinsurance for 2006 and 2007. In addition, for 2007, the actuarial value of deductibles and coinsurance is being shown for non-ESRD only, since the plan bids will not include ESRD benefits in 2007. These data were furnished by the Office of the Actuary.

Increase in the National Per Capita MA Growth Percentages for 2007

	Prior Increases	Current Increases			NPCMAGP for 2007 With Sec.1853(c)(6)(C) adjustment[1]
	2003 to 2006	2003 to 2006	2006 to 2007	2003 to 2007	
Aged	18.73%	22.45%	3.53%	26.77%	6.77%
Disabled	17.80	24.02	4.04	29.03	9.53
ESRD	16.00	21.10	-0.13	20.93	4.25
Aged+Disabled	18.53	22.57	3.60	26.99	7.13

[1]Current increases for 2003 to 2007 divided by the prior increases for 2003 to 2006.

Monthly Actuarial Value of Medicare Deductible and Coinsurance for 2006 and 2007

	2006	2007	Change	2007 non-ESRD
Part A Benefits	$30.64	$33.19	8.3%	$31.81
Part B Benefits[2]	94.31	102.39	8.6%	96.99
Total Medicare	124.95	135.58	8.5%	128.80

[2]Includes the amounts for outpatient psychiatric charges.

The maximum deductible for Medical Savings Account (MSA) plans for 2007 is $9,500.

Enclosure II

Key Assumptions and Financial Information

The USPCCs are the basis for the National Per Capita MA Growth Percentages. Attached is a table that compares the published United States Per Capita Costs (USPCC) with current estimates for 2000 to 2007. In addition, this table shows the current projections of the USPCCs through 2009. In prior years, information in these tables was presented back to 1997. Since the passage of the MMA, formula changes in the law do not require the use of the USPCCs back to 1997 for the purpose of calculating the 2007 rates (e.g., the area-specific rate is not tabulated for years after 2004 and no adjustments to prior years' estimates are allowed for years before 2004 for calculating the minimum update percentage).

We are also providing an attached set of tables that summarizes many of the key Medicare assumptions used in the calculation of the USPCCs. Most of the tables include information for the years 2000 through 2009. All of the information provided in this enclosure applies to the Medicare Part A and Part B programs. Caution should be employed in the use of this information. It is based upon nationwide averages, and local conditions can differ substantially from conditions nationwide.

None of the data presented here pertain to the new Medicare prescription drug benefit.

Comparison of Current Estimates of the USPCC with Published Estimates

PART A:

Calendar Year	Aged			Disabled			Aged and Disabled		
	Current Estimate	Published Estimate	Ratio	Current Estimate	Published Estimate	Ratio	Current Estimate	Published Estimate	Ratio
2000	$263.37	$286.18	1.087	$219.00	$230.48	1.052	$257.42	$278.61	1.082
2001[1]	$284.44	$288.62	1.015	$236.00	$235.50	0.998	$277.77	$281.25	1.013
2001[2]	$284.44	$298.43	1.049	$236.00	$242.00	1.025	$277.77	$290.59	1.046
2002	$297.70	$294.46	0.989	$250.20	$242.06	0.967	$290.97	$287.10	0.987
2003	$304.68	$290.50	0.953	$255.97	$234.89	0.918	$297.53	$282.50	0.949
2004	$322.74	$326.78	1.013	$273.89	$271.69	0.992	$315.35	$318.43	1.010
2005	$341.10	$348.28	1.021	$288.87	$291.45	1.009	$333.04	$339.49	1.019
2006	$355.30	$351.38	0.989	$301.83	$295.15	0.978	$346.86	$342.67	0.988
2007	$370.34	$370.34	1.000	$318.17	$318.17	1.000	$362.06	$362.06	1.000
2008	$384.95	--	--	$333.11	--	--	$376.67	--	--
2009	$399.11	--	--	$347.21	--	--	$390.77	--	--

PART B:

Calendar Year	Aged			Disabled			Aged and Disabled		
	Current Estimate	Published Estimate	Ratio	Current Estimate	Published Estimate	Ratio	Current Estimate	Published Estimate	Ratio
2000	$199.20	$218.78	1.098	$194.54	$195.91	1.007	$198.62	$216.03	1.088
2001[1]	$220.01	$217.57	0.989	$216.06	$191.99	0.889	$219.50	$214.32	0.976
2001[2]	$220.01	$223.83	1.017	$216.06	$198.69	0.920	$219.50	$220.63	1.005
2002	$238.56	$244.17	1.024	$239.31	$218.23	0.912	$238.66	$240.76	1.009
2003	$250.94	$232.24	0.925	$257.05	$211.58	0.823	$251.77	$229.47	0.911
2004	$277.01	$263.39	0.951	$283.55	$252.74	0.891	$277.93	$261.89	0.942
2005	$303.55	$281.90	0.929	$314.23	$272.79	0.868	$305.10	$280.58	0.920
2006	$325.04	$311.28	0.958	$334.42	$316.82	0.947	$326.42	$312.09	0.956
2007	$334.02	$334.02	1.000	$343.76	$343.76	1.000	$335.47	$335.47	1.000
2008	$347.34	--	--	$358.51	--	--	$349.02	--	--
2009	$358.74	--	--	$370.92	--	--	$360.59	--	--

PART A & PART B:

Calendar Year	Aged			Disabled			Aged and Disabled		
	Current Estimate	Published Estimate	Ratio	Current Estimate	Published Estimate	Ratio	Current Estimate	Published Estimate	Ratio
2000	$462.57	$504.96	1.092	$413.54	$426.39	1.031	$456.04	$494.64	1.085
2001[1]	$504.45	$506.19	1.003	$452.06	$427.49	0.946	$497.27	$495.57	0.997
2001[2]	$504.45	$522.26	1.035	$452.06	$440.69	0.975	$497.27	$511.22	1.028
2002	$536.26	$538.63	1.004	$489.51	$460.29	0.940	$529.63	$527.86	0.997
2003	$555.62	$522.74	0.941	$513.02	$446.47	0.870	$549.30	$511.97	0.932
2004	$599.75	$590.17	0.984	$557.44	$524.43	0.941	$593.28	$580.32	0.978
2005	$644.65	$630.18	0.978	$603.10	$564.24	0.936	$638.14	$620.07	0.972
2006	$680.34	$662.66	0.974	$636.25	$611.97	0.962	$673.28	$654.76	0.972
2007	$704.36	$704.36	1.000	$661.93	$661.93	1.000	$697.53	$697.53	1.000
2008	$732.29	--	--	$691.62	--	--	$725.69	--	--
2009	$757.85	--	--	$718.13	--	--	$751.36	--	--

[1]Applies to M+C ratebook for January to February, 2001

[2]Applies to M+C ratebook for March to December, 2001

Comparison of Current Estimates of the USPCC with Published Estimates-continued

PART A:

Calendar Year	ESRD Current Estimate	ESRD Published Estimate	Ratio
2000	$1,366.70	$1,443.13	1.056
2001[1]	$1,494.57	$1,541.76	1.032
2001[2]	$1,494.57	$1,597.34	1.069
2002	$1,608.84	$1,435.62	0.892
2003	$1,737.24	$1,596.58	0.919
2004	$1,844.12	$1,685.25	0.914
2005	$1,905.51	$1,759.90	0.924
2006	$1,881.98	$1,717.97	0.913
2007	$1,874.54	$1874.54	1.000
2008	$1,911.33	--	--
2009	$1,938.38	--	--

PART B:

Calendar Year	ESRD Current Estimate	ESRD Published Estimate	Ratio
2000	$1,508.57	$2,436.13	1.615
2001[1]	$1,722.43	$1,875.57	1.089
2001[2]	$1,722.43	$1,921.53	1.116
2002	$1,845.75	$2,014.79	1.092
2003	$1,855.91	$1,847.53	0.995
2004	$2,039.75	$2,552.18	1.251
2005	$2,188.84	$2,739.99	1.252
2006	$2,469.16	$2,454.98	0.994
2007	$2,470.81	$2,470.81	1.000
2008	$2,591.87	--	--
2009	$2,691.33	--	--

PART A & PART B:

Calendar Year	ESRD Current Estimate	ESRD Published Estimate	Ratio
2000	$2,875.27	$3,879.26	1.349
2001[1]	$3,217.00	$3,417.33	1.062
2001[2]	$3,217.00	$3,518.87	1.094
2002	$3,454.59	$3,450.41	0.999
2003	$3,593.15	$3,444.11	0.959
2004	$3,883.87	$4,237.43	1.091
2005	$4,094.35	$4,499.89	1.099
2006	$4,351.14	$4,172.95	0.959
2007	$4,345.35	$4,345.35	1.000
2008	$4,503.20	--	--
2009	$4,629.71	--	--

[1]Applies to M+C ratebook for January to February, 2001

[2]Applies to M+C ratebook for March to December, 2001

Summary of Key Projections Under Present Law[1]

Part A

Year	Calendar Year CPI Percent Increase	Fiscal Year PPS Update Factor	FY Part A Total Reimbursement (Incurred)
2000	3.5	1.1	-0.8
2001	2.7	3.4	8.2
2002	1.4	2.8	7.9
2003	2.2	3.0	4.0
2004	2.6	3.4	9.0
2005	3.5	3.3	7.4
2006	3.1	3.7	5.9
2007	2.4	3.4	6.4
2008	2.4	3.3	6.0
2009	2.4	2.9	5.9

Part B[2]

Calendar Year	Physician Fee Schedule		Part B Hospital	Total
	Fees	Residual[3]		
2000	5.9	3.6	-0.8	10.4
2001	5.3	4.1	12.5	9.8
2002	-4.2	6.1	-1.4	8.0
2003	1.4	4.5	5.3	5.0
2004	3.8	6.1	11.3	9.8
2005	1.5	7.8	10.6	9.2
2006	0.0	5.7	7.9	6.0
2007	-6.5	7.0	7.4	1.8
2008	-4.6	5.7	7.1	3.5
2009	-4.7	5.3	6.4	2.8

[1]Percent change over prior year.
[2]Percent change in charges per Aged Part B enrollee.
[3]Residual factors are factors other than price, including volume of services, intensity of services, and age/sex changes.

Medicare Enrollment Projections Under Present Law (In Millions)

Non-ESRD

Calendar Year	Part A		Part B	
	Aged	Disabled	Aged	Disabled
2000	33.699	5.224	32.421	4.590
2001	33.903	5.416	32.581	4.747
2002	34.080	5.618	32.713	4.916
2003	34.426	5.929	33.014	5.187
2004	34.835	6.207	33.241	5.445
2005	35.187	6.423	33.510	5.675
2006	35.564	6.659	33.857	5.873
2007	36.134	6.817	34.320	6.022
2008	36.806	6.989	34.885	6.174
2009	37.515	7.183	35.486	6.342

ESRD Part A

Calendar Year	Part A			
	Aged	Disabled	299I[1]	Total
2000	0.137	0.107	0.090	0.334
2001	0.144	0.112	0.094	0.350
2002	0.152	0.117	0.098	0.366
2003	0.160	0.121	0.102	0.383
2004	0.167	0.126	0.104	0.396
2005	0.174	0.129	0.106	0.409
2006	0.182	0.132	0.109	0.423
2007	0.189	0.135	0.111	0.435
2008	0.196	0.138	0.113	0.446
2009	0.202	0.141	0.114	0.457

ESRD Part B

Calendar Year	Part B			
	Aged	Disabled	299I	Total
2000	0.138	0.102	0.083	0.324
2001	0.145	0.107	0.086	0.338
2002	0.153	0.111	0.090	0.354
2003	0.161	0.115	0.093	0.369
2004	0.167	0.119	0.093	0.379
2005	0.174	0.122	0.095	0.390
2006	0.181	0.125	0.097	0.403
2007	0.188	0.127	0.099	0.413
2008	0.194	0.129	0.100	0.424
2009	0.201	0.132	0.101	0.434

[1] Individuals who qualify for Medicare based on ESRD only.

Part A Projections Under Present Law [1]

Calendar Year	Inpatient Hospital		SNF		Home Health		Managed Care		Hospice: Total Reimbursement (in Millions)	
	Aged	Disabled	Aged	Disabled	Aged	Disabled	Aged	Disabled	Aged	Disabled
2000	2,218.26	2,385.73	310.23	104.89	99.05	70.37	593.36	269.74	2,772	146
2001	2,417.28	2,596.81	376.99	129.10	118.53	89.82	571.77	245.26	3,541	186
2002	2,593.73	2,785.85	412.55	145.20	124.91	95.03	523.26	224.23	4,614	243
2003	2,672.82	2,867.99	421.38	150.41	131.93	100.69	522.57	218.84	5,927	312
2004	2,780.04	3,036.09	475.32	175.80	150.42	115.69	569.17	238.65	7,190	378
2005	2,865.61	3,148.79	490.52	182.35	163.73	126.74	682.44	293.33	8,122	427
2006	2,826.59	3,187.11	462.47	176.18	165.05	131.19	919.11	402.18	9,088	478
2007	2,798.98	3,265.88	455.34	179.93	164.51	135.70	1,135.34	504.06	10,111	532
2008	2,846.37	3,373.84	459.45	185.34	170.16	143.18	1,256.76	563.70	10,614	559
2009	2,882.07	3,469.14	463.13	190.70	173.86	149.20	1,386.00	626.99	11,293	594

[1]Average reimbursement per enrollee on an incurred basis, except where noted.

Part B Projections Under Present Law[1]

Calendar Year	Physician Fee Schedule		Part B Hospital		Durable Medical Equipment	
	Aged	Disabled Non-ESRD	Aged	Disabled Non-ESRD	Aged	Disabled Non-ESRD
2000	1,003.19	951.68	238.98	299.75	118.54	184.46
2001	1,131.49	1,064.16	326.94	412.41	137.14	215.29
2002	1,177.53	1,109.80	333.63	436.59	158.42	261.54
2003	1,263.85	1,191.28	377.90	485.10	182.32	302.60
2004	1,397.33	1,318.57	434.27	561.49	181.83	303.83
2005	1,511.62	1,439.79	485.24	638.20	184.73	316.74
2006	1,515.82	1,473.88	513.72	672.22	179.21	317.45
2007	1,436.95	1,437.94	531.09	716.13	174.82	318.68
2008	1,420.20	1,436.89	563.82	769.92	179.32	330.38
2009	1,394.89	1,428.32	593.25	821.06	173.07	322.72

Calendar Year	Carrier Lab		Other Carrier		Intermediary Lab	
	Aged	Disabled Non-ESRD	Aged	Disabled Non-ESRD	Aged	Disabled Non-ESRD
2000	58.89	58.02	201.38	195.17	46.25	62.53
2001	64.86	63.70	239.97	231.14	47.73	67.87
2002	70.96	71.16	286.98	281.75	55.39	78.15
2003	76.46	75.67	337.44	352.06	60.30	83.53
2004	82.57	82.82	363.52	401.42	64.87	91.70
2005	90.00	91.57	381.39	463.80	70.43	100.77
2006	91.15	95.53	395.64	501.70	71.44	104.95
2007	91.22	98.18	405.27	526.10	71.89	108.69
2008	93.04	101.13	424.18	554.97	73.57	112.47
2009	96.28	105.80	439.95	581.06	76.05	117.66

Calendar Year	Other Intermediary		Home Health		Managed Care	
	Aged	Disabled Non-ESRD	Aged	Disabled Non-ESRD	Aged	Disabled Non-ESRD
2000	117.91	228.27	129.45	99.19	531.83	221.42
2001	138.59	238.66	128.68	75.42	498.03	189.90
2002	173.76	287.38	138.37	81.59	556.87	230.86
2003	179.75	276.55	141.05	84.20	481.39	199.55
2004	206.77	280.99	153.29	91.29	538.97	234.94
2005	237.78	317.04	167.20	99.27	625.73	267.73
2006	256.63	339.11	168.58	102.93	842.92	367.40
2007	237.66	320.82	168.41	106.29	1,029.86	453.33
2008	246.13	336.14	174.57	112.14	1,142.37	507.46
2009	253.83	351.88	178.72	116.91	1,257.19	563.44

[1]Average reimbursement per enrollee on an incurred basis.

Claims Processing Costs as a Fraction of Benefits

Calendar Year	Part A	Part B
2000	0.002195	0.014790
2001	0.001862	0.013223
2002	0.001496	0.011708
2003	0.001849	0.011194
2004	0.001676	0.010542
2005	0.001515	0.009540
2006	0.001515	0.009540
2007	0.001515	0.009540
2008	0.001515	0.009540
2009	0.001515	0.009540

Approximate Calculation of the USPCC and the National MA Growth Percentage for Aged Beneficiaries

The following procedure will approximate the actual calculation of the USPCCs from the underlying assumptions for the contract year for both Part A and Part B.

Part A:

The Part A USPCC for aged beneficiaries can be approximated by using the assumptions in the tables titled "Part A Projections Under Present Law" and "Claims Processing Costs as a Fraction of Benefits." Information in the "Part A Projections" table is presented on a calendar year per capita basis. First, add the per capita amounts for the aged over all types of providers (excluding hospice). Next, multiply this amount by 1 plus the loading factor for administrative expenses from the "Claims Processing Costs" table. Then, divide by 12 to put this amount on a monthly basis. The last step is to multiply by .97435 to get the USPCC for the aged non-ESRD. This final factor of .97435 is the relationship between the total and non-ESRD per capita reimbursements in 2007. This factor does not necessarily hold in any other year.

Part B:

The Part B USPCC can be approximated by using the assumptions in the tables titled "Part B Projections Under Present Law" and "Claims Processing Costs as a Fraction of Benefits." Information in the "Part B Projections" table is presented on a calendar year per capita basis. First, add the per capita amounts for the aged over all types of providers. Next, multiply by 1 plus the loading factor for administrative expenses and divide by 12 to put this amount on a monthly basis. Then multiply by .95737 to get the USPCC for the aged non-ESRD.

The National Per Capita MA Growth Percentage:

The National Per Capita MA Growth Percentage for 2007 (before adjustment for prior years' over/under estimates) is calculated by adding the USPCCs for Part A and Part B for 2007 and then dividing by the sum of the current estimates of the USPCCs for Part A and Part B for 2006.

Enclosure III. CMS' Responses to Public Comments

Summary

CMS received comments from 9 organizations on the February 17, 2006 Advance Notice of Methodological Changes for CY 2007 MA Payment Rates and Part D Payment (Advance Notice). Our responses to comments are organized as follows:

Section A: Estimate of the National Per Capita MA Growth Percentage for Calendar Year 2007
Section B: Budget Neutral Risk Adjustment Factor (BN Factor) and Other Rate Issues
Section C: Updates to Risk Adjustment Methodology for MA Organizations including the FFS Normalization Factor
Section D: Part D Payment Policy

Section A: Estimate of the National Per Capita MA Growth Percentage for Calendar Year 2007

Comment: A number of commenters asked why the preliminary estimate of the trend change for 2007 of 2.5% was so low. Several commenters also pointed out that trend rates that CMS published in the Rate Announcement for the prior three years were significantly higher than the estimated 2.5 percent for 2007: 8.0, 7.6, and 5.5 percent for 2004 to 2006, respectively.

Response: The final trend change estimate for 2007 is 3.6 percent, which is higher than the preliminary estimate of 2.5 percent announced February 17, 2006 in the Advance Notice, but still lower than revised estimates for recent years. There are several reasons why the growth trend for 2007 is expected to be lower than the three prior years.

First, for 2004 to 2006, Congress has reversed a scheduled reduction in physician payment rates and set the fee schedule updates at 1.5 percent in 2004 and 2005 and 0 percent in 2006. However, Congress has not reversed the scheduled reduction in physician payment rates for 2007. Under current law, the update for physician payments for 2007 is estimated to be -4.6%. CMS, therefore, is required to estimate a 2007 trend that reflects this scheduled 4.6% reduction. Given that roughly 20 percent of Medicare expenditures are for physician services, the overall 2007 trend growth rate is lower by almost 1 percent than it would be if the update for physicians were 0 percent or slightly positive.

Second, the Deficit Reduction Act (DRA) of 2005 included several FFS provisions that will reduce Medicare expenditures in 2007. The DRA provisions that most affect the 2007 growth rate are those that result in reduced expenditures for therapy, imaging, and home health services.

Third, outpatient prospective payment system (OPPS) expenditures are assumed to grow at a slower rate due to a more gradual change in the coinsurance buy-down. When the OPPS was

implemented in 2000, coinsurance rates for most ambulatory payment codes (APC) were initially well above 20 percent. With the phasing-in of required changes to the OPPS coinsurance percentage, Medicare expenditures increased in the short term while the Medicare share of total costs increased to 80 percent. These larger buy downs have occurred in the recent past, and sped up expenditure growth, but are not expected to occur in 2007. Therefore, 2007 growth in expenditures has slowed relative to earlier years.

Lastly, utilization rates for various other services in recent years have tended to slow down or flatten out relative to the rates in earlier years, thus contributing to a lower overall growth rate.

Comment: Several commenters noted that the Medicare 2007 growth trend does not track with other estimates of health expenditure cost growth, and requested that CMS use its discretion to revise the preliminary estimate of the 2.5% trend for 2007. One commenter noted that underlying growth trend in overall healthcare spending is expected to be 7.4% in 2005 and 7.3% in 2006, and asked why the 2007 Medicare growth is trend so much lower.

Response: OACT is required annually to model Medicare expenditure growth based on current law and assumptions from the President's budget. Assumptions from these sources are combined with modeling assumptions OACT has developed (e.g., population demographic trends, medical cost trends, etc.) to produce Medicare growth estimates.

Using current law, budget assumptions will produce Medicare trends that are different from trends in underlying total medical costs that are developed for other purposes. For example, the national health expenditure growth trends, which were 7.4% and 7.3% for 2005 and 2006, respectively, are measuring more than just Medicare expenditures. In particular, the growth estimates used for the purposes of determining MA capitation rates reflect estimates for medical costs, but do not reflect estimates of prescription drug costs. The national health expenditure growth trends include drug costs, which are growing at a much faster rate than non-drug costs. Also, national health expenditures reflect increases in non-Medicare physician expenditures which are much higher since those expenditures are not subject to the limitations in payments for Medicare physician services. In addition, trends in other services will vary between Medicare and non-Medicare due to different payment rules and utilization effects.

The assumptions used in the Medicare models are discussed in detail in the annual Trustees Reports, found on the CMS website at http://www.cms.hhs.gov/ReportsTrustFunds/01_Overview.asp. This year, due to a delay in the release of the 2006 Trustees Report, the final estimates for the Medicare growth rates are based on the estimates from the President's FY 2007 Budget.

Comment: One commenter remarked that the preliminary estimate of the 2007 growth trend of 6.9% is in stark contrast to the 5% across-the-board reduction projected for Medicare physician payment rates in 2007. In addition, the 2006 Medicare Trustees report is expected to project cuts in physician payment rates totaling 34 percent through 2015. The commenter urged the Administration, along with the Congress, to take all steps necessary to establish

parity in Medicare payment rates between physicians and other health care providers, such as MA plans.

Response: The issue of parity in payments between types of Medicare providers is beyond the scope of this announcement.

The calculation of MA payment rates is established by §1853 of the Act. One of the factors CMS calculates each year is an estimate of the National Per Capita MA Growth Percentage, which is the underlying growth trend in Medicare program expenditures for the upcoming year. A preliminary estimate of the National Per Capita MA Growth Percentage is published annually in the Advance Notice, and the final estimate is published annually in the Rate Announcement. The preliminary estimate for 2007 was 6.9%, and the final estimate of the 2007 growth percentage is 7.1%.

The estimate of the 2007 growth trend is one of several components CMS must use to calculate the annual county capitation rates. It is not possible to calculate what the final rates will be by simply multiplying last year's rates by this percentage, because other factors must be applied to determine the final rates, such as the budget neutrality factor, rebasing FFS rates, and recalibrating the risk adjustment model.

Comment: One commenter asked what the impact is on the 2007 National Per Capita MA Growth Percentage (growth trend) of the phase-out of BN factor mandated by the DRA.

Response: Section 5301 of the DRA includes several provisions defining how CMS calculates MA capitation rates, beginning with CY 2007. First, the DRA establishes a single risk ratebook for monthly capitation rates, because the statutory transition for MA plans from payment based on the demographic rates and adjustment factors to payment based on risk adjustment rates and risk adjustment factors is completed in 2007. Effective 2007, 100 percent of payments to virtually all MA plans will be based on risk rates.

The DRA defines the risk rates as the base ratebook, so we now will publish two sets of rates – risk and demographic rates. We will continue to publish the demographic rates because they are used in the BN factor calculations. The BN factor is calculated as the estimated difference between payments to MA organizations at 100% of the demographic rates and payments at 100% of the risk rates. Also, the demographic rates will be used in 2007 to determine payments to certain demonstrations and PACE organizations, which lag one year in the transition blend so that 25% of their payments will be based on demographic rates.

Second, the DRA mandates the phase-out schedule for the BN factor from 2006 through 2010: in 2007, 55% of the BN factor will be applied to every risk rate and from 2008 through 2010, the phase-out percentages are 40%, 25%, and 5% respectively. Moreover, the DRA specifies how CMS will calculate the numerator and denominator of the BN factor, including an adjustment to risk scores to reflect changes in treatment and coding practices in the FFS sector (referred to as "FFS coding intensity" and "FFS normalization."). See Section C below for further information on FFS normalization.

Regarding the commenter's question about the impact of BN phase-out on the growth trend, there is no effect. The growth trend is determined before the BN factor is applied to the risk rates. The trend is used to develop the pre-BN rates. Once the pre-BN capitation rates are tabulated through application of the "highest-of" rate-setting methodology established by the 2003 MMA, then the BN factor is applied to arrive at the final rate.

Comment: Two commenters requested greater detail on what factors affect CMS' revisions to prior years' estimates of the growth trend. The commenters recommended that CMS release trend estimates for years beyond the upcoming year.

Response: As the law provides, CMS must adjust the national MA growth rates for prior years' over and under-estimates of the National Per Capita MA Growth Percentage. This is accomplished by comparing the latest baseline projection of Medicare per capita expenses (data in Enclosure II) to prior baseline projections. Baseline projections are prepared each year by OACT for use in the President's budget and the Trustees Report. Projections are prepared by type of service and type of Medicare beneficiary, and are aggregated over all services to get the appropriate per capita amount increases. OACT's projection methodology is basically the same as has been used for years. A description of the projection methodology can be found in an appendix of the annual Trustees' Report.

Enclosure II of this announcement includes tables with underlying assumptions for the USPCC growth rates. Comparing these tables with tables in prior announcements can give interested parties a sense of which factors have changed in recent years and therefore contribute to the revisions of prior year estimates.

In terms of future year growth trend estimates, each year in the Rate Announcement, the estimated USPCCs for out-years are published in the first table in Enclosure II. This year estimates through 2009 are shown. Future estimates of growth trends can be tabulated by dividing one year's USPCC by the USPCC for the prior year.

Comment: Several commenters requested that CMS provide more information in the Advance Notice on the assumptions and methodologies used in calculating all of the components of the MA capitation rates, including the growth trend, revisions to prior years' estimates of the growth trend, the FFS capitation rates, the FFS normalization factor, the BN factor, and the Part D benefit indexing factors. In addition, several commenters requested that in years when the risk adjustment model is recalibrated or revised, CMS publish in the Advance Notice the draft coefficients for all models instead of just the community model, and a description of the methodology used for simulation of payment impacts.

Response: We expect to provide additional information on the assumptions and methodologies used in determining the annual capitation rates, not only in this announcement and future Advance Notices and Rate Announcements, but also in the upcoming revision of the payment chapter in the Managed Care Manual. Regarding release of draft coefficients for updated risk adjustment models, in years when we recalibrate the models, we intend to release in the Advance Notice all draft coefficients that are available at the time of publication.

Comment: One commenter argued that Section 1853(c)(1)(C) of the Social Security Act ("minimum percentage increase") represents Congressional intent that, after all calculations are made, MA payment rates should be raised a minimum of 2% in every county. The commenter believed that Congress designed the determination of MA payment rates with this guaranteed minimum 2% increase as a protection against the reality of health care inflation and so that Medicare beneficiaries receive protection from significant changes in their benefits year-over-year.

Response: Section 5301 of the DRA defines how CMS must calculate the MA capitation rates, beginning with CY 2007. The DRA directs that the minimum percentage increase be applied to pre-BN rates, i.e., the capitation rates before the application of the BN factor. In addition, the DRA also provides the Secretary with authority to make adjustments to the capitation rates to accommodate new or updated risk adjustment methodologies. As a result, the statutory formula for computing capitation rates does not guarantee that the county capitation rates in any given year will be at least 2% greater than the capitation rates (including the BN factor) from the prior year.

Comment: One commenter asked CMS to clarify in future Advance Notices that the preliminary estimate of the National Per Capita MA Growth Percentage is only one of several factors that affect the MA capitation rates.

Response: We will communicate in future Advance Notices that the preliminary estimate of the National Per Capita MA Growth Percentage is one of several factors that determines the final capitation rates for a year, and therefore final capitation rates cannot be predicted solely from this growth percentage.

Section B. BN Factor and Other Rate Issues

Comment: One commenter requested that CMS make available additional information about a number of variables that are used in calculating the BN factor, including assumptions about average risk scores in the various MA plan types, estimated enrollment in each of these plan types, and if these assumptions will be taken into account in the calculation of the adjustment.

Response: As discussed in Section A, the DRA specifies the components that CMS must include in the estimate of budget neutral (BN) risk adjustment factor, and codifies the phase-out of the BN factor. As in prior years, the BN factor was calculated as the difference between the calculation of payments to plans using 100 percent demographic payments and the calculation of payments to plans using 100 percent risk adjustment payments, expressed as a percent of risk adjusted payments. For purposes of the calculation, CMS assumes that payments to plans will be at the local benchmarks, adjusted for each plan's demographic and risk scores. CMS calculates a single BN factor for all MA plan enrollees. For 2007, the first

year of the phase-out of BN, 55% of the full BN factor is applied to the rates, as the same percentage for all counties.

The BN factor for 2007 is 3.9%. This factor was calculated based on a full BN factor of 7.1%, multiplied by 55% (the BN phase-out percentage specified in the DRA).

In calculating the BN factor, CMS used the same methodology for 2007 as was used for the 2006 BN factor, with one exception. For 2006, OACT assumed that risk scores of enrollees in regional plans would be consistent with the assumptions in the President's FY 2006 Budget baseline and the 2005 Trustees Report, and modified the observed average risk score to account for expected differences due to growth in enrollment in the new regional PPOs. This year, however, preliminary data indicate that average risk scores for some new plans are lower than the observed group, while other new plans have higher scores. Therefore, we have decided not to make any specific adjustment to the average risk score of the observed group of plans for projected enrollment when calculating the BN factor. This is consistent with the assumptions used in the President's Budget baseline.

Comment: One commenter noted that for the most accurate BN factor calculation, the demographic and risk rates should be based on the same years of data. The commenter was concerned that demographic rates will be calculated using 5 years of data, and the risk rates with 3 years of data, which would create inconsistent demographic and risk costs per county, and thus an inaccurate BN factor.

Response: The commenter's discussion of 3 versus 5 years of data is a comment on the methodology for calculating FFS rates, which has an indirect relationship to the BN calculation. At least every three years, CMS must rebase the MA FFS capitation rates. By law, in rebasing years, the final capitation rate for a county is the higher of the FFS rate or the minimum percentage increase rate. CMS typically rebases (i.e., recalculates) the FFS rates, using a rolling 5-year average of geographic indices, where each year's index is the ratio of county per capita costs to national per capita costs.

When a new risk model is developed, initially there may not be 5 years worth of data under the new model to develop the geographic adjustments. For example, when FFS rates were rebased in 2005, only three years of data under the HCC model were available. However, for 2007 CMS was able to develop five years worth of data under the new recalibrated model. Therefore, the 2007 FFS rates for both the demographic and risk models are based on an average of the five most recent years of complete claims data available – from 2000 through 2004, thereby minimizing inconsistency.

Comment: Several commenters requested that CMS publish a draft BN factor, in addition to the preliminary estimate of the growth trend, in the Advance Notice.

Response: It is not feasible to provide a draft BN estimate in the Advance Notice. In order to do a preliminary estimate of the BN factor, we would have to create preliminary demographic and risk model rates in early February, which means we would have to generate the preliminary estimate of the growth rate in January. This is not possible, given the timing

of the President's Budget and timing of data extracts and analysis needed to produce growth trends and rates.

Comment: One commenter asked how new treatments and technologies are reflected in the capitation rates and national growth trend. The commenter noted, as an example, that new and costly treatments for "wet" macular degeneration have emerged in the last year and will likely become fully incorporated into treatment of the Medicare population, but currently are not covered under a National Coverage Determination. The commenter was concerned that the FFS rates and national growth trend do not reflect the cost of this and other significant new technologies that may be numerous or costly in a given benefit year. The commenter was also concerned that the factors in the risk adjustment model do not reflect the cost of this and other significant new technologies, particularly with respect to those diagnoses that previously did not generate high expenditures but which now can reasonably be expected to do so.

Response: Costs for new Medicare-covered technologies are taken into account in two ways. First, the USPCC includes, among other estimates, projected expenditures for new Medicare-covered technologies at the national level. Any projected costs for new technologies are averaged across all counties in the growth trend, and in this way are built into both the minimum percentage update rate and the FFS rate on a projected basis.

In addition, county-level expenditures reflecting coverage mandated by local medical review policies (LMRPs) are included in the FFS cost data used to calculate the FFS rates. In years when CMS rebases the MA FFS rates, CMS uses county-level cost data that reflect expenditures for Medicare-covered services in that locale, including new technologies. For example, the 2007 FFS rates are based on historical county-level expenditures from 2000 through 2004. For each of these years, CMS calculated a Geographic Index (GI) of the county per capita FFS costs to the national per capita FFS costs. The average of these GIs for a county (called an Average Geographic Adjustment or AGA) is applied to the FFS USPCC to get the FFS rate for that county. To the extent that local areas differ from each other in cost levels in these historical data, this difference will be built into the AGAs.

In terms of reflecting new technologies in the risk adjustment model, the relationship between diagnosis patterns and expenditures changes over time due to changes in utilization, treatment patterns, and coding. We recalibrate the CMS-HCC model periodically to take account of these changes. As described above, general increases in the costs of health care are reflected in the ratebook.

Comment: Two commenters noted CMS' announcement that the FFS rates will be rebased in 2007, and requested that the Office of the Actuary consider calculating FFS expenditures by county using prospective cost estimates rather than historical claims data. The commenters stated that the current methodology for calculating FFS costs includes applying AGAs that are at least 3 years old. Many rural areas have seen recent increases in costs that are not reflected in these AGAs. Examples of increased reimbursement in rural areas include increased reimbursement in provider shortage areas (PSAs) and hospital wage index reclassifications. The commenters were concerned that CMS is incenting providers in rural

areas to continue to participate in the Medicare program through increased FFS reimbursement, yet payments to MA plans do not support this incentive.

Response: The commenter suggested that CMS reflect the payment system rules and provider classifications that will be in effect for the upcoming payment year, instead of historical reimbursement rules and classifications. During a future rebasing year, we expect to look at the feasibility of reflecting structural changes in FFS payment so that the geographic adjustments will reflect the rules and classifications in place for the upcoming payment year.

Comment: One commenter asked how the demographic payment rates that will comprise 25 percent of the benchmarks for Social HMOs will be determined.

Response. The demographic capitation rates have been determined using the methodology for calculating demographic rates established in the statute, as described in Section A. Because CMS is rebasing FFS rates for 2007, the final capitation rate for a county in 2007 for both the demographic and the risk portion of payments for Social HMOs will be the higher of the minimum percentage increase rate or the FFS rate.

Comment: Several commenters were concerned that the Advance Notice did not discuss CMS' plans for implementation of a mechanism for incorporating into the payment methodology costs associated with Medicare covered services provided to beneficiaries in Veterans' Administration (VA) and Department of Defense (DoD) facilities. The commenters emphasized that the Medicare Modernization Act established a requirement for incorporating these costs into the CY 2004 payment methodology (in the "blended" rates and in the 100 percent of FFS rates), but CMS indicated that the Agency was unable to do this at that time due to a lack of reliable data. The commenters recommended that CMS should include these costs when rebasing the FFS rates, and one commenter requested that CMS provide information about the challenges obtaining reliable data and the methodology CMS will use to incorporate these costs.

Response: Incorporating costs associated with Medicare-covered services provided to beneficiaries in VA and DoD facilities into the payment methodology is a multi-year project that will involve developing methods for matching coverage determinations, pricing of services, etc. CMS will continue to work on obtaining and sorting through the data. CMS is looking into the possibility of subtracting out dual eligibles (dually eligible for VA/DoD and Medicare) from the calculation of the county FFS costs. This method would simplify the methods for integrating VA and DoD data by greatly reducing the data needed. This approach would allow CMS, the VA, and DOD to focus on identifying all the dual eligibles, but would eliminate the multi-year project of identifying all costs associated with each dual eligible and analyzing all of these VA/DOD costs from the vantage of Medicare coverage rules and Medicare pricing. Under this possible approach, once the dual eligibles are identified, CMS could estimate the adjustment by subtracting out the dual eligible enrollees and their Medicare dollars from the county per capita cost estimates. We are evaluating this approach and working with the VA and DoD to identify these individuals.

Until CMS determines whether the approach of subtracting dual eligibles (the beneficiaries and their associated dollars) is feasible or whether CMS will continue with the multi-year project of developing a methodology for identifying the Medicare-covered costs for these dual eligible beneficiaries and adding these costs to the FFS rate calculation, we expect that the adjustment will continue to be zero.

Section C: Updates to Risk Adjustment Methodology for MA Organizations Including the FFS Normalization Factor

Comment: One commenter offered support for CMS' decision to retain the current CMS-HCC Risk Adjustment Model and recalibrate this model for CY 2007.

Response: We appreciate the commenter's agreement with our decision to recalibrate the CMS-HCC model. Recalibration will help to ensure that the CMS-HCC model better reflects current treatment, coding and expenditure trends in FFS Medicare.

Comment: Several commenters requested additional information about the development of the new coefficients for the CMS-HCC risk adjustment model. One commenter requested that future Advance Notices include the value, or CMS' estimate, of average costs for FFS beneficiaries used as the denominator in determining the relative risk scores for the recalibrated risk adjustment model, and a description of any factors that contribute to significant changes in these coefficients.

Response: As stated in the February 17, 2006 Advance Notice for payment year 2007, FFS claims data for the years 2002 and 2003 will be used in the recalibration of the model and the updated model coefficients will reflect newer treatment and coding patterns in FFS Medicare. We did not make any changes to the methodology used to develop the risk adjustment model coefficients. Please refer to the following documents for additional methodological information about the development of the model, including the calculation of the coefficients:

- The Advance Notice for payment year 2004: http://www.cms.hhs.gov/MedicareAdvtgSpecRateStats/Downloads/Advance2004.pdf
- Pope, Kautter, et al., "Risk Adjustment of Medicare Capitation Payments Using the CMS-HCC Model," *Health Care Financing Review*, Summer 2004, 25(4):119-141. http://www.cms.hhs.gov/HealthCareFinancingReview/03_2004_Edition.asp#TopOfPage

The denominator used to calculate the relative coefficients for each version (community, long-term institutional, and new enrollee) of the newly calibrated non-ESRD model is $6,496.03, which is based on 2005 data. We are aware of the importance of this information to plans in planning their upcoming contract year and will continue to provide as much information as possible in future Advance Notices. For 2007, we will continue to use the ESRD model coefficients already in use.

Comment: Several commenters noted that the coefficients in several categories of the recalibrated model are lower or higher than in the current model. One commenter noted that, for example, diabetes payment weights decrease by nearly 17 percent, while cancer payment weights increase by nearly 11 percent. Another commenter asked why there are significant changes in the coefficients when the new data used for recalibration is only three years later.

Response: The new coefficients in the recalibrated CMS-HCC risk adjustment model are the result of more recent diagnosis and expenditure data. In addition, the CMS-HCC Institutional model has been recalibrated using a 100% long-term institutional sample, resulting in a more precise estimate of the coefficients.

Recalibration with newer data will cause changes in the values of particular coefficients for a number of reasons. First, changes in coding practices in FFS could result in people with lower severity of diseases being categorized in certain, relatively higher-cost HCCs. If greater numbers of beneficiaries with lower average costs are assigned an ICD-9 code that places them in an HCC previously populated by people with relatively higher costs, the presence of these "lower cost" beneficiaries can have the effect of reducing the dollar value of the HCC, thus lowering the coefficient.

Second, although most coefficients in the model have increased in dollar terms, some have increased more than average and some have increased less than average. For those conditions whose dollar coefficients have increased less than average, the relative coefficients have decreased.

For example, the relative coefficient for diabetes decreased (although the dollar coefficients have increased) because the proportion of people in the FFS population who were coded as diabetic has increased. It appears that coding intensity initiatives have led to an increase in the coding of patients with less severe diabetes. In addition, some beneficiaries who previously were coded with less severe manifestations of diabetes are now coded as more severe. In both these situations, people with relatively low costs are moving higher in the diabetes hierarchy and lowering the average costs in each HCC.

Third, coefficients for some other diseases have increased because, in the intervening years between model calibrations, treatments for these diseases have become more expensive. For example, coefficients for cancer have increased because many chemotherapy drugs (paid for under Part B, and thus captured in the CMS-HCC model) have become more expensive.

Finally, in addition to the changes in the coefficients due to more recent diagnosis and expenditure data described above, the recalibrated model uses a denominator two years later (2005) than the data used to calibrate the coefficients (2003). This is an effective approach for accounting for two years of FFS normalization, but means that the relative coefficients are lower than if the denominator used to calculate the relative factors were based on data from the same year as the data used in the recalibration (2003).

Comment: Several commenters requested that CMS publish the number of observations per HCC, by type of beneficiary.

Response: We will soon be releasing on the CMS Web site a frequency table of the estimated number of FFS beneficiaries with diagnoses coded into each HCC.

Comment: Several commenters asked CMS to describe the methodology for estimating the impact on plans of the recalibrated CMS-HCC model.

Response: When making comparisons of risk scores, it is important to take into account the FFS normalization factor so that comparisons are always done between normalized risk scores. Risk scores calculated using the 2004-2006 CMS-HCC model coefficients with recent data should be multiplied by 1/1.05, the FFS normalization factor that has been used in payment since 2004. Applying this normalization factor provides a more accurate comparison of risk scores from the old and new calibrations of the model, the latter of which is normalized to 2005. We estimated the impact on payment of changes in risk scores due to recalibration of the CMS-HCC model using a standard cohort and an appropriately adjusted ratebook. A key step in this process was normalizing risk scores to the appropriate year.

Comment: Several commenters requested that the coefficients for the long-term institutional model also be published in future Advance Notices.

Response: The coefficients for the Long-Term Institutional risk adjustment model are published in this Rate Announcement. We understand the interest in these coefficients, especially given new products focused on institutionalized Medicare beneficiaries. As we noted in the Advance Notice, we have used a larger sample to develop these coefficients and believe that the Long-Term Institutional risk adjustment model is improved significantly by having this larger sample, with more precise estimates, particularly for HCCs with small proportions of the population.

Comment: One commenter expressed concern that recalibration of the CMS-HCC risk adjustment model may disproportionately affect plans enrolling dual eligible beneficiaries and recommended that CMS continue to evaluate and test the new risk adjustment model to ensure that certain segments of plan populations are not adversely affected.

Response: The CMS-HCC risk adjustment model takes into account the effect on expenditures of dual enrollment status, in addition to other demographics and diseases. Moreover, the recalibration reflects coding and expenditure patterns based on the most recent data available. It is our belief that we are paying plans appropriately given various demographic and disease characteristics of their enrollees. We will continue to evaluate, however, various potential modifications to the model that may enhance payment accuracy for particular subgroups of enrollees.

Comment: The commenter recommended that CMS provide each renewing MA plan an estimate of the plan-specific impact of the recalibrated model on plan risk scores and revenue.

Response: CMS plans to release plan-specific impacts through HPMS in the near future.

Comment: One commenter expressed concern about the impact of the recalibrated CMS-HCC model on smaller and medium-sized plans in emerging markets that have different risk profiles than larger MA plans.

Response: As discussed in the responses above, the recalibrated CMS-HCC model more accurately takes into account more recent diagnosis and expenditure data and will result in more accurate predicted costs. We have no evidence that plan size explains variation in risk.

Comment: One commenter, addressing the elimination of diagnostic radiology from the recalibrated risk adjustment model, noted that plans may want to use CPT and HCPCS codes, rather than physician specialty type, to differentiate between diagnostic and interventional radiology.

Response: For those plans that use CPT codes to screen diagnosis codes submitted to CMS, please note that the CPT range for radiology is 70000 through 79999. The following CPT codes indicate diagnostic radiology and diagnoses on claims and should not be submitted to CMS in risk adjustment data: 70010 through 76999 and 78000 through 78999.

Comment: One commenter requests that CMS maintain a dialogue with MA organizations as CMS progresses with consideration of a payment adjustment for enrollees' frailty in future years.

Response: We appreciate the plans' interest in this issue and look forward to future discussions.

Comment: Several commenters requested information regarding the methodology used to determine the FFS normalization factor. Commenters requested information about the assumptions used, the data sources, analysis sample timeframe, conclusions drawn from the data, and the nature of the model used. Another commenter wanted the coding intensity factor to be reduced to reflect, to the greatest extent possible, the fact that the risk adjustment model will have been updated to reflect more current and accurate data than had been used previously. One commenter did not want the adjustment for coding intensity to include adjustments for real changes in risk (e.g., an aging population). One commenter is concerned that, if the coding intensity adjustment is not eliminated with the recalibration of the CMS-HCC risk adjustment model, their estimated increase in payment will be eliminated. Another commenter wanted the FFS normalization factor to be eliminated because of concerns that MA plans will be forced to increase beneficiary premiums and/or reduce benefits in 2007. One commenter requested that CMS discuss the manner in which it will be applied to the risk adjustment scores.

Response: A risk adjustment model calibrated on a particular year's data, in this case expenditures for year 2003, will produce coefficients and dollar predictions appropriate to the population and data for that year. The CMS-HCC model is calibrated on the fee-for-service population. A coefficient indicates incremental costs for someone with a specific condition. Coefficients represented in dollar terms can be summed to calculate an average expected expenditure for a beneficiary with a given set of diagnoses; coefficients represented in

relative terms can be summed to determine the risk score for a beneficiary with a specific set of diagnoses. When the model with fixed coefficients is used to predict expenditures for other years, predictions for prior years are lower and predictions for succeeding years are higher than for the calibration year.

As discussed above, CMS will use the 2005 denominator to normalize the risk scores in the new CMS-HCC model to 2005; therefore, we need only account for changes in the predicted expenditures for 2 years (between 2005 and 2007) in the payment system. To estimate this effect, we used the recalibrated CMS-HCC model to predict national mean per capita expenditures for the FFS population for each year from 2000 to 2005. The increasing predicted national mean per capita expenditures indicate that the predicted average risk score will exceed 1.0 in years subsequent to 2005. Using a linear projection, CMS estimates that the average increase in the predicted mean from 2005 to 2007 will be 2.9%. Therefore, the FFS normalization factor for 2007 is (1/1.029).

Comment: One commenter was concerned that changes in the rescaling factor applied to the ratebook might change the category that a county falls in when CMS determines the increase in the county rate, e.g., the resulting county rates may not benefit from the rate minimum applicable to floor counties.

Response: The county rates are developed using normalized risk factors for each year of expenditure data. The projected FFS normalization factor used to normalize risk scores in futures years has no impact on the determination of rates or the category in which a county falls.

The FFS normalization factor is applied after the "higher-of" method, so this adjustment does not affect whether a county rate is a "floor rate."

Counties that were floor rates in 2004, and were never FFS rates in subsequent years, are often referred to informally as "floor counties," because these "high floor" and "low floor" rates have been grown by the national growth trend in 2005 and 2006, thus remaining identifiable as rate amounts shared by many counties. Recall that floor rates were rates established by the Congress in 1997 and again in 2000 as minimum amounts appropriate for certain geographic areas. The MMA required CMS to revise the 2004 ratebook using a transitional "higher of 4 rates" method, where a county rate was the higher of the floor rate, blend rate, minimum percentage increase rate, and the new FFS rate. This was the last year CMS officially tabulated a floor rate for any county.

Effective for 2005 and subsequent years, the MMA changed the "higher-of" methodology, where a county capitation rate is – in rebasing years - the higher of the minimum percentage increase rate and the FFS rate. In non-rebasing years all capitation rates are the minimum percentage increase rate.

Comment: One commenter noted that the FFS normalization factor was meant to be a temporary adjustment, so it should be eliminated when calculating the 2007 rates.

Response: The DRA requires CMS to apply the FFS normalization factor.

Section D: Part D Payment Policy

Comment: One commenter recommended that CMS provide an estimate for the index factor to annually increase the threshold values for the Part D deductible, initial coverage limit, and catastrophic limit in the defined standard Part D benefit in the Advance Notice. The commenter also recommends that CMS clarify how this factor will be determined for 2007 and provide additional information on CMS' estimates of the impact of this factor. Another commenter recommends that CMS provide the estimate as soon as possible.

Response: In the future, CMS plans to provide an estimate for the index factors in the Advance Notice and the final factors in March. CMS will provide this year's index factors and the methodology for their determination under separate guidance in the near future.

Comment: One commenter recommends that CMS use the latest possible reference month for the weights for each plan used in calculating the national average bid amount and the regional low-income premium subsidy amount. In particular, the commenter encourages CMS to use a reference month after the end of the extended open enrollment period in May 2006.

Response: In the Advance Notice, CMS outlined a methodology for weighting the regional low-income premium subsidy amount. The final approach that will be used for this calculation is under consideration and CMS will issue subsequent guidance specifying the methodology. We plan to release the reference month for calculation of the national average bid amount and the regional low-income premium subsidy amount in the announcement of the national average bid amount.

ENCLOSURE IV: CMS-HCC Risk Adjustment Factors

EXHIBIT 1. Community and Institutional Factors for CMS-HCC 70 Model

Variable	Disease Group	Community Factors	Institutional Factors
Age/Sex Factors			
Female 0-34 Years		0.223	1.240
Female 35-44 Years		0.224	0.879
Female 45-54 Years		0.304	0.879
Female 55-59 Years		0.370	0.879
Female 60-64 Years		0.422	0.879
Female 65-69 Years		0.298	0.945
Female 70-74 Years		0.371	0.885
Females 75-79 Years		0.468	0.822
Female 80-84 Years		0.546	0.757
Female 85-89 Years		0.637	0.694
Female 90-94 Years		0.788	0.617
Female 95 Years or Over		0.783	0.482
Male 0-34 Years		0.107	1.059
Male 35-44 Years		0.167	0.822
Male 45-54 Years		0.197	0.842
Male 55-59 Years		0.297	0.916
Male 60-64 Years		0.401	0.970
Male 65-69 Years		0.330	1.140
Male 70-74 Years		0.416	1.093
Male 75-79 Years		0.520	1.093
Male 80-84 Years		0.617	1.056
Male 85-89 Years		0.744	1.033
Male 90-94 Years		0.830	0.895
Male 95 Years or Over		0.960	0.775
Medicaid & Originally Disabled Interactions with Age & Sex			
Medicaid Female, Disabled		0.137	0.077
Medicaid Female, Aged		0.177	0.077
Medicaid Male, Disabled		0.090	0.077
Medicaid Male, Aged		0.202	0.077
Originally-Disabled, Female		0.232	0.019
Originally-Disabled, Male		0.181	0.019
Disease Group Factors			
HCC1	HIV/AIDS	0.933	0.735
HCC2	Septicemia/Shock	0.887	0.762
HCC5	Opportunistic Infections	0.410	0.476
HCC7	Metastatic Cancer and Acute Leukemia	1.648	0.568
HCC8	Lung, Upper Digestive Tract, and Other Severe Cancers	1.648	0.568

Variable	Disease Group	Community Factors	Institutional Factors
HCC9	Lymphatic, Head and Neck, Brain, and Other Major Cancers	0.771	0.402
HCC10	Breast, Prostate, Colorectal and Other Cancers and Tumors	0.258	0.241
HCC15	Diabetes with Renal or Peripheral Circulatory Manifestation[1]	0.608	0.466
HCC16	Diabetes with Neurologic or Other Specified Manifestation[1]	0.452	0.466
HCC17	Diabetes with Acute Complications[1]	0.364	0.466
HCC18	Diabetes with Ophthalmologic or Unspecified Manifestation[1]	0.265	0.466
HCC19	Diabetes without Complication[1]	0.181	0.257
HCC21	Protein-Calorie Malnutrition	0.820	0.395
HCC25	End-Stage Liver Disease	0.996	0.768
HCC26	Cirrhosis of Liver	0.519	0.363
HCC27	Chronic Hepatitis	0.303	0.363
HCC31	Intestinal Obstruction/Perforation	0.347	0.349
HCC32	Pancreatic Disease	0.383	0.277
HCC33	Inflammatory Bowel Disease	0.270	0.263
HCC37	Bone/Joint/Muscle Infections/Necrosis	0.550	0.482
HCC38	Rheumatoid Arthritis and Inflammatory Connective Tissue Disease	0.363	0.233
HCC44	Severe Hematological Disorders	1.136	0.477
HCC45	Disorders of Immunity	0.841	0.443
HCC51	Drug/Alcohol Psychosis	0.250	0.000
HCC52	Drug/Alcohol Dependence	0.250	0.000
HCC54	Schizophrenia	0.515	0.347
HCC55	Major Depressive, Bipolar, and Paranoid Disorders	0.370	0.308
HCC67	Quadriplegia, Other Extensive Paralysis	0.961	0.337
HCC68	Paraplegia	0.961	0.291
HCC69	Spinal Cord Disorders/Injuries	0.511	0.152
HCC70	Muscular Dystrophy	0.466	0.000
HCC71	Polyneuropathy	0.324	0.253
HCC72	Multiple Sclerosis	0.472	0.174
HCC73	Parkinson's and Huntington's Diseases	0.547	0.089
HCC74	Seizure Disorders and Convulsions	0.280	0.165

Variable	Disease Group	Community Factors	Institutional Factors
HCC75	Coma, Brain Compression/Anoxic Damage	0.446	0.000
HCC77	Respirator Dependence/Tracheostomy Status	1.860	1.360
HCC78	Respiratory Arrest	1.448	0.984
HCC79	Cardio-Respiratory Failure and Shock	0.629	0.464
HCC80	Congestive Heart Failure	0.395	0.231
HCC81	Acute Myocardial Infarction	0.349	0.474
HCC82	Unstable Angina and Other Acute Ischemic Heart Disease	0.332	0.474
HCC83	Angina Pectoris/Old Myocardial Infarction	0.231	0.296
HCC92	Specified Heart Arrhythmias	0.295	0.198
HCC95	Cerebral Hemorrhage	0.366	0.175
HCC96	Ischemic or Unspecified Stroke	0.303	0.175
HCC100	Hemiplegia/Hemiparesis	0.410	0.065
HCC101	Cerebral Palsy and Other Paralytic Syndromes	0.212	0.000
HCC104	Vascular Disease with Complications	0.645	0.495
HCC105	Vascular Disease	0.324	0.164
HCC107	Cystic Fibrosis	0.398	0.327
HCC108	Chronic Obstructive Pulmonary Disease	0.398	0.327
HCC111	Aspiration and Specified Bacterial Pneumonias	0.761	0.644
HCC112	Pneumococcal Pneumonia, Emphysema, Lung Abscess	0.233	0.188
HCC119	Proliferative Diabetic Retinopathy and Vitreous Hemorrhage	0.278	0.527
HCC130	Dialysis Status	1.432	2.211
HCC131	Renal Failure	0.389	0.411
HCC132	Nephritis	0.182	0.290
HCC148	Decubitus Ulcer of Skin	1.167	0.474
HCC149	Chronic Ulcer of Skin, Except Decubitus	0.463	0.239
HCC150	Extensive Third-Degree Burns	0.818	0.000
HCC154	Severe Head Injury	0.446	0.000
HCC155	Major Head Injury	0.182	0.000
HCC157	Vertebral Fractures without Spinal Cord Injury	0.501	0.109
HCC158	Hip Fracture/Dislocation	0.450	0.000

Variable	Disease Group	Community Factors	Institutional Factors
HCC161	Traumatic Amputation	0.736	0.224
HCC164	Major Complications of Medical Care and Trauma	0.299	0.219
HCC174	Major Organ Transplant Status	1.073	0.449
HCC176	Artificial Openings for Feeding or Elimination	0.758	0.843
HCC177	Amputation Status, Lower Limb/Amputation Complications	0.653	0.224
Disabled/Disease Interactions			
D-HCC5	Disabled*Opportunistic Infections	0.941	0.280
D-HCC44	Disabled*Severe Hematological Disorders	0.551	0.419
D-HCC51	Disabled*Drug/Alcohol Psychosis	0.801	0.425
D-HCC52	Disabled*Drug/Alcohol Dependence	0.356	0.425
D-HCC107	Disabled*Cystic Fibrosis	1.391	0.000
Disease Interactions			
INT1	DM*CHF[2]	0.204	0.088
INT2	DM*CVD	0.149	0.026
INT3	CHF*COPD	0.216	0.194
INT4	COPD*CVD*CAD	0.174	0.042
INT5	RF*CHF[2]	0.248	0.000
INT6	RF*CHF*DM[2]	0.664	0.203

Note: The 2005 denominator of $6,496.03 was used to calculate both the community and institutional factors.

[1]Includes Type I or Type II Diabetes Mellitus.

[2]Beneficiaries with the three-way interaction RF*CHF*DM are excluded from the two-way interactions DM*CHF and RF*CHF. Thus, the three-way interaction term RF*CHF*DM is not additive to the two-way interaction terms DM*CHF and RF*CHF. Rather, it is hierarchical to, and excludes these interaction terms. All other interaction terms are additive.

DM is diabetes mellitus (HCCs 15-19).
CHF is congestive heart failure (HCC 80).
COPD is chronic obstructive pulmonary disease (HCC 108).
CVD is cerebrovascular disease (HCCs 95, 96, 100, and 101).
CAD is coronary artery disease (HCCs 81-83).
RF is renal failure (HCC 131).

SOURCES:
Community Factors: RTI International analysis of 2002/2003 Medicare 5% sample.
Institutional Factors: RTI International analysis of 2002/2003 Medicare 100% institutional sample.

EXHIBIT 2. List Hierarchies for the CMS-HCC Model

DISEASE HIERARCHIES		
Hierarchical Condition Category (HCC)	**If the Disease Group is Listed in This Column…**	**…Then Drop the Associated Disease Group(s) Listed in This Column**
	Disease Group Label	
5	Opportunistic Infections	112
7	Metastatic Cancer and Acute Leukemia	8,9,10
8	Lung, Upper Digestive Tract, and Other Severe Cancers	9, 10
9	Lymphatic, Head and Neck, Brain and Other Major Cancers	10
15	Diabetes with Renal Manifestations or Peripheral Circulatory Manifestation	16,17,18,19
16	Diabetes with Neurologic or Other Specified Manifestation	17,18,19
17	Diabetes with Acute Complications	18,19
18	Diabetes with Ophthalmologic or Unspecified Manifestations	19
25	End-Stage Liver Disease	26,27
26	Cirrhosis of Liver	27
51	Drug/Alcohol Psychosis	52
54	Schizophrenia	55
67	Quadriplegia/Other Extensive Paralysis	68,69,100,101,157
68	Paraplegia	69,100,101,157
69	Spinal Cord Disorders/Injuries	157
77	Respirator Dependence/ Tracheostomy Status	78,79
78	Respiratory Arrest	79
81	Acute Myocardial Infarction	82,83
82	Unstable Angina and Other Acute Ischemic Heart Disease	83
95	Cerebral Hemorrhage	96
100	Hemiplegia/Hemiparesis	101
104	Vascular Disease with Complications	105,149
107	Cystic Fibrosis	108
111	Aspiration and Specified Bacterial Pneumonias	112
130	Dialysis Status	131,132
131	Renal Failure	132
148	Decubitus Ulcer of Skin	149
154	Severe Head Injury	75,155
161	Traumatic Amputation	177

How Payments are Made with a Disease Hierarchy -- EXAMPLE: If a beneficiary triggers HCCs 148 (Decubitus Ulcer of the Skin) and 149 (Chronic Ulcer of Skin, Except Decubitus), then HCC 149 will be dropped. In other words, payment will always be associated with the HCC in column 1 if a HCC in column 3 also occurs during the same collection period. Therefore, the MA organization's payment will be based on HCC 148 rather than HCC 149.

EXHIBIT 3. CMS-HCC Model for New Enrollees[1]

	Non-Medicaid & Non-Originally Disabled	Medicaid & Non-Originally Disabled	Non-Medicaid & Originally Disabled	Medicaid & Originally Disabled
Female				
0-34 Years	0.515	0.830	0.000	0.000
35-44 Years	0.653	0.969	0.000	0.000
45-54 Years	0.858	1.173	0.000	0.000
55-59 Years	0.969	1.285	0.000	0.000
60-64 Years	1.079	1.394	0.000	0.000
65 Years	0.510	0.980	1.111	1.581
66 Years	0.545	1.015	1.146	1.617
67 Years	0.572	1.042	1.173	1.643
68 Years	0.615	1.085	1.216	1.687
69 Years	0.644	1.114	1.245	1.716
70-74 Years	0.756	1.193	1.367	1.805
75-79 Years	0.960	1.333	1.459	1.833
80-84 Years	1.106	1.480	1.605	1.979
85-89 Years	1.245	1.618	1.744	2.118
90-94 Years	1.354	1.727	1.853	2.227
95 Years or Over	1.199	1.573	1.699	2.072
Male				
0-34 Years	0.329	0.672	0.000	0.000
35-44 Years	0.576	0.919	0.000	0.000
45-54 Years	0.695	1.039	0.000	0.000
55-59 Years	0.872	1.215	0.000	0.000
60-64 Years	1.023	1.366	0.000	0.000
65 Years	0.543	1.018	1.079	1.553
66 Years	0.562	1.036	1.173	1.647
67 Years	0.665	1.139	1.276	1.750
68 Years	0.668	1.142	1.279	1.753
69 Years	0.685	1.160	1.296	1.770
70-74 Years	0.872	1.283	1.371	1.782
75-79 Years	1.113	1.550	1.473	1.910
80-84 Years	1.305	1.742	1.664	2.101
85-89 Years	1.504	1.941	1.863	2.300
90-94 Years	1.594	2.031	1.953	2.391
95 Years or Over	1.580	2.017	1.939	2.376

Note: The 2005 denominator of $6,496.03 was used to calculate the new enrolle factors.

[1]For payment purposes, a new enrollee is a beneficiary who did not have 12 months of Part B eligibility in the calendar year prior to the payment year. The CMS-HCC New Enrollee model is not based on diagnoses, but includes factors for different age and gender combinations by Medicaid status and the original reason for Medicare entitlement.

SOURCE: RTI International analysis of 2002/2003 Medicare 5% sample.

EXHIBIT 4. Frailty Factors for the Community Population Aged 55-and-Over[1]

Difficulty in Activities of Daily Living (ADLs)	Additive Frailty Factor
0 ADLs	-0.141
1-2	+0.171
3-4	+0.344
5-6	+1.088

[1]Frailty factors are applied to PACE plans and certain demonstrations.

April 2, 2007

NOTE TO: All Medicare Advantage Organizations and Other Interested Parties

SUBJECT: Announcement of Calendar Year (CY) 2008 Medicare Advantage Capitation Rates and Payment Policies

In accordance with section 1853(b)(1) of the Social Security Act (the Act), we are notifying you of the annual Medicare Advantage (MA) capitation rate for each MA payment area for 2008, and the risk and other factors to be used in adjusting such rates. Attached is a spreadsheet containing the capitation rate tables for CY 2008. Also included is a spreadsheet which shows the statutory component of the regional benchmarks. The rates are posted on the Centers for Medicare & Medicaid Services (CMS) web site at http://www.cms.hhs.gov/MedicareAdvtgSpecRateStats/ under Ratebooks and Supporting Data.

Enclosure I shows the final estimates of the increase in the National Per Capita MA Growth Percentage for 2008. As discussed in Enclosure I, the final estimate of the increase in the National Per Capita MA Growth Percentage for combined aged and disabled beneficiaries is 5.71 percent. Since these estimates are all larger than 2 percent, these growth rates will be used as the minimum update percentage in calculating the 2008 rates. The CMS has decided not to rebase the county fee-for-service (FFS) rates for 2008. Therefore, all 2008 non-ESRD capitation rates increase a uniform amount over 2007 rates, reflecting application of the National Per Capita MA Growth Percentage and the change in budget neutrality (BN) factor discussed in Enclosure III.

Enclosure II provides a set of tables that summarizes many of the key Medicare assumptions used in the calculation of the National Per Capita MA Growth Percentage.

Section 1853(b)(4) of the Act requires CMS to release county-specific per capita FFS expenditure information on an annual basis, beginning with March 1, 2001. In accordance with this requirement, FFS data for CY 2005 is being posted on the above website at this time as well.

We received 34 comments from 16 organizations and individuals in response to CMS' request for comments on the Advance Notice of Methodological Changes for CY 2008 MA Capitation Rates (Advance Notice), published on February 16, 2007. Enclosure III presents our responses to the issues raised in the comments related to the Advance Notice. Enclosure IV contains the updated ESRD CMS-HCC risk adjustment factors effective CY 2008.

Questions can be directed to:
Sol Mussey at (410) 786-6386 for Enclosures I and II
Anne Hornsby (410) 786-1181 and Rebecca Paul at (410) 786-0852 for Enclosure III and IV.

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Enclosures

Enclosure I

Final Estimate of the Increase in the National Per Capita Growth Percentages for 2007

The first table below shows the National Per Capita MA Growth Percentages (NPCMAGP) used to determine the minimum update percentages for 2008. Adjustments of 1.24 percent, 2.08 percent, 7.08 percent and 1.33 percent for aged, disabled, ESRD, and combined aged and disabled, respectively, are included in the NPCMAGP to account for corrections to prior years estimates as required by section 1853(c)(6)(C). The combined aged and disabled increase is used in the development of the risk-adjusted ratebook.

The second table below shows the monthly actuarial value of the Medicare deductible and coinsurance for 2007 and 2008. In addition, for 2008, the actuarial value of deductibles and coinsurance is being shown for non-ESRD only, since the plan bids will not include ESRD benefits in 2008. These data were furnished by the Office of the Actuary.

Increase in the National Per Capita MA Growth Percentages for 2008

	Prior Increases	Current Increases			NPCMAGP for 2008 With Sec.1853(c)(6)(C) adjustment[1]
	2003 to 2007	2003 to 2007	2007 to 2008	2003 to 2008	
Aged	26.77%	28.34%	4.23%	33.78%	5.53%
Disabled	29.03%	31.71%	4.85%	38.10%	7.03%
ESRD[2]	20.93%	29.49%	–0.39%	28.99%	6.66%
Aged+Disabled	26.99%	28.68%	4.32%	34.24%	5.71%

[1]Current increases for 2003 to 2008 divided by the prior increases for 2003 to 2007.

[2]Starting in 2008, increases for ESRD will reflect an estimate of the increase for dialysis-only beneficiaries.

Monthly Actuarial Value of Medicare Deductible and Coinsurance for 2007 and 2008

	2007	2008	Change	2008 non-ESRD
Part A Benefits	$33.19	$36.71	10.6%	$35.26
Part B Benefits[3]	102.39	105.69	3.2%	98.99
Total Medicare	135.58	142.40	5.0%	134.25

[3]Includes the amounts for outpatient psychiatric charges.

Medical Savings Account (MSA) Plans. The maximum deductible for current law MSA plans for 2008 is $10,050.

Enclosure II

Key Assumptions and Financial Information

The USPCCs are the basis for the National Per Capita MA Growth Percentages. Attached is a table that compares the published United States Per Capita Costs (USPCC) with current estimates for 2000 to 2008. In addition, this table shows the current projections of the USPCCs through 2010. In prior years, information in these tables was presented back to 1997. Since the passage of the MMA, formula changes in the law do not require the use of the USPCCs back to 1997 for the purpose of calculating the 2008 rates (e.g., the area-specific rate is not tabulated for years after 2004 and no adjustments to prior years' estimates are allowed for years before 2004 for calculating the minimum update percentage).

We are also providing an attached set of tables that summarizes many of the key Medicare assumptions used in the calculation of the USPCCs. Most of the tables include information for the years 2000 through 2010. All of the information provided in this enclosure applies to the Medicare Part A and Part B programs. Caution should be employed in the use of this information. It is based upon nationwide averages, and local conditions can differ substantially from conditions nationwide.

None of the data presented here pertain to the Medicare prescription drug benefit.

Comparison of Current Estimates of the USPCC with Published Estimates

PART A:

Calendar Year	Aged			Disabled			Aged and Disabled		
	Current Estimate	Published Estimate	Ratio	Current Estimate	Published Estimate	Ratio	Current Estimate	Published Estimate	Ratio
2000	$263.29	$286.18	1.087	$218.77	$230.48	1.054	$257.31	$278.61	1.083
2001[1]	$283.70	$288.62	1.017	$234.57	$235.50	1.004	$276.93	$281.25	1.016
2001[2]	$283.70	$298.43	1.052	$234.57	$242.00	1.032	$276.93	$290.59	1.049
2002	$297.99	$294.46	0.988	$247.83	$242.06	0.977	$290.89	$287.10	0.987
2003	$302.46	$290.50	0.960	$251.43	$234.89	0.934	$294.96	$282.50	0.958
2004	$317.80	$326.78	1.028	$264.28	$271.69	1.028	$309.66	$318.43	1.028
2005	$340.27	$348.28	1.024	$285.26	$291.45	1.022	$331.68	$339.49	1.024
2006	$346.43	$351.38	1.014	$300.74	$295.15	0.981	$339.20	$342.67	1.010
2007	$367.71	$370.34	1.007	$325.23	$318.17	0.978	$360.95	$362.06	1.003
2008	$385.61	$385.61	1.000	$344.31	$344.31	1.000	$379.02	$379.02	1.000
2009	$403.96	--	--	$363.94	--	--	$397.52	--	--
2010	$422.56	--	--	$383.27	--	--	$416.18	--	--

PART B:

Calendar Year	Aged			Disabled			Aged and Disabled		
	Current Estimate	Published Estimate	Ratio	Current Estimate	Published Estimate	Ratio	Current Estimate	Published Estimate	Ratio
2000	$199.19	$218.78	1.098	$183.35	$195.91	1.069	$197.23	$216.03	1.095
2001[1]	$219.71	$217.57	0.990	$206.72	$191.99	0.929	$218.06	$214.32	0.983
2001[2]	$219.71	$223.83	1.019	$206.72	$198.69	0.961	$218.06	$220.63	1.012
2002	$233.02	$244.17	1.048	$226.12	$218.23	0.965	$232.12	$240.76	1.037
2003	$250.74	$232.24	0.926	$246.45	$211.58	0.859	$250.16	$229.47	0.917
2004	$276.69	$263.39	0.952	$274.68	$252.74	0.920	$276.41	$261.89	0.947
2005	$296.95	$281.90	0.949	$295.62	$272.79	0.923	$296.75	$280.58	0.946
2006	$322.89	$311.28	0.964	$309.39	$316.82	1.024	$320.89	$312.09	0.973
2007	$342.29	$334.02	0.976	$330.54	$343.76	1.040	$340.52	$335.47	0.985
2008	$354.44	$354.44	1.000	$343.26	$343.26	1.000	$352.75	$352.75	1.000
2009	$369.71	--	--	$358.65	--	--	$368.02	--	--
2010	$385.38	--	--	$375.33	--	--	$383.83	--	--

PART A & PART B:

Calendar Year	Aged			Disabled			Aged and Disabled		
	Current Estimate	Published Estimate	Ratio	Current Estimate	Published Estimate	Ratio	Current Estimate	Published Estimate	Ratio
2000	$462.48	$504.96	1.092	$402.12	$426.39	1.060	$454.54	$494.64	1.088
2001[1]	$503.41	$506.19	1.006	$441.29	$427.49	0.969	$494.99	$495.57	1.001
2001[2]	$503.41	$522.26	1.037	$441.29	$440.69	0.999	$494.99	$511.22	1.033
2002	$531.01	$538.63	1.014	$473.95	$460.29	0.971	$523.01	$527.86	1.009
2003	$553.20	$522.74	0.945	$497.88	$446.47	0.897	$545.12	$511.97	0.939
2004	$594.49	$590.17	0.993	$538.96	$524.43	0.973	$586.07	$580.32	0.990
2005	$637.22	$630.18	0.989	$580.88	$564.24	0.971	$628.43	$620.07	0.987
2006	$669.32	$662.66	0.990	$610.13	$611.97	1.003	$660.09	$654.76	0.992
2007	$710.00	$704.36	0.992	$655.77	$661.93	1.009	$701.47	$697.53	0.994
2008	$740.05	$740.05	1.000	$687.57	$687.57	1.000	$731.77	$731.77	1.000
2009	$773.67	--	--	$722.59	--	--	$765.54	--	--
2010	$807.94	--	--	$758.60	--	--	$800.01	--	--

[1]Applies to M+C ratebook for January to February, 2001
[2]Applies to M+C ratebook for March to December, 2001

Comparison of Current Estimates of the USPCC with Published Estimates- continued

PART A:

Calendar Year	ESRD Current Estimate	ESRD Published Estimate	Ratio
2000	$1,311.80	$1,443.13	1.100
2001[1]	$1,423.77	$1,541.76	1.083
2001[2]	$1,423.77	$1,597.34	1.122
2002	$1,450.00	$1,435.62	0.990
2003	$1,555.07	$1,596.58	1.027
2004	$1,662.06	$1,685.25	1.014
2005	$1,587.07	$1,759.90	1.109
2006	$1,619.29	$1,717.97	1.061
2007	$1,753.14	$1874.54	1.069
2008	$1,855.03	$1855.03	1.000
2009	$1,950.63	--	--
2010	$2,045.63	--	--

PART B:

Calendar Year	ESRD Current Estimate	ESRD Published Estimate	Ratio
2000	$1,678.28	$2,436.13	1.452
2001[1]	$1,885.07	$1,875.57	0.995
2001[2]	$1,885.07	$1,921.53	1.019
2002	$2,000.07	$2,014.79	1.007
2003	$2,032.89	$1,847.53	0.909
2004	$2,182.58	$2,552.18	1.169
2005	$2,494.71	$2,739.99	1.098
2006	$2,730.52	$2,454.98	0.899
2007	$2,892.85	$2,470.81	0.854
2008	$2,773.04	$2,773.04	1.000
2009	$2,921.90	--	--
2010	$3,069.59	--	--

PART A & PART B:

Calendar Year	ESRD Current Estimate	ESRD Published Estimate	Ratio
2000	$2,990.08	$3,879.26	1.297
2001[1]	$3,308.84	$3,417.33	1.033
2001[2]	$3,308.84	$3,518.87	1.063
2002	$3,450.07	$3,450.41	1.000
2003	$3,587.96	$3,444.11	0.960
2004	$3,844.64	$4,237.43	1.102
2005	$4,081.78	$4,499.89	1.102
2006	$4,349.81	$4,172.95	0.959
2007	$4,645.99	$4,345.35	0.935
2008	$4,628.07	$4,628.07	1.000
2009	$4,872.53	--	--
2010	$5,115.22	--	--

[1]Applies to M+C ratebook for January to February, 2001
[2]Applies to M+C ratebook for March to December, 2001

Summary of Key Projections Under Present Law[1]

Part A

Year	Calendar Year CPI Percent Increase	Fiscal Year PPS Update Factor	FY Part A Total Reimbursement (Incurred)
2000	3.5	1.1	–0.8
2001	2.7	3.4	7.9
2002	1.4	2.8	8.1
2003	2.2	3.0	2.9
2004	2.6	3.4	7.9
2005	3.5	3.3	8.9
2006	3.4	3.7	5.1
2007	1.9	3.4	7.4
2008	2.4	3.8	7.7
2009	2.7	4.0	7.3
2010	2.8	3.9	7.0

Part B[2]

Calendar Year	Physician Fee Schedule		Part B Hospital	Total
	Fees	Residual[3]		
2000	5.5	3.6	–0.8	10.4
2001	4.8	4.1	12.5	9.7
2002	–4.8	6.1	–1.4	6.1
2003	1.7	4.5	5.3	6.9
2004	1.5	6.0	11.0	9.8
2005	1.5	3.5	10.7	7.5
2006	0.2	5.1	13.5	7.9
2007	0.0	5.4	9.9	5.4
2008	–9.9	7.1	10.0	3.0
2009	–5.0	6.5	9.7	3.8
2010	–5.4	3.7	9.1	3.8

[1]Percent change over prior year.
[2]Percent change in charges per Aged Part B enrollee.
[3]Residual factors are factors other than price, including volume of services, intensity of services, and age/sex changes.

Medicare Enrollment Projections Under Present Law (In Millions)

Non-ESRD

Calendar Year	Part A		Part B	
	Aged	Disabled	Aged	Disabled
2000	33.700	5.223	32.421	4.590
2001	33.904	5.417	32.582	4.747
2002	34.080	5.619	32.713	4.915
2003	34.427	5.929	33.027	5.187
2004	34.837	6.249	33.282	5.459
2005	35.241	6.524	33.584	5.719
2006	35.715	6.707	33.948	5.914
2007	36.436	6.893	34.241	6.066
2008	37.169	7.055	34.832	6.217
2009	37.911	7.276	35.448	6.405
2010	38.607	7.494	36.013	6.590

ESRD Part A

Calendar Year	Part A			
	Aged	Disabled	299I[1]	Total
2000	0.136	0.108	0.089	0.333
2001	0.144	0.114	0.092	0.349
2002	0.151	0.119	0.095	0.366
2003	0.160	0.124	0.098	0.383
2004	0.167	0.130	0.102	0.399
2005	0.175	0.134	0.106	0.416
2006	0.183	0.138	0.109	0.430
2007	0.190	0.141	0.112	0.443
2008	0.197	0.144	0.114	0.456
2009	0.204	0.148	0.116	0.468
2010	0.209	0.152	0.118	0.479

ESRD Part B

Calendar Year	Part B			
	Aged	Disabled	299I	Total
2000	0.138	0.104	0.082	0.324
2001	0.145	0.109	0.085	0.338
2002	0.153	0.113	0.088	0.354
2003	0.161	0.118	0.090	0.369
2004	0.168	0.123	0.091	0.381
2005	0.176	0.127	0.093	0.396
2006	0.183	0.130	0.095	0.408
2007	0.190	0.133	0.097	0.420
2008	0.197	0.135	0.098	0.431
2009	0.203	0.139	0.099	0.442
2010	0.209	0.143	0.101	0.452

[1] Individuals who qualify for Medicare based on ESRD only.

Part A Projections Under Present Law [1]

Calendar Year	Inpatient Hospital		SNF		Home Health		Managed Care		Hospice: Total Reimbursement (in Millions)	
	Aged	Disabled	Aged	Disabled	Aged	Disabled	Aged	Disabled	Aged	Disabled
2000	2,218.26	2,385.85	310.23	104.90	99.05	70.38	593.36	269.74	2,772	146
2001	2,406.91	2,595.68	376.02	129.04	121.53	64.75	571.77	255.43	3,575	188
2002	2,586.77	2,777.00	412.54	145.12	130.82	69.84	523.26	216.79	4,410	232
2003	2,639.34	2,830.01	421.23	150.31	132.98	72.04	522.57	217.07	5,429	286
2004	2,723.57	2,949.25	474.43	174.72	143.43	78.01	569.12	236.94	6,501	342
2005	2,827.79	3,102.93	518.86	196.28	151.84	83.07	675.66	302.44	7,532	396
2006	2,753.70	3,101.38	520.61	202.05	154.50	86.83	825.25	482.05	8,473	446
2007	2,873.93	3,311.31	541.40	215.47	160.25	92.35	944.37	566.88	9,169	483
2008	2,961.13	3,463.58	567.47	230.68	169.02	99.33	1,044.68	633.78	9,853	519
2009	3,034.11	3,606.42	585.36	243.32	175.71	105.43	1,174.83	721.01	10,600	558
2010	3,124.53	3,756.36	600.08	253.84	181.61	110.71	1,294.14	800.84	11,394	600

[1]Average reimbursement per enrollee on an incurred basis, except where noted.

Part B Projections Under Present Law[1]

Calendar Year	Physician Fee Schedule		Part B Hospital		Durable Medical Equipment	
	Aged	Disabled Non-ESRD	Aged	Disabled Non-ESRD	Aged	Disabled Non-ESRD
2000	1,003.19	951.69	238.98	290.69	118.54	184.47
2001	1,131.49	1,064.17	326.94	400.14	137.14	215.29
2002	1,177.47	1,109.73	333.67	423.49	158.40	261.50
2003	1,263.24	1,191.06	378.12	470.59	182.16	302.43
2004	1,393.90	1,312.21	433.20	545.30	180.69	300.46
2005	1,454.70	1,371.79	487.49	618.30	179.68	301.83
2006	1,464.55	1,369.29	547.41	675.06	186.89	320.05
2007	1,469.46	1,385.02	588.91	739.00	188.72	331.44
2008	1,419.75	1,349.25	644.63	815.64	193.52	343.85
2009	1,372.97	1,320.87	698.61	894.65	185.11	334.03
2010	1,320.86	1,282.47	756.00	976.89	189.75	346.37

Calendar Year	Carrier Lab		Other Carrier		Intermediary Lab	
	Aged	Disabled Non-ESRD	Aged	Disabled Non-ESRD	Aged	Disabled Non-ESRD
2000	58.89	58.02	201.38	195.17	46.25	59.31
2001	64.86	63.70	239.97	231.14	47.73	64.78
2002	70.96	71.15	286.95	281.69	55.38	74.69
2003	76.42	75.62	337.20	350.32	60.27	79.99
2004	82.38	82.39	362.49	398.36	65.27	88.16
2005	87.01	87.62	372.15	431.45	69.70	96.46
2006	89.30	90.80	375.20	404.39	75.22	103.46
2007	91.96	95.30	407.45	448.48	77.85	109.03
2008	95.52	99.70	449.82	493.62	79.28	111.96
2009	100.21	105.74	491.69	540.61	83.18	118.88
2010	105.36	112.12	536.44	589.57	87.48	126.17

Calendar Year	Other Intermediary		Home Health		Managed Care	
	Aged	Disabled Non-ESRD	Aged	Disabled Non-ESRD	Aged	Disabled Non-ESRD
2000	117.91	108.13	129.45	99.19	531.83	221.42
2001	138.59	114.61	125.20	104.59	498.03	189.91
2002	173.74	143.90	131.98	110.78	494.67	205.08
2003	179.79	137.99	139.32	117.10	481.20	199.56
2004	205.79	167.35	159.59	133.74	537.12	233.85
2005	237.06	187.72	183.43	155.76	626.96	262.95
2006	246.89	206.72	187.05	161.83	865.42	354.84
2007	268.58	232.80	196.33	172.46	996.79	424.87
2008	256.99	223.48	207.64	185.23	1,086.52	467.30
2009	266.49	234.09	216.34	196.82	1,215.77	527.71
2010	276.85	245.65	224.17	206.88	1,334.28	586.00

[1]Average reimbursement per enrollee on an incurred basis.

Claims Processing Costs as a Fraction of Benefits

Calendar Year	Part A	Part B
2000	0.002195	0.014790
2001	0.001862	0.013223
2002	0.001496	0.011708
2003	0.001849	0.011194
2004	0.001676	0.010542
2005	0.001515	0.009540
2006	0.001245	0.007126
2007	0.001245	0.007126
2008	0.001245	0.007126
2009	0.001245	0.007126
2010	0.001245	0.007126

Approximate Calculation of the USPCC and the National MA Growth Percentage for Aged Beneficiaries

The following procedure will approximate the actual calculation of the USPCCs from the underlying assumptions for the contract year for both Part A and Part B.

Part A:
The Part A USPCC for aged beneficiaries can be approximated by using the assumptions in the tables titled "Part A Projections Under Present Law" and "Claims Processing Costs as a Fraction of Benefits." Information in the "Part A Projections" table is presented on a calendar year per capita basis. First, add the per capita amounts for the aged over all types of providers (excluding hospice). Next, multiply this amount by 1 plus the loading factor for administrative expenses from the "Claims Processing Costs" table. Then, divide by 12 to put this amount on a monthly basis. The last step is to multiply by 0.97454 to get the USPCC for the aged non-ESRD. This final factor of 0.97454 is the relationship between the total and non-ESRD per capita reimbursements in 2008. This factor does not necessarily hold in any other year.

Part B:
The Part B USPCC can be approximated by using the assumptions in the tables titled "Part B Projections Under Present Law" and "Claims Processing Costs as a Fraction of Benefits." Information in the "Part B Projections" table is presented on a calendar year per capita basis. First, add the per capita amounts for the aged over all types of providers. Next, multiply by 1 plus the loading factor for administrative expenses and divide by 12 to put this amount on a monthly basis. Then multiply by 0.95253 to get the USPCC for the aged non-ESRD.

The National Per Capita MA Growth Percentage:
The National Per Capita MA Growth Percentage for 2008 (before adjustment for prior years' over/under estimates) is calculated by adding the USPCCs for Part A and Part B for 2008 and then dividing by the sum of the current estimates of the USPCCs for Part A and Part B for 2007.

Enclosure III. CMS' Responses to Public Comments

Summary of Enclosure III
CMS received 34 comments from 16 organizations and individuals on the February 16, 2007 Advance Notice of Methodological Changes for CY 2007 MA Capitation Rates. Our responses to comments are organized as follows:

Section A. Estimate of the National Per Capita MA Growth Percentage for Calendar Year 2008
Section B. Impact of the Budget Neutrality (BN) Factor on MA Rates
Section C: MA Coding Intensity Adjustment
Section D: Updates to the Risk Adjustment Methodology, including the FFS Normalization Factor
Section E: Operational Policy Issues

Key Changes from the Advance Notice
Enclosure I provides the final estimate of the National MA growth trend, and the maximum deductible for MSA plans for 2008, which also is the 2008 out-of-pocket maximum for MSA demonstrations plans.

Enclosure III, Section C announces the policy decision on the MA coding intensity adjustment for 2008.

Enclosure III, Section D announces a change for PACE organizations from a 4-year to a 5-year transition to the revised frailty factors.

Enclosure III, Section E announces that we will delay until 2009 the transition to a valid ICD-9 code set. This section also provides clarification on Medicaid status reporting.

As in past years, policies proposed in the Advance Notice that are not modified or retracted in the Rate Announcement become effective in the upcoming payment year, as set forth in the Advance Notice. Clarifications in the Announcement supersede materials in the Advance Notice.

Section A. Estimate of the National Per Capita MA Growth Percentage for Calendar Year 2008

As mentioned in Enclosure I, the final estimate of the 2008 MA growth trend for combined aged and disabled beneficiaries is 5.71 percent, which is higher than the preliminary estimate of 4.1 percent announced February 16, 2007 in the Advance Notice. The President's Budget baseline was used for the preliminary estimate, and a more recent baseline was used for the final estimate.

The manner in which the Tax Relief and Health Care Act (TRHCA) of 2006 structured the physician fee schedule increase affected the revised 2007 trend and the 2008 trend. About 1 percent of the 2.6 percent increase in the 2007 trend is due to the physician fee schedule update, because the previously expected -5 percent adjustment for 2007 was eliminated. However, this 1 percent increase is offset by a reduction in the 2008 trend change. That is, under the TRHCA the 2007 increase has no effect on the 2008 physician fee schedule, which is different than how physician fee schedule increases have been structured in prior legislation. For 2008, the current law baseline reflects a -10 percent update for physician fees. The net impact of this -10 percent update on the overall USPCC is about a 2 percent decrease in the trend.

Comment: Three commenters asked why the preliminary estimate of the 2008 national MA growth percentage is so low. The commenters felt that the underlying trend change from 2007 to 2008 understates expected increases in health care costs. One of these commenters claimed that there is a pattern of CMS' understating trends, noting specifically that the trend change for 2008 is significantly lower than the four prior years and that trend changes for the past four years have been underestimated, requiring subsequent adjustments to prior years' estimates. The other two commenters also expressed concern about the downward adjustment to prior years' estimates for 2004, 2005, and 2006, and asked for explanation of these adjustments. All three commenters requested that CMS provide a detailed explanation of the 2008 national MA growth percentage.

Response: The 2008 trend may seem low because of the impact of the physician fee schedule increase on the MA national growth trend, explained above. We do not believe there is a pattern in underestimating trends and below we describe CMS' process for generating trend estimates.

OACT is required annually to model Medicare expenditure growth based on current law and assumptions from the President's budget. Assumptions from these sources are combined with modeling assumptions OACT has developed (e.g., population demographic trends, medical cost trends, etc.) to produce Medicare growth estimates. The assumptions used in the Medicare models are discussed in detail in the annual Trustees Reports, found on the CMS website at http://www.cms.hhs.gov/ReportsTrustFunds/01_Overview.asp.

To develop the MA growth trend for 2008, OACT first had to conduct the annual historical reconstruction of Medicare expenditures done in the fall of each year. Given time lags in claims processing (from providers to claims processors to CMS systems), OACT must project the preliminary and final estimates of the 2008 national MA growth trend without any claims data for 2007, less than 50 percent of the claims data for 2006, and about 97 percent of claims data for 2005. (Similarly, last year's historical reconstruction for the 2007 MA growth trend was based on data reported through June 2005. Hence, OACT had no data for 2006 and 2007, less than 50 percent of the data for 2005, and about 97 percent of the data for 2004.) A change of half a percent for estimates in years 2004 to 2006 is quite reasonable in light of the fact that estimates for the most recent years typically have very little reported claims data. Finally, OACT must project the 2008 trend in early 2007, in time for the Advance Notice and Rate Announcement, and any delay in conducting the historical reconstruction would make it impossible to meet the statutory deadline of the first Monday in April for release of the MA capitation rates.

The final estimates (which include adjustments to prior years' estimates) of the MA national growth percentage have been reasonably accurate. For example:

- The final estimate for 2004 was 6.1 percent compared to the revised 2004 estimate in this Announcement of 7.5 percent. (The final estimate originally published for 2004 was the first estimate of the impact of the MMA legislation on the Medicare growth trend.)
- The final estimate for 2005 was 6.6 percent compared to the revised 2005 estimate in this Announcement of 7.2 percent;
- The final estimate for 2006 was 4.8 percent compared to the revised 2006 estimate in this Announcement of 5.0 percent; and
- The final estimate for 2007 was 7.1 percent compared to the revised 2007 estimate of 6.3 percent in this Announcement.

Impact of physician fee schedule updates. For 2004 and 2005, the final estimates included the actual updates for physicians for those years. However, for 2006 and 2007, the legislated physician updates occurred after the MA rates were announced. Therefore, the final estimate for 2006 would have been about 1 percent higher if the physician update had been legislated before the 2006 rate announcement. For 2007, the impact of the physician update on the final estimates as originally published reflected a "canceling out" effect, because the 2006 physician update fix was incorporated in the 2007 update as an adjustment for prior years growth rate, and the physician update fix for 2007 was not yet law at the time the 2007 rates were released. Finally, as discussed above, the structure of the update in the TRHCA affected the final estimate of the 2008 growth trend differently than in prior years.

Adjustments to prior years' estimates. As the law provides, CMS must adjust the national MA growth rates for prior years' over- and under-estimates of the national MA growth trend. This is accomplished by comparing the latest baseline projection of Medicare per capita expenses (data in Enclosure II) to prior baseline projections. Baseline projections are prepared each year by OACT for use in the President's budget and the Trustees Report. Projections are prepared by type of service and type of Medicare beneficiary, and are aggregated over all services to get the appropriate per capita amount increases. OACT's projection methodology is basically the same as has been used for years. A description of the projection methodology can be found in an appendix of the annual Trustees' Report.

Enclosure II of this announcement includes tables with underlying assumptions for the USPCC growth rates. Comparing these tables with tables in prior announcements can give interested parties a sense of which factors have changed in recent years and therefore contribute to the revisions of prior year estimates.

In terms of future year growth trend estimates, each year in the Rate Announcement, the estimated USPCCs for out-years are published in the first table in Enclosure II. This year estimates through 2010 are shown. Future estimates of growth trends can be tabulated by dividing one year's USPCC by the USPCC for the prior year.

Comment: One commenter argued that Section 1853(c)(1)(C) of the Social Security Act ("minimum percentage increase") represents Congressional intent that, after all calculations are

made, MA payments should be raised a minimum of 2 percent in every county. The commenter believed that Congress designed the determination of MA payment rates with this guaranteed minimum 2 percent increase as a protection against the reality of health care inflation and so that Medicare beneficiaries receive protection from significant changes in their benefits year-over-year.

Response: Section 5301 of the DRA defines how CMS must calculate the MA capitation rates, beginning with CY 2007. (Keep in mind that the statutory provisions address rates, not payment amounts.) The DRA directs that the minimum percentage increase be applied to the capitation rates before the application of the BN factor. That is, the first step in calculating the county rates for the upcoming year is to back-out the BN factor for the previous year before applying the minimum percentage increase and then applying the estimate of the BN factor for the upcoming year. In addition, the DRA also provides the Secretary with authority to make adjustments to the capitation rates to accommodate new or updated risk adjustment methodologies. As a result, the statutory formula for computing capitation rates does not guarantee that the county capitation rates will be at least 2 percent greater than the capitation rates (including the BN factor) from the prior year.

Comment: Two commenters stated that CMS should annually rebase the FFS rates to better align funding increases with medical cost trends occurring in the counties, thus encouraging stability in the program.

Response: CMS is not rebasing FFS rates for 2008. Given that we rebased FFS rates for 2007 and that only those counties with above-average growth trends in FFS expenditures in the year(s) since CMS last rebased would be assigned the FFS rate, it is likely that only one year later there would be very few counties with above-average FFS growth trends (and above the minimum payment amounts, i.e., the implicit floors) large enough to put their FFS rate over their minimum percentage increase rate.

Comment: Two commenters state their concern that CMS has not made adjustments to estimates of Medicare per capita costs to reflect costs that would have been incurred if beneficiaries did not receive services from VA/DoD facilities, as provided for in section 1853(C)(1)(D)(iii). The commenters contend that failing to make such an adjustment has resulted in CMS underestimating FFS costs for five years (2004-2008). One commenter feels that CMS should have had the ability to make such an adjustment.

Response: Incorporating costs associated with Medicare-covered services provided to beneficiaries in VA and DoD facilities into the payment methodology is a multi-year project that will involve developing methods for matching coverage determinations, pricing of services, etc. Because we are not rebasing the FFS rates for 2008, this adjustment does not apply. We anticipate that this multi-year project will be completed by next year, which would allow us to have a better estimate of this adjustment for 2009.

Comment: One commenter recommended that CMS include an adjustment in the growth rate to account for new therapies that are covered through local coverage decisions similar to what CMS does for National Coverage Determinations (NCDs). For example, the commenter estimates that

the cost impact of new "wet" macular degeneration treatments covered under local coverage decisions is extremely significant and is not captured in the historical data used to develop the MA rate book. In a benefit year where such developments in technology are unusually numerous or costly, and are not offset by corresponding reductions in the cost of old technologies, the fact that there is at least a year lag in incorporating those costs into the rates and risk adjustors can have a serious detrimental impact on the rates for the lag year.

Response: Assumptions about new technologies are implicitly included in the National Per Capita Growth Trend. To the extent that new technologies have been ongoing for a number of years, the growth trends reflect a level of growth consistent with historical trends.

New technologies that apply on a local level are also implicit in the local average geographic adjustments which are determined in years that CMS rebases fee-for-service rates. It is virtually impossible to explicitly estimate the impacts of local coverage determinations (LCDs). The level of LCDs reflected in the historical years is the best approximation of the impact on local fee-for-service costs for the future.

Section B. Impact of the Budget Neutrality (BN) Factor on MA Rates

The final estimate of the National Per Capita MA Growth Percentage is not the only factor that determines the final capitation rates for a year. For 2008, because we are not rebasing the FFS rates or updating the aged/disabled risk adjustment model, the only other factor that affects the 2008 capitation rates is the budget neutral risk adjustment (BN) factor.

The DRA specifies the components that CMS must include in the estimate of budget neutral (BN) risk adjustment factor, and codifies the phase-out of the BN factor. As in prior years, the BN factor was estimated as the difference between aggregate payments to plans using 100 percent demographic payments and aggregate payments to plans using 100 percent risk adjustment payments, expressed as a percent of risk adjusted payments. For purposes of the calculation, CMS assumes that risk payments to plans will be at the local benchmarks, adjusted for each plan's risk score. CMS calculates a single BN factor for all MA plan enrollees.

The BN factor estimate for 2008 is 1.69 percent. This factor was calculated based on a full BN factor of 4.22 percent, multiplied by the BN phase-out percentage of 40 percent. As 2008 is the second year of the phase-out required by the DRA of 2005, 40 percent of the full BN factor is applied to the rates, as the same percentage for all counties.

Comment: One commenter recommended that when estimating the 2008 BN factor, CMS should use current enrollment data.

Response: The BN factor is an estimate of the difference in aggregate payments between the demographic-only model and the risk model, expressed as a percentage of the aggregate payments made in the risk model.

To estimate aggregate payments under both the demographic and risk models, we used demographic factors and risk scores for the July 2006 cohort, adjusted for more recent

enrollment patterns. We applied the demographic and risk scores and enrollment to pre-BN 2008 rates.

Comment: One commenter requested that CMS use data from the same time period to develop both the demographic and the risk rates.

Response: The demographic and risk rates used for tabulating the 2008 BN factor are all minimum percentage increase rates. Specifically, the 2007 demographic rates and the 2007 pre-BN risk rates were increased by the 2008 national MA growth percentage for aged and disabled beneficiaries in order to estimate 2008 MA program payments.

If the commenter is referring to the rebased 2007 FFS rates, we did use the same years of data for both demographic and risk FFS rates: each county's share of the national average per capita costs (based on 2001-2005 claims data) was applied to the projected 2007 $USPCC_{FFS}$ to get the county FFS rate.

Section C. MA Coding Intensity Adjustment

As required by the Deficit Reduction Act (DRA), we have analyzed whether there are coding pattern differences between Medicare Advantage and fee-for-service. As discussed in the Advance Notice, we conducted two studies to assess the extent of coding differences.

Persistence Analysis. The first study looked at how well Medicare Advantage and fee-for-service consistently identify beneficiaries with ongoing, chronic conditions from year to year. Because some beneficiaries have conditions that we know persist from year to year, e.g., diabetes, we would expect a beneficiary who has been identified as diabetic in one year to also be identified as diabetic in the following year. The intent of this analysis is to assess the extent to which any coding differences between MA and FFS can be attributed to a higher rate of year-to-year "persistence" in diagnosis coding in MA. In our analysis, we looked at beneficiaries enrolled in an MA plan over a two-year period (either 2004-2005 or 2005-2006) to see if diagnosis codes from the first year were reported in the following year. Our results indicated that by 2006 there were no notable differences in persistence coding between MA plans and FFS providers.

Disease Progression Analysis. For this second study, we looked separately at risk score trends for various groups of enrollees in MA and FFS: specifically, we looked at the risk scores of those who joined FFS or enrolled in MA plans ("joiners"), those who disenrolled from FFS (either due to death or because they enrolled in an MA plan) or from an MA plan (either due to death or because they returned to FFS) ("leavers"), and those who stayed in an MA plan from one year to the next or who stay in FFS ("stayers").

Findings Regarding Risk Score Trends. We found that, over the period from 2004–2006, MA risk scores increased faster than FFS risk scores. FFS risk scores increased approximately 2 percent per year, while MA risk scores increased approximately 4.5 percent per year. We found two dynamics that explained this differential growth in risk scores. The first dynamic was enrollment patterns.

- Joiners: The risk scores of those who enroll in MA plans are, on average, higher than the risk scores of those who enroll in FFS – new enrollees in FFS are largely newly-eligible beneficiaries who have just turned 65 years old; among new enrollees into MA plans, more than twice as many have switched from FFS than are newly-eligible for the program; and

- Leavers: Those who disenroll from MA plans -- either decedents or those who are switching to FFS – have an average risk score that is lower than the average risk scores of disenrollees from FFS, who are largely decedents.

With FFS losing higher risk beneficiaries than MA, and with MA enrolling higher risk beneficiaries than FFS, MA risk scores were pushed up at a faster rate than risk scores in FFS.

The second dynamic is related to those who stayed enrolled in an MA plan or in FFS from one year to the next ("stayers"). We looked specifically at the disease (HCC) portion of stayers' risk scores so that we could isolate the effect of coding and exclude the effect of demographic changes, such as aging, on risk scores. The disease portion of the MA stayers' risk scores increased more than the disease portion of those stayed in FFS.

We found that part of the difference in the increase between MA and FFS risk scores is due to the effect of different enrollment patterns in MA versus FFS and changes in the demographic characteristics of enrollees (such as aging into brackets with higher relative factors or obtaining Medicaid eligibility). We would not want to adjust payment for such factors since they are unrelated to coding patterns.

We also found that part of the differential increase in risk scores is due to the increase in the disease component of MA stayers' risk scores. However, we have not been able to measure the possible causes of this differential. For example, it is unclear how much of the increase in risk scores is due to changes in coding patterns versus changes in health status. In addition, to the extent that the increase is due to coding, it is unclear how much is due to catch-up (MA plans increasing their coding to "catch up" to the level of FFS) versus coding patterns that exceed FFS. This overall industry pattern can be seen to varying degrees on a plan-by-plan basis – some MA plans have experienced significantly high changes in the disease portion of the risk scores of the enrollees who stay enrolled in their plan while some have experienced very little.

Given that we cannot yet definitively attribute the difference in MA and FFS risk scores to underlying coding patterns differences, we will not make a coding intensity adjustment to MA payment for 2008. We will continue to study this issue, with particular focus on the plans that have experienced significant increases in risk scores, in an effort to determine what the appropriate adjustment might be for 2009 and 2010.

Comment: Several commenters thought it would be inappropriate to make adjustments related to activities that serve to improve beneficiaries' health and quality of life, and to coding patterns that are derived from the historical period 2004-2006, since coding patterns could have since changed. Commenters also suggested various factors that could explain differences in MA and

FFS coding patterns: selection bias, differences in local coding practices across particular markets, differences in the urban/rural mix of MA enrollment to beneficiaries in the fee-for-service program, emphasis placed by MA plans on preventive care and early diagnosis, techniques such as discharge planning, health risk assessments and medical management that contribute to improved care coordination, under-reporting of claims at start-up and subsequent improved coding practices. One commenter recommended that CMS release detailed methodology and data to support all coding pattern adjustments to MA rates and payments and provide MA plans with an opportunity to review and comment.

Response: We appreciate the input of the commenters. We look forward to future discussion regarding our ongoing analysis of differences in coding patterns between MA and FFS.

Section D. Updates to the Risk Adjustment Methodology, including the FFS Normalization Factor

FFS Normalization Factor for 2008.

The fee-for-service normalization factor for 2008 is 1.04. Because average predicted FFS expenditures increase after the model calibration year, CMS applies a FFS normalization factor to adjust beneficiaries' risk scores so that the average risk score is 1.0 in any particular year. The CMS-HCC model to be used in 2008 must be normalized to a 1.0 risk score for 2005 (calibration year).

Comment: One commenter recommended that CMS reduce the FFS normalization factor to the 2007 level and continue to reduce this factor as the BN factor is phased-out. The commenter recognized that the Deficit Reduction Act of 2005 legislated inclusion of the FFS normalization adjustment, but noted that continuing high negative adjustments will negatively impact MA payments as budget neutral risk-adjustment is phased out.

Response: We are required by law to phase-out the BN factor. We also are required by law to apply a FFS normalization factor, and we have no authority to phase-out the FFS normalization factor. We do not believe there is a methodological rationale for phasing-out the FFS normalization factor because average FFS risk scores increase each year and we need to adjust risk scores back to an average 1.0 in the years following a model calibration year.

Frailty Adjustment: No Program-Wide Application of Frailty Adjustment

Comment: Several commenters expressed support for CMS' decision not to adopt the frailty adjustment program-wide at this time, with one noting the methodological problems associated with use of survey data for calculating payments for the entire program. The commenters encouraged CMS to continue conducting research and evaluation that could lead to refinement of the risk adjustment methodology for high-cost beneficiaries. Several commenters encouraged CMS to move forward with determining an appropriate industry-wide frailty adjuster. One commenter noted that implementing a frailty adjuster is significant to ensure that MA plans are

not penalized for enrolling a frailer, sicker population. Two commenters requested information on the impacts of data sources and calibration methodology on the updated frailty factors and requested a timetable for incorporating frailty into CMS-HCC Model.

Response: As noted in the Advance Notice, CMS is conducting research to refine the CMS-HCC model to better capture the costs of high-cost enrollees. As required by law, CMS would use any revision of the CMS-HCC model to pay all MA plans, including SNPs. CMS is committed to refining the CMS-HCC model to appropriately reflect the cost for all beneficiaries enrolled in MA plans, including high-cost beneficiaries, but cannot specify a date at this time.

Update to Frailty Factors for PACE and Certain Demonstrations

Comment: Several commenters wanted clarification of the decision to continue applying the frailty adjuster to the PACE program and not to SNPs that serve similar populations.

Response: CMS is continuing to pay PACE the frailty adjuster under section 1894(d)(2) of the Act, a provision that applies only to the PACE program and requires CMS to make payments taking into account frailty of their enrollees into account.

Under the rules that apply to SNPs absent the exercise of demonstration waiver authority, CMS is required to pay for SNP enrollees, and risk adjust payments for such enrollees, using the same statutory rules applicable to all coordinated care plans, per Section 1853(a)(3)(d) of the Act. The SNPs receiving frailty adjustments have been receiving these adjustments under demonstration waiver authority. As indicated in the Advance Notice, these SNPS are transitioning to regular MA-SNP status, and as of January 1, 2008, all demonstration waivers other than those required to provide for a phase-out of the frailty adjustment will end. As mentioned in the Advance Notice and the preceding response, CMS is working to refine the CMS-HCC model to better predict the cost of high-cost enrollees, which will allow CMS to apply any change in methodology program-wide on a budget neutral basis.

Comment: One commenter requested that CMS delay application of the updated frailty factors to PACE plans until at least 2009. Another commenter requested that PACE plans be given a one-year delay in the transition schedule or a five-year, rather than a four-year, transition period in order to have time to learn more about the revised frailty factors, to see the results of the BBA-mandated evaluation of the PACE program, and to provide more time for current and new PACE plans to adjust to their frailty scores based on the recalibrated model.

Response: In the Advance Notice, CMS announced that we have updated and refined the frailty adjustment factors currently applied to PACE plan payments. We also proposed to transition PACE plan payments to 100 percent of the revised frailty factors over a four-year period.

In response to concerns about the transition to the revised frailty factors, CMS will change the transition period for PACE plans to a five-year transition from a four-year transition. This extended transition will give PACE organizations additional time to be fully informed of the assumptions underlying the new model. While we understand PACE organizations' concerns

about the application of the revised factors, CMS must balance these concerns with the need to implement frailty factors that accurately reflect the differential in expected Medicare expenditures for PACE enrollees.

The extended transition schedule will mean that, for the remainder of 2007, PACE payments will be based 100 percent on the current factors, and for 2008 and beyond the transition schedule will be as follows:

- In 2008 (year 1): 90% of the current frailty factors and 10% of the revised frailty factors.
- In 2009 (year 2): 70% of the current frailty factors and 30% of the revised frailty factors.
- In 2010 (year 3): 50% of the current frailty factors and 50% of the revised frailty factors.
- In 2011 (year 4): 25% of the current frailty factors and 75% of the revised frailty factors.
- In 2012 (year 5): 100% of the revised frailty factors.

Comment: One commenter requested clarification regarding how the revised frailty factors will be used to calculate the organization-level frailty adjuster(s) for each PACE organization. Because there are now distinct frailty factors for non-Medicaid and Medicaid enrollees, the commenter asked whether CMS will calculate two organizational-level adjusters and if CMS will calculate a single frailty factor, how will it be weighted and using what data?

Response: The frailty adjuster, or contract-level frailty score, will continue to be annually calculated, based on results from the HOS-M survey, by weighting the frailty factor for each ADL level by the proportion of the contract's enrollees with that ADL level. Instead of four factors, the new model has eight factors: one factor for 5-6 ADLs and Medicaid eligible, one for 5-6 ADLs and not Medicaid eligible, etc. The weighted factors will be summed to get the contract-level frailty score.

Table III-1. Revised Frailty Factors*

ADL	Current Factor	Revised Model Factors	
		Non-Medicaid	Medicaid
0	–0.141	–0.089	–0.183
1-2	+0.171	+0.110	+0.024
3-4	+0.344	+0.200	+0.132
5-6	+1.088	+0.377	+0.188

*Same as the factors published in the Advance Notice.

Comment: One commenter noted that there are a variety of operational issues that will need to be addressed as the frailty adjustment phase-out is implemented and urged CMS to work closely with affected MA organizations in the development of guidance on these issues to ensure that practical considerations can be addressed.

Response: To resolve operational issues, we will be working closely with the MA organizations as they transition to full SNP status and the PACE organizations as they transition to the new frailty factors. In general, we foresee a continuation of our current operations. For example, we will continue to calculate the contract-level frailty score annually based on results from the HOS-

M survey. Contract-level frailty scores will be calculated using the appropriate factors and blended according to the schedule published in the February 16, 2007 Advance Notice for 2008 for the demonstrations transitioning to SNP status, and according to the schedule above for PACE organizations. For SHMO plans and the dual eligible demonstrations, this means that the published 2007 frailty factors will be used in calculating their contract-level frailty scores for any given year, and each contract score will be adjusted by the blend percentage. For PACE this means that we will calculate two contract-level frailty scores, using the current factors and new factors, and then blend the scores.

Refinement of Growth Trend for ESRD State Rates

Comment: One commenter requested that CMS develop dialysis/transplant rates at the county level (instead of the current State rates) in order to more accurately predict costs in different cost markets.

Response: We appreciate the commenters concern about the relationship of the ESRD State ratebook to various submarkets within a States. However, the number of ESRD Medicare beneficiaries nationwide is too small to calculate county-level rates.

Comment: One commenter asked if the growth trend includes only dialysis-related services or costs of all services of dialysis and transplant Medicare beneficiaries.

Response: The growth trend for dialysis beneficiaries, which is applied to State capitation rates, includes all Medicare expenditures for beneficiaries in dialysis status, including those months of dialysis expenditures for beneficiaries who subsequently had a transplant.

Comment: One commenter asks if the new ESRD State rates will be used for dialysis and transplants patients in 2008.

Response: Yes, we will continue to apply the State rates to payments for enrollees in dialysis and transplant status. Further information on the ESRD CMS-HCC risk adjustment model is available through the "Risk Adjustment Customer Support" link on the CMS website at http://www.cms.hhs.gov/MedicareAdvtgSpecRateStats/06_Risk_adjustment.asp#TopOfPage. This link is to CSSC Operations, and on their Training Page you will find the RAPS Participant Guide. Section 1.9 discusses ESRD payments under the risk adjustment model.

ESRD CMS-HCC Risk Adjustment Model

The ESRD dialysis normalization factor is 3.9 percent. The normalization factor will be applied to the risk scores of beneficiaries in dialysis and transplant status, which will be determined under the recalibrated ESRD model. The normalized risk scores will then be applied to the blended ESRD State rates. (For functioning graft beneficiaries, we will continue to apply the FFS normalization factor applicable to the aged-disabled CMS-HCC model, which for 2008 is 1.04 as announced above.)

We will post software for the recalibrated ESRD model by June 2007 on the CMS website at athttp://www.cms.hhs.gov/MedicareAdvtgSpecRateStats/06_Risk_adjustment.asp#TopOfPage.

Comment: One commenter encouraged CMS to coordinate the recalibration of the ESRD model with the recalibration of the aged/disabled model.

Response: CMS agrees with the commenter and will make every effort to recalibrate and implement all portions of the CMS-HCC risk adjustment model in the same payment year.

Comment: One commenter requested that CMS use its discretion to ensure that risk factors in the CMS-HCC model reflect the cost of highly significant new technologies that Medicare has begun covering after the calibration of the model.

Response: The CMS-HCC model projects health expenditures in the payment year based on enrollees' demographic and diagnostic profiles in the previous year. The hierarchical condition categories (clusters of diagnoses) that are included in the model have been shown to be strong predictors of health expenditures. Changing the model to include different sets of HCCs is a significant undertaking that requires many months of research, including convening technical panels and quantitative costs analysis. Further, because risk adjustment models are predictive, and because real-time models are not possible given data submission timelines, there is an inevitable lag between model calibration (when the relative factors are established) and payment year. In addition, because the factors for each HCC and demographic factor are relative to one another, we must update all the factors at the same time. Please note that, because risk factors are relative to each other, a cost increase in one HCC may not result in an increase in the relative factor for that HCC if the underlying costs of other HCCs have increased more. We recalibrate periodically to take into account shifting patterns of diseases and their relative costs.

Section E: Operational policy issues

Reporting of Medicaid Status for Part C Payment

Comment: A number of commenters requested a transition process to move from use of plan-reported Medicaid status to the State MMA files. Several commenters have asked that CMS continue to allow plans to report Medicaid status for both existing and new Medicare enrollees until implementation of this new procedure is fully tested. Such proof and validation should include, for example, further review and comparisons of the MMA State files against plan submitted data to determine the extent to which the plan-submitted data captured omissions from the state files.

Response: For 2008, CMS will continue using plan-reported status (via "01" transactions) and the Third Party files while it adds Medicaid status information from the MMA State files for risk payments for full risk enrollees (those who have had 12 or more months of Part B in 2007), effectively providing a transition process in 2008.

As mentioned in the Advance Notice, CMS has undertaken a study to assess the completeness of the MMA State files by comparing the Medicare beneficiaries reported on the MMA State files to those reported by plans and on the Third Party files. There are 974,000 Medicaid beneficiaries on the MMA State files who were previously not reported to CMS on the Third Party Files or by MA plans. Of all the Medicare beneficiaries reported on one of the three sources, 96.1 percent are listed on the MMA State files.

Of those reported on the Third Party files, 96.6 percent are on the MMA State files. Because of the way the Third Party files have been constructed, individuals who are reported on the Third Party files because a State has paid their Part B premiums, but who are ineligible for title XIX, cannot be identified. For example, our conversations with one large state indicate that they pay Part B premiums for approximately 50,000 Medicare beneficiaries who are not eligible for title XIX. We believe that many of the individuals who have been reported solely on the Third Party files are in this category.

Of those reported solely by plans as dual eligible, the vast majority (93 percent) are in Puerto Rico. Because Puerto Rico does not submit MMA State files (or Third Party files), CMS is establishing a parallel reporting mechanism with Puerto Rico (see other comment below).

Comment: Several commenters had questions regarding submission of Medicaid status retrospectively. They asked if plans will be able to continue submitting retrospective adjustments to the Medicaid indicator. In addition, a number of commenters expressed support for and interest in learning about the exceptions process as soon as possible.

Response: To clarify what change will be made regarding plan-reported Medicaid status, information regarding Medicaid status submitted by plans via "01" transactions after December 31, 2007, will not be taken into account to calculate beneficiaries' risk factors. Please note that, since full risk enrollees' risk factors are calculated using data from the previous year, payment for full risk enrollees in 2008 will use Medicaid status submitted in 2007, including information submitted in "01" transaction. Since new enrollees' risk factors are calculated using Medicaid status in the concurrent year, payment for new enrollees in 2008 will not use information submitted via "01" transactions.

In place of the information obtained via "01" transactions, CMS will use the information from the MMA State files to indicate Medicaid status. States can, and do, submit information regarding retroactive Medicaid eligibility to CMS via the MMA State files.

In addition, the exceptions process will utilize the current Integrigard process, which allows plans to submit retroactive Medicaid status to CMS. CMS is exploring ways to make this process more accurate and will release draft guidance as soon as possible.

Please note that for Part C risk adjustment purposes, a beneficiary has to be Medicaid for a minimum of one month during the data collection year (the year prior to the payment year for full risk enrollees and the payment year for new enrollees) to receive the Medicaid factor. Since final risk scores are reconciled after the end of the payment year, Medicaid status only needs to

be reported within applicable reporting time periods to be incorporated into an enrollee's risk score.

Comment: One commenter expressed concern about the identification of dual eligible beneficiaries in the U.S. Territories, since dual eligibles in the Territories are not reported on the MMA State files and are only reported on the Third Party Buy-In files for selected Territories. This commenter requested that plans in the U.S. Territories continue to have the ability to report Medicaid status for Part C risk adjustment purposes until CMS can demonstrate that it has accurate data on dual eligible Medicare beneficiaries in the Territories.

Response: CMS is making changes to its systems to improve the identification of the dual eligibility status of Medicare beneficiaries in the U.S. Territories in order to make appropriate payments to MA (and PDP) plans in the Territories. The commenter is correct that Territories do not report data on the State MMA files, nor do all Territories' Medicaid beneficiaries appear on the Third Party Buy-In files. CMS is working closely with Puerto Rico to submit a file of their dual eligible beneficiaries and we will use this information to appropriately calculate Part C risk scores of MA enrollees in Puerto Rico. (Other Territories' Medicaid beneficiaries are reported on the Third Party Buy files and CMS will use the Medicaid beneficiaries listed on these files to properly pay enrollees in these other Territories.) We will calculate 2008 risk payments for MA full-risk enrollees in the Territories similarly to how we calculate such payments in other jurisdictions: the source of Medicaid status will continue to utilize plan-reported data (and Third Party data where we have it), with the addition of the data submitted to CMS from Puerto Rico. CMS will provide operational guidance on how MA organizations operating in the Territories can obtain information about the Medicaid status of their enrollees and such organizations will have access to the exceptions process discussed above.

Comment: One commenter asked if these changes in plan reporting of Medicaid status means that plans' outreach programs to dual eligibles would be eliminated.

Response: Changes in plan reporting of Medicaid status should not affect any plans' efforts to market to dual eligible Medicaid beneficiaries.

Clarification on Institutional Status under Part C CMS-HCC Models

Comment: One commenter asked for more details about the appeals process, noting that plans will need to be ready with systems in place should exceptions be identified that need to be reported.

Response: The notification regarding post-reconciliation changes in institutional status described in the Advance Notice is not an appeals process, but is a discussion of the timeframe within which plans should inform CMS that a beneficiary's institutional status may be incorrect for Part C risk payment. As stated in the Advance Notice, CMS encourages plans to track the institutional status of their members and reconcile this status with their payments throughout the payment year. As described in the Advance Notice, the beneficiary's final residence status (long term institutional (LTI) or community) for the payment year is not determined until final risk

adjustment payment reconciliation (approximately 6 months after the end of the payment year). MA organizations have 45 days from the receipt of the MMR containing the final risk adjustment reconciliation payment to inform CMS of any discrepancies in LTI status. CMS will consider payments based on LTI status final unless discrepancies are reported in this timeframe. This does not preclude MA organizations from reporting discrepancies between their member's residence status and CMS' reporting of the member's residence status at any time prior to the final risk adjustment reconciliation.

Comment: One commenter asked, in reference to the need to notify CMS within 45 days of final reconciliation of any discrepancies in Long Term Institutional Status between what is reported on the MMR and our own records of residency, if these discrepancies be sent to Integriguard or directly to CMS.

Response: In our risk adjustment training sessions (June and August 2007, and forthcoming through the customer service link on our website at http://www.cms.hhs.gov/MedicareAdvtgSpecRateStats/06_Risk_adjustment.asp#TopOfPage), we will include guidance on the elements required for reporting these discrepancies to CMS.

Standard set of ICD-9 Diagnosis Codes for Risk Adjustment

Comment: One commenter expressed support of CMS' issuance of a comprehensive list of acceptable codes for the CMS risk adjustment models, but noted that significant provider education will be needed in order for MA organizations to establish a data stream consistent with the issued list. The commenter recommended that CMS defer mandating use of the comprehensive list until the 2009 payment year. Another commenter asked for clarification about: (1) CMS's definition of valid ICD9 code; (2) how the list of valid codes will be phased in; and (3) what dates of service will be affected by this change. Finally, the commenter asked CMS to provide a list of the valid codes.

Response: We will defer until 2009 the mandate to submit a standard set of ICD-9 codes. In the Advance Notice we proposed to move in 2008 to a standard set of codes against which to validate the diagnoses received from plans into our Risk Adjustment System (RAS). We made the distinction between valid and acceptable codes:

- Valid codes are ICD-9-CM code sets for each fiscal year that are approved and published on the website of the National Center for Health Statistics (NCHS) at http://www.cdc.gov/nchs/icd9.htm.)
- Acceptable codes are those that RAS will accept.

Currently, there are more acceptable codes than valid codes because RAS is "flexible" (e.g., still accepts an old ICD-9 code that has been superseded by a later NCHS code, and does not send an error message to the plan, instead simply storing it).

The goal of this transition to a standard set of codes for a payment year is to synchronize the list of codes RAS accepts and stores with the list of valid codes. Having a standard set of codes for each year will make it easier for CMS and plans to manage risk adjustment processing, editing,

and error reporting. The list of currently acceptable codes can be found on our website at http://www.cms.hhs.gov/MedicareAdvtgSpecRateStats/06_Risk_adjustment.asp#TopOfPage.

Effective for 2009, the standard set of acceptable codes for a payment year is defined as that list of valid codes for the three fiscal years prior to the payment year, as described in Table III-2.

Table III-2. Phase-in Schedule for New Lists of Diagnosis Codes for Risk Adjustment

Year of Payment	Date of Service	Source of codes
2007	1/06 – 12/06	The list of codes published on our website at http://www.cms.hhs.gov/MedicareAdvtgSpecRateStats/06_Risk_adjustment.asp#TopOfPage (which lists acceptable codes by year)
2008	1/07 – 12/07	The list of codes published on our website at http://www.cms.hhs.gov/MedicareAdvtgSpecRateStats/06_Risk_adjustment.asp#TopOfPage (which lists acceptable codes by year)
2009	1/08 – 12/08	Valid diagnoses in Fiscal Years 2006, 2007, 2008
2010	1/09 – 12/09	Valid diagnoses in Fiscal Years 2007, 2008, 2009
2011	1/10 – 12/10	Valid diagnoses in Fiscal Years 2008, 2009, 2010

CMS will issue guidance as soon as possible with further detail on the transition to a standard set of codes for payment year 2009.

Enclosure IV Coefficients for CMS-HCC End Stage Renal Disease Model*

*Note: the following tables are identical to those published in the February 16, 2007 Advance Notice.

Enclosure IV Coefficients for CMS-HCC End Stage Renal Disease Model

Exhibit 1. Relative Factors for CMS-HSS ESRD Model

Table 1-1. Relative Factors for CMS-HCC ESRD Dialysis Model[1]

Risk factors are relative to average total Medicare expenditures per capita for dialysis patients[2].

Variable	Disease Group	Relative Factors
Age/Sex Groups		
Female		
0-34 Years		0.699
35-44 Years		0.699
45-54 Years		0.715
55-59 Years		0.746
60-64 Years		0.749
65-69 Years		0.813
70-74 Years		0.813
75-79 Years		0.831
80-84 Years		0.850
85 Years or Over		0.872
Male		
0-34 Years		0.614
35-44 Years		0.650
45-54 Years		0.675
55-59 Years		0.699
60-64 Years		0.722
65-69 Years		0.776
70-74 Years		0.776
75-79 Years		0.790
80-84 Years		0.790
85 Years or Over		0.826
Disease Group Factors		
HCC1	HIV/AIDS	0.235
HCC2	Septicemia/Shock	0.073
HCC5	Opportunistic Infections	0.051
HCC7	Metastatic Cancer and Acute Leukemia	0.189
HCC8	Lung, Upper Digestive Tract, and Other Severe Cancers	0.189
HCC9	Lymphatic, Head and Neck, Brain, and Other Major Cancers	0.160
HCC10	Breast, Prostate, Colorectal and Other Cancers and Tumors	0.058
HCC15	Diabetes with Renal or Peripheral Circulatory Manifestation	0.080
HCC16	Diabetes with Neurologic or Other Specified Manifestation	0.080
HCC17	Diabetes with Acute Complications	0.080
HCC18	Diabetes with Ophthalmologic or Unspecified Manifestation	0.080
HCC19	Diabetes without Complication	0.079
HCC21	Protein-Calorie Malnutrition	0.050
HCC25	End-Stage Liver Disease	0.259
HCC26	Cirrhosis of Liver	0.095
HCC27	Chronic Hepatitis	0.051
HCC31	Intestinal Obstruction/Perforation	0.057

HCC32	Pancreatic Disease	0.084
HCC33	Inflammatory Bowel Disease	0.088
HCC37	Bone/Joint/Muscle Infections/Necrosis	0.115
HCC38	Disease	0.077
HCC44	Severe Hematological Disorders[3]	0.000
HCC45	Disorders of Immunity	0.113
HCC51	Drug/Alcohol Psychosis[4]	0.000
HCC52	Drug/Alcohol Dependence[4]	0.000
HCC54	Schizophrenia	0.179
HCC55	Major Depressive, Bipolar, and Paranoid Disorders	0.123
HCC67	Quadriplegia, Other Extensive Paralysis	0.229
HCC68	Paraplegia	0.229
HCC69	Spinal Cord Disorders/Injuries	0.148
HCC70	Muscular Dystrophy[3]	0.000
HCC71	Polyneuropathy	0.056
HCC72	Multiple Sclerosis	0.087
HCC73	Parkinson's and Huntington's Diseases	0.038
HCC74	Seizure Disorders and Convulsions	0.094
HCC75	Coma, Brain Compression/Anoxic Damage	0.201
HCC77	Respirator Dependence/Tracheostomy Status	0.349
HCC78	Respiratory Arrest	0.156
HCC79	Cardio-Respiratory Failure and Shock	0.088
HCC80	Congestive Heart Failure	0.086
HCC81	Acute Myocardial Infarction	0.107
HCC82	Unstable Angina and Other Acute Ischemic Heart Disease	0.107
HCC83	Angina Pectoris/Old Myocardial Infarction	0.027
HCC92	Specified Heart Arrhythmias	0.061
HCC95	Cerebral Hemorrhage	0.058
HCC96	Ischemic or Unspecified Stroke	0.058
HCC100	Hemiplegia/Hemiparesis	0.088
HCC101	Cerebral Palsy and Other Paralytic Syndromes	0.040
HCC104	Vascular Disease with Complications	0.169
HCC105	Vascular Disease	0.059
HCC107	Cystic Fibrosis	0.078
HCC108	Chronic Obstructive Pulmonary Disease	0.078
HCC111	Aspiration and Specified Bacterial Pneumonias	0.123
HCC112	Pneumococcal Pneumonia, Emphysema, Lung Abscess	0.051
HCC119	Proliferative Diabetic Retinopathy and Vitreous Hemorrhage[3]	0.000
HCC130	Dialysis Status[7]	0.000
HCC131	Renal Failure[7]	0.000
HCC132	Nephritis[7]	0.000
HCC148	Decubitus Ulcer of Skin	0.182
HCC149	Chronic Ulcer of Skin, Except Decubitus	0.110
HCC150	Extensive Third-Degree Burns[5]	0.088
HCC154	Severe Head Injury	0.201
HCC155	Major Head Injury	0.022
HCC157	Vertebral Fractures without Spinal Cord Injury	0.035
HCC158	Hip Fracture/Dislocation	0.054
HCC161	Traumatic Amputation	0.073

HCC164	Major Complications of Medical Care and Trauma[3]	0.000
HCC174	Major Organ Transplant Status	0.199
HCC176	Artificial Openings for Feeding or Elimination	0.062
HCC177	Amputation Status, Lower Limb/Amputation Complications	0.073
Medicaid Interactions With Age and Sex		
Medicaid_Female_Disabled		0.051
Medicaid_Female_Aged		0.031
Medicaid_Male_Disabled		0.043
Medicaid_Male_Aged		0.069
Originally Disabled Interactions With Sex		
Female, 65+, Originally Entitled due to ESRD/ w or wo Disability		-0.054
Male, 65+, Originally Entitled due to ESRD/ w or wo Disability		-0.047
Female, 65+, Originally Entitled due to Disability (non-ESRD)		0.056
Male, 65+, Originally Entitled due to Disability (non-ESRD)		0.032
Disabled/Disease Interactions		
D_HCC5	Disabled_Opportunistic Infections	0.081
D_HCC44	Disabled_Severe Hematological Disorders	0.050
D_HCC45	Disabled_Disorders of Immunity[4]	0.000
D_HCC51	Disabled_Drug/Alcohol Psychosis	0.190
D_HCC52	Disabled_Drug/Alcohol Dependence	0.190
D_HCC107	Disabled_Cystic Fibrosis[5]	0.149
Disease Interactions[6]		
INT1	DM_CHF	0.020
INT2	DM_CVD	0.051
INT3	CHF_COPD[4]	0.000
INT4	COPD_CVD_CAD[3]	0.000

[1]This model is used for those enrollees who have a full year of base year claims data

[2]Mean Year 2003 Total Expenditures=$60,471. Mean is over all dialysis patients including those with Medicare as secondary payer.

[3]Coefficients of variables with unconstrained coefficients less than 0 were constrained to equal 0.

[4]Coefficients of variables with coefficients with t-statistics < 1.0 were constrained to equal 0.

[5]Coefficient was constrained to equal coefficient from the CMS-HCC Aged-Disabled Community Model (2002-2003 Calibration).

[6]The interaction DM_CHF_RF (where RF = renal failure) is the same in this population as DM_CHF because all sample members have renal failure. Hence, this three-way interaction is not included.

[7]These coefficients are set to zero because beneficiaries on whom the model is calibrated have renal failure and are in dialysis status.

Table 1-2. CMS-HCC Dialysis Model for New Enrollees[1]

Variable	Relative Factors
Age/Sex Groups	
Female	
0-34 Years	0.912
35-44 Years	0.943
45-54 Years	0.974
55-59 Years	1.020
60-64 Years	1.020
65-69 Years	1.134
70-74 Years	1.162
75-79 Years	1.218
80-84 Years	1.232
85 Years or Over	1.236
Male	
0-34 Years	0.754
35-44 Years	0.894
45-54 Years	0.911
55-59 Years	0.959
60-64 Years	0.977
65-69 Years	1.090
70-74 Years	1.118
75-79 Years	1.151
80-84 Years	1.151
85 Years or Over	1.191
Medicaid Interactions With Age and Sex	
Medicaid_Female_Disabled	0.100
Medicaid_Female_Aged	0.069
Medicaid_Male_Disabled	0.087
Medicaid_Male_Aged	0.114
Originally Disabled Interactions With Sex	
Originally Disabled_Female, Age Less than 65	0.237
Originally Disabled_Female	0.237
Originally Disabled_Male, Age Less than 65	0.211
Originally Disabled_Male	0.211

Notes:

[1]New enrollees are those enrollees who do not have a full year of base year claims data.

Mean Year 2003 Total Expenditures=$60,471. Mean is over all dialysis patients including those with Medicare as secondary payer.

Table 1-3. Transplant Calculations

Under the CMS-HCC risk adjustment system of payments for ESRD patients, payment for transplants is carved out of the payments for all ESRD patients. The payment factor for a transplant is based on the average Medicare costs for transplant admissions and the two months subsequent to discharge. When CMS is notified of a transplant, three monthly payments are made. Instead of a dialysis risk factor being the basis for payment in those months, a transplant factor is used and applied to the dialysis rate book. After the three months, payment is made at the functioning graft rate or at the dialysis rate, as appropriate.

Transplant Calculations

	Kidney Only Dollars	**Kidney Plus Pancreas Dollars**	**Kidney Only Relative Factor**	**Kidney Plus Pancreas Relative Factor**
Month 1	$32,558	$55,310	6.46	10.98
Month 2	$5,106	$7,434	1.01	1.48
Month 3	$5,106	$7,434	1.01	1.48
Total	$42,770	$70,178		

Note: To compute the relative factors, the national mean of annual dialysis patient costs was converted to a monthly amount and the transplant monthly costs were divided by this number.

Mean annual dialysis costs: $60,471
Costs per month: $5,039

Table 1-4.

CMS-HCC Community and Institutional Models for Functioning Graft [1]

Additional payment factors for functioning graft status are at bottom of table.

Variable	Disease Group	Community Relative Factor	Constraints[2]	Institutional Relative Factor	Constraints[2]
Age/Sex Groups					
Female					
0-34 Years		0.223		1.240	
35-44 Years		0.224		0.879	
45-54 Years		0.304		0.879	
55-59 Years		0.370		0.879	
60-64 Years		0.422		0.879	
65-69 Years		0.298		0.945	
70-74 Years		0.371		0.885	
75-79 Years		0.468		0.822	
80-84 Years		0.546		0.757	
85-89 Years		0.637		0.694	
90-94 Years		0.788		0.617	
95 Years or Over		0.783		0.482	
Male					
0-34 Years		0.107		1.059	
35-44 Years		0.167		0.822	
45-54 Years		0.197		0.842	
55-59 Years		0.297		0.916	
60-64 Years		0.401		0.970	
65-69 Years		0.330		1.140	
70-74 Years		0.416		1.093	
75-79 Years		0.520		1.093	
80-84 Years		0.617		1.056	
85-89 Years		0.744		1.033	
90-94 Years		0.830		0.895	
95 Years or Over		0.960		0.775	
Medicaid and Originally Disabled Interactions With Age and Sex[5]					
Medicaid_Female_Disabled		0.137		0.000	
Medicaid_Female_Aged		0.177		0.000	
Medicaid_Male_Disabled		0.090		0.000	
Medicaid_Male_Aged		0.202		0.000	
Female, 65+, originally entitled due to disability		0.232		0.000	
Male, 65+, originally entitled due to disability		0.181		0.000	
Disease Group Factors					
HCC1	HIV/AIDS	0.933		0.735	
HCC2	Septicemia/Shock	0.887		0.762	
HCC5	Opportunistic Infections	0.410		0.476	
HCC7	Metastatic Cancer and Acute Leukemia	1.648		0.568	
HCC8	Lung, Upper Digestive Tract, and Other Severe Cancers	1.648		0.568	
HCC9	Lymphatic, Head and Neck, Brain, and Other Major Cancers	0.771		0.402	

HCC10	Breast, Prostate, Colorectal and Other Cancers and Tumors	0.258		0.241	
HCC15	Diabetes with Renal or Peripheral Circulatory Manifestation	0.608		0.466	
HCC16	Diabetes with Neurologic or Other Specified Manifestation	0.452		0.466	
HCC17	Diabetes with Acute Complications	0.364		0.466	
HCC18	Diabetes with Ophthalmologic or Unspecified Manifestation	0.265		0.466	
HCC19	Diabetes without Complication	0.181		0.257	
HCC21	Protein-Calorie Malnutrition	0.820		0.395	
HCC25	End-Stage Liver Disease	0.996		0.768	
HCC26	Cirrhosis of Liver	0.519		0.363	
HCC27	Chronic Hepatitis	0.303		0.363	
HCC31	Intestinal Obstruction/Perforation	0.347		0.349	
HCC32	Pancreatic Disease	0.383		0.277	
HCC33	Inflammatory Bowel Disease	0.270		0.263	
HCC37	Bone/Joint/Muscle Infections/Necrosis	0.550		0.482	
HCC38	Rheumatoid Arthritis and Inflammatory Connective Tissue Disease	0.363		0.233	
HCC44	Severe Hematological Disorders	1.136		0.477	
HCC45	Disorders of Immunity	0.841		0.443	
HCC51	Drug/Alcohol Psychosis	0.250		0.000	
HCC52	Drug/Alcohol Dependence	0.250		0.000	
HCC54	Schizophrenia	0.515		0.347	
HCC55	Major Depressive, Bipolar, and Paranoid Disorders	0.370		0.308	
HCC67	Quadriplegia, Other Extensive Paralysis	0.961		0.337	
HCC68	Paraplegia	0.961		0.291	
HCC69	Spinal Cord Disorders/Injuries	0.511		0.152	
HCC70	Muscular Dystrophy	0.466		0.000	
HCC71	Polyneuropathy	0.324		0.253	
HCC72	Multiple Sclerosis	0.472		0.174	
HCC73	Parkinson's and Huntington's Diseases	0.547		0.089	
HCC74	Seizure Disorders and Convulsions	0.280		0.165	
HCC75	Coma, Brain Compression/Anoxic Damage	0.446	C1	0.000	
HCC77	Respirator Dependence/Tracheostomy Status	1.860		1.360	

HCC78	Respiratory Arrest	1.448		0.984	
HCC79	Cardio-Respiratory Failure and Shock	0.629		0.464	
HCC80	Congestive Heart Failure	0.395		0.231	
HCC81	Acute Myocardial Infarction	0.349		0.474	
HCC82	Unstable Angina and Other Acute Ischemic Heart Disease	0.332		0.474	
HCC83	Angina Pectoris/Old Myocardial Infarction	0.231		0.296	
HCC92	Specified Heart Arrhythmias	0.295		0.198	
HCC95	Cerebral Hemorrhage	0.366		0.175	
HCC96	Ischemic or Unspecified Stroke	0.303		0.175	
HCC100	Hemiplegia/Hemiparesis	0.410		0.065	
HCC101	Cerebral Palsy and Other Paralytic Syndromes	0.212		0.000	
HCC104	Vascular Disease with Complications	0.645		0.495	
HCC105	Vascular Disease	0.324		0.164	
HCC107	Cystic Fibrosis	0.398		0.327	
HCC108	Chronic Obstructive Pulmonary Disease	0.398		0.327	
HCC111	Aspiration and Specified Bacterial Pneumonias	0.761		0.644	
HCC112	Pneumococcal Pneumonia, Emphysema, Lung Abscess	0.233		0.188	
HCC119	Proliferative Diabetic Retinopathy and Vitreous Hemorrhage	0.278		0.527	
HCC130	Dialysis Status[3]	0.000		0.000	
HCC131	Renal Failure[3]	0.000		0.000	
HCC132	Nephritis	0.182		0.290	
HCC148	Decubitus Ulcer of Skin	1.167		0.474	
HCC149	Chronic Ulcer of Skin, Except Decubitus	0.463		0.239	
HCC150	Extensive Third-Degree Burns	0.818		0.000	
HCC154	Severe Head Injury	0.446	C1	0.000	
HCC155	Major Head Injury	0.182		0.000	
HCC157	Vertebral Fractures without Spinal Cord Injury	0.501		0.109	
HCC158	Hip Fracture/Dislocation	0.450		0.000	
HCC161	Traumatic Amputation	0.736		0.224	C1
HCC164	Major Complications of Medical Care and Trauma	0.299		0.219	
HCC174	Major Organ Transplant Status	0.362		0.362	
HCC176	Artificial Openings for Feeding or Elimination	0.758		0.843	
HCC177	Amputation Status, Lower Limb/Amputation Complications	0.653		0.224	C1

Disabled/Disease Interactions					
D_HCC5	Disabled_Opportunistic Infections	0.941		0.280	
D_HCC44	Disabled_Severe Hematological Disorders	0.551		0.419	
D_HCC51	Disabled_Drug/Alcohol Psychosis	0.801		0.425	
D_HCC52	Disabled_Drug/Alcohol Dependence	0.356		0.425	
D_HCC107	Disabled_Cystic Fibrosis	1.391		0.000	
Disease Interactions					
INT1	DM_CHF[4]	0.204		0.088	
INT2	DM_CVD	0.149		0.026	
INT3	CHF_COPD	0.216		0.194	
INT4	COPD_CVD_CAD	0.174		0.042	
INT5	RF_CHF[4]	0.248		0.000	
INT6	RF_CHF_DM[4]	0.664		0.203	
Graft Factors[6]					
Aged <65, with duration since transplant of 4-9 months		3.391		3.391	
Aged 65+, with duration since transplant of 4-9 months		3.391		3.391	
Aged <65, with duration since transplant of 10 months or more		1.152		1.152	
Aged 65+, with duration since transplant of 10 months or more		1.323		1.323	

[1]To determine payments for persons with functioning grafts, the computed risk score should be applied to the appropriate cell in the CMS-HCC county risk ratebook for the aged and disabled. For payment in any month, duration is measured from the month of transplant to the first day of that month. All coefficients except for the graft factors and HCC174 were constrained to the values estimates for the 2003 Calibration CMS-HCC Aged-Disabled Community Model.
[2]_____ means coefficients of HCCs are constrained to be equal, and C1 denotes a non-continguous constraint. For the community model C1=.446; for the institutional model C1=.224.

[3]Kidney failure and Dialysis status HCCs are not captured in the model for functioning graft beneficiaries. The cost of treating their transplanted kidney is captured instead in the post-graft factors. Should a post-graft patient have failure again they would return to dialysis status and be paid under the dialysis model.
[4]Diseases in interactions are:

DM is diabetes mellitus (HCCs 15-19)
CHF is congestive heart failure (HCC 80)
COPD is chronic obstructive pulmonary disease (HCC 108)
CVD is cerebrovascular disease (HCCs 95,96,100, and 101)
RF is renal failure (HCC 131)

Beneficiaries with the three-way interaction RF*CHF*DM are excluded from the two-way interactions DM*CHF and RF*CHF. Thus, the three-way interaction term RF*CHF*DM is not additive to the two-way interaction terms DM*CHF and RF*CHF. Rather, it is hierarchical to, and excludes these interaction terms. A beneficiary with all three conditions is not "credited" with the two-way interactions. All other interaction terms are additive.
[5]These HCCs are not present in the institutional model.
[6]The graft factors are additive, similar to any other factors in the CMS-HCC model. The factor is higher during the months immediately after transplant to accoun for a high level of monitoring and services.

Table 1-5. List Hierarchies for the CMS-HCC Model

DRAFT DISEASE HIERARCHIES		
Hierarchical Condition Category (HCC)	**If the Disease Group is Listed in This Column…**	**…Then Drop the Associated Disease Group(s) Listed in This Column**
	Disease Group Label	
5	Opportunistic Infections	112
7	Metastatic Cancer and Acute Leukemia	8,9,10
8	Lung, Upper Digestive Tract, and Other Severe Cancers	9, 10
9	Lymphatic, Head and Neck, Brain and Other Major Cancers	10
15	Diabetes with Renal Manifestations or Peripheral Circulatory Manifestation	16,17,18,19
16	Diabetes with Neurologic or Other Specified Manifestation	17,18,19
17	Diabetes with Acute Complications	18,19
18	Diabetes with Ophthalmologic or Unspecified Manifestations	19
25	End-Stage Liver Disease	26,27
26	Cirrhosis of Liver	27
51	Drug/Alcohol Psychosis	52
54	Schizophrenia	55
67	Quadriplegia/Other Extensive Paralysis	68,69,100,101,157
68	Paraplegia	69,100,101,157
69	Spinal Cord Disorders/Injuries	157
77	Respirator Dependence/ Tracheostomy Status	78,79
78	Respiratory Arrest	79
81	Acute Myocardial Infarction	82,83
82	Unstable Angina and Other Acute Ischemic Heart Disease	83
95	Cerebral Hemorrhage	96
100	Hemiplegia/Hemiparesis	101
104	Vascular Disease with Complications	105,149
107	Cystic Fibrosis	108
111	Aspiration and Specified Bacterial Pneumonias	112
130	Dialysis Status	131,132
131	Renal Failure	132
148	Decubitus Ulcer of Skin	149
154	Severe Head Injury	75,155
161	Traumatic Amputation	177

How Payments are Made with a Disease Hierarchy -- EXAMPLE: If a beneficiary triggers HCCs 148 (Decubitus Ulcer of the Skin) and 149 (Chronic Ulcer of Skin, Except Decubitus), then HCC 149 will be dropped. In other words, payment will always be associated with the HCC in column 1 if a HCC in column 3 also occurs during the same collection period. Therefore, the MA organization's payment will be based on HCC 148 rather than HCC 149.

April 7, 2008

NOTE TO: All Medicare Advantage Organizations, Prescription Drug Plan Sponsors, and Other Interested Parties

SUBJECT: Announcement of Calendar Year (CY) 2009 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies

In accordance with section 1853(b)(1) of the Social Security Act (the Act), we are notifying you of the annual Medicare Advantage (MA) capitation rate for each MA payment area for 2009, and the risk and other factors to be used in adjusting such rates. Attached is a spreadsheet containing the capitation rate tables for CY 2009. Also included is a spreadsheet which shows the statutory component of the regional benchmarks. The rates are posted on the Centers for Medicare & Medicaid Services (CMS) web site at http://www.cms.hhs.gov/MedicareAdvtgSpecRateStats/ under Ratebooks and Supporting Data.

Attachment I shows the final estimates of the increase in the National Per Capita MA Growth Percentage for 2009. As discussed in Attachment I, the final estimate of the increase in the National Per Capita MA Growth Percentage for combined aged and disabled beneficiaries is 4.24 percent. These growth rates will be used as the minimum update percentage in calculating the 2009 rates, except for the ESRD State rates, which are subject to a 2 percent minimum increase under Section 1853(a)(1)(H). The county fee-for-service (FFS) rates for 2009 were rebased. Under section 1853(c)(1) of the Act, MA capitation rates in 2009 will be based on the higher of the county FFS per capita amount or a minimum percent increase over the 2008 rate.

Attachment II provides a set of tables that summarizes many of the key Medicare assumptions used in the calculation of the National Per Capita MA Growth Percentage.

Section 1853(b)(4) of the Act requires CMS to release county-specific per capita FFS expenditure information on an annual basis, beginning with March 1, 2001. In accordance with this requirement, FFS data for CY 2006 is being posted on the above website at this time as well.

We received comments from 30 organizations in response to CMS' request for comments on the Advance Notice of Methodological Changes for CY 2009 MA Capitation Rates and Part D Payment Policies (Advance Notice), published on February 22, 2008. Six comments were from Associations, 23 comments were from plans, and one comment was from the Congress. Attachment III summarizes key policy changes from the approaches proposed in the Advance Notice , the key policies adopted as proposed in the Advance Notice, and then presents responses to comments on Part C and Part D issues in the Advance Notice. Attachment IV contains tables with the 2009 CMS-HCC risk adjustment factors, Part D benefit parameters, and other information. The CMS-HCC factors are also available in Excel files on the CMS website at http://www.cms.hhs.gov/MedicareAdvtgSpecRateStats/RSD/list.asp#TopOfPage.

Questions can be directed to:

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Attachments

Attachment I. Final Estimate of the Increase in the National Per Capita MA Growth Percentages for 2009

The first table below shows the National Per Capita MA Growth Percentages (NPCMAGP) used to determine the minimum update percentages for 2009. Adjustments of 0.22 percent, 2.07 percent, -11.69 percent and 0.48 percent for aged, disabled, ESRD, and combined aged and disabled, respectively, are included in the NPCMAGP to account for corrections to prior years' estimates as required by section 1853(c)(6)(C). The combined aged and disabled increase is used in the development of the ratebook.

The second table below shows the monthly actuarial value of the Medicare deductible and coinsurance for 2008 and 2009. In addition, for 2009, the actuarial value of deductibles and coinsurance is being shown for non-ESRD only, since the plan bids will not include ESRD benefits in 2009. These data were furnished by the Office of the Actuary.

Increase in the National Per Capita MA Growth Percentages for 2009

	Prior Increases	Current Increases			NPCMAGP for 2009 With Sec.1853(c)(6)(C) adjustment[1]
	2003 to 2008	2003 to 2008	2008 to 2009	2003 to 2009	
Aged	33.78%	34.07%	3.66%	38.97%	3.88%
Disabled	38.10%	40.96%	4.20%	46.87%	6.35%
ESRD[2]	28.99%	13.91%	1.34%	15.44%	- 10.51%[3]
Aged+Disabled	34.24%	34.89%	3.74%	39.94%	4.24%

[1]Current increases for 2003 to 2009 divided by the prior increases for 2003 to 2008.

[2]Starting in 2008, increases for ESRD reflect an estimate of the increase for dialysis-only beneficiaries.

[3]The NPCMAGP for ESRD for 2009 will be the minimum 2 percent increase.

Monthly Actuarial Value of Medicare Deductible and Coinsurance for 2008 and 2009

	2008	2009	Change	2009 non-ESRD
Part A Benefits	36.71	37.94	3.35%	36.35
Part B Benefits[4]	105.69	97.97	- 7.30%	92.30
Total Medicare	142.40	135.91	- 4.56%	128.65

[4]Includes the amounts for outpatient psychiatric charges.

Medical Savings Account (MSA) Plans. The maximum deductible for current law MSA plans for 2009 is $10,500. For MSA demonstration plans, the 2009 minimum deductible amount is $2,200, the maximum out-of-pocket amount is $10,500, and the minimum difference between the deductible and deposit is $1,000.

Attachment II. Key Assumptions and Financial Information

The USPCCs are the basis for the National Per Capita MA Growth Percentages. Attached is a table that compares the published United States Per Capita Costs (USPCC) with current estimates for 2000 to 2009. In addition, this table shows the current projections of the USPCCs through 2011. We are also providing an attached set of tables that summarizes many of the key Medicare assumptions used in the calculation of the USPCCs. Most of the tables include information for the years 2000 through 2011.

All of the information provided in this enclosure applies to the Medicare Part A and Part B programs. Caution should be employed in the use of this information. It is based upon nationwide averages, and local conditions can differ substantially from conditions nationwide.

None of the data presented here pertain to the Medicare prescription drug benefit.

Comparison of Current Estimates of the USPCC with Published Estimates

PART A:

Calendar Year	Aged Current Estimate	Aged Published Estimate	Aged Ratio	Disabled Current Estimate	Disabled Published Estimate	Disabled Ratio	Aged and Disabled Current Estimate	Aged and Disabled Published Estimate	Aged and Disabled Ratio
2000	$263.29	$286.18	1.087	$218.80	$230.48	1.053	$257.32	$278.61	1.083
2001[1]	$283.70	$288.62	1.017	$234.62	$235.50	1.004	$276.94	$281.25	1.016
2001[2]	$283.70	$298.43	1.052	$234.62	$242.00	1.031	$276.94	$290.59	1.049
2002	$297.13	$294.46	0.991	$248.90	$242.06	0.973	$290.30	$287.10	0.989
2003	$304.89	$290.50	0.953	$254.01	$234.89	0.925	$297.41	$282.50	0.950
2004	$321.69	$326.78	1.016	$268.45	$271.69	1.012	$313.59	$318.43	1.015
2005	$344.77	$348.28	1.010	$288.32	$291.45	1.011	$335.90	$339.49	1.011
2006	$354.98	$351.38	0.990	$302.34	$295.15	0.976	$346.55	$342.67	0.989
2007	$369.31	$370.34	1.003	$326.21	$318.17	0.975	$362.38	$362.06	0.999
2008	$395.22	$385.61	0.976	$356.44	$344.31	0.966	$389.02	$379.02	0.974
2009	$414.22	$414.22	1.000	$378.40	$378.40	1.000	$408.50	$408.50	1.000
2010	$430.77			$395.77			$425.13		
2011	$445.76			$412.87			$440.46		

PART B:

Calendar Year	Aged Current Estimate	Aged Published Estimate	Aged Ratio	Disabled Current Estimate	Disabled Published Estimate	Disabled Ratio	Aged and Disabled Current Estimate	Aged and Disabled Published Estimate	Aged and Disabled Ratio
2000	$199.17	$218.78	1.098	$183.62	$195.91	1.067	$197.24	$216.03	1.095
2001[1]	$219.73	$217.57	0.990	$206.93	$191.99	0.928	$218.10	$214.32	0.983
2001[2]	$219.73	$223.83	1.019	$206.93	$198.69	0.960	$218.10	$220.63	1.012
2002	$233.03	$244.17	1.048	$226.37	$218.23	0.964	$232.16	$240.76	1.037
2003	$250.81	$232.24	0.926	$246.76	$211.58	0.857	$250.26	$229.47	0.917
2004	$276.49	$263.39	0.953	$274.60	$252.74	0.920	$276.22	$261.89	0.948
2005	$296.08	$281.90	0.952	$292.35	$272.79	0.933	$295.54	$280.58	0.949
2006	$318.61	$311.28	0.977	$312.22	$316.82	1.015	$317.66	$312.09	0.982
2007	$332.84	$334.02	1.004	$329.40	$343.76	1.044	$332.32	$335.47	1.009
2008	$349.79	$354.44	1.013	$349.43	$343.26	0.982	$349.74	$352.75	1.009
2009	$358.03	$358.03	1.000	$357.10	$357.10	1.000	$357.89	$357.89	1.000
2010	$370.01			$371.74			$370.27		
2011	$381.97			$386.31			$382.63		

PART A & PART B:

Calendar Year	Aged Current Estimate	Aged Published Estimate	Aged Ratio	Disabled Current Estimate	Disabled Published Estimate	Disabled Ratio	Aged and Disabled Current Estimate	Aged and Disabled Published Estimate	Aged and Disabled Ratio
2000	$462.46	$504.96	1.092	$402.42	$426.39	1.060	$454.56	$494.64	1.088
2001[1]	$503.43	$506.19	1.005	$441.55	$427.49	0.968	$495.04	$495.57	1.001
2001[2]	$503.43	$522.26	1.037	$441.55	$440.69	0.998	$495.04	$511.22	1.033
2002	$530.16	$538.63	1.016	$475.27	$460.29	0.968	$522.46	$527.86	1.010
2003	$555.70	$522.74	0.941	$500.77	$446.47	0.892	$547.67	$511.97	0.935
2004	$598.18	$590.17	0.987	$543.05	$524.43	0.966	$589.81	$580.32	0.984
2005	$640.85	$630.18	0.983	$580.67	$564.24	0.972	$631.44	$620.07	0.982
2006	$673.59	$662.66	0.984	$614.56	$611.97	0.996	$664.21	$654.76	0.986
2007	$702.15	$704.36	1.003	$655.61	$661.93	1.010	$694.70	$697.53	1.004
2008	$745.01	$740.05	0.993	$705.87	$687.57	0.974	$738.76	$731.77	0.991
2009	$772.25	$772.25	1.000	$735.50	$735.50	1.000	$766.39	$766.39	1.000
2010	$800.78			$767.51			$795.40		
2011	$827.73			$799.18			$823.09		

[1]Applies to M+C ratebook for January to February, 2001
[2]Applies to M+C ratebook for March to December, 2001

Comparison of Current Estimates of the USPCC with Published Estimates- continued

PART A:

Calendar Year	ESRD Current Estimate	ESRD Published Estimate	Ratio
2000	$1,311.44	$1,443.13	1.100
2001[1]	$1,424.11	$1,541.76	1.083
2001[2]	$1,424.11	$1,597.34	1.122
2002	$1,459.75	$1,435.62	0.983
2003	$1,570.85	$1,596.58	1.016
2004	$1,682.53	$1,685.25	1.002
2005	$1,589.31	$1,759.90	1.107
2006	$1,635.76	$1,717.97	1.050
2007	$1,687.04	$1,874.54	1.111
2008	$1,812.40	$1,855.03	1.024
2009	$1,911.06	$1,911.06	1.000
2010	$1,996.18		
2011	$2,077.10		

PART B:

Calendar Year	ESRD Current Estimate	ESRD Published Estimate	Ratio
2000	$1,676.80	$2,436.13	1.453
2001[1]	$1,880.19	$1,875.57	0.998
2001[2]	$1,880.19	$1,921.53	1.022
2002	$1,995.37	$2,014.79	1.010
2003	$2,021.40	$1,847.53	0.914
2004	$2,161.10	$2,552.18	1.181
2005	$2,304.98	$2,739.99	1.189
2006	$2,257.38	$2,454.98	1.088
2007	$2,308.31	$2,470.81	1.070
2008	$2,279.51	$2,773.04	1.217
2009	$2,235.70	$2,235.70	1.000
2010	$2,250.59		
2011	$2,269.06		

PART A & PART B:

Calendar Year	ESRD Current Estimate	ESRD Published Estimate	Ratio
2000	$2,988.24	$3,879.26	1.298
2001[1]	$3,304.30	$3,417.33	1.034
2001[2]	$3,304.30	$3,518.87	1.065
2002	$3,455.12	$3,450.41	0.999
2003	$3,592.25	$3,444.11	0.959
2004	$3,843.63	$4,237.43	1.102
2005	$3,894.29	$4,499.89	1.156
2006	$3,893.14	$4,172.95	1.072
2007	$3,995.35	$4,345.35	1.088
2008	$4,091.91	$4,628.07	1.131
2009	$4,146.77	$4,146.77	1.000
2010	$4,246.77		
2011	$4,346.16		

[1]Applies to M+C ratebook for January to February, 2001
[2]Applies to M+C ratebook for March to December, 2001

Summary of Key Projections Under Present Law[1]

Part A

Year	Calendar Year CPI Percent Increase	Fiscal Year PPS Update Factor	FY Part A Total Reimbursement (Incurred)
2000	3.5	1.1	-0.8
2001	2.7	3.4	7.9
2002	1.4	2.8	7.7
2003	2.2	3.0	3.9
2004	2.6	3.4	8.5
2005	3.5	3.3	8.9
2006	3.2	3.7	5.8
2007	2.8	3.4	6.5
2008	2.8	3.3	8.3
2009	2.5	2.8	7.9
2010	2.8	1.4	6.4
2011	2.8	2.8	6.0

Part B[2]

Calendar Year	Physician Fee Schedule		Part B Hospital	Total
	Fees	Residual[3]		
2000	5.5	3.6	-0.8	10.4
2001	4.8	4.1	12.5	9.7
2002	–4.8	6.1	-1.4	6.1
2003	1.7	4.5	5.4	6.9
2004	1.5	5.9	9.9	9.7
2005	1.5	3.3	8.3	6.8
2006	0.2	4.7	4.5	5.9
2007	0.0	4.0	2.2	3.3
2008	–4.6	5.2	4.7	3.9
2009	–10.4	6.6	6.5	1.7
2010	–5.5	3.2	7.0	2.9
2011	–5.3	3.2	6.6	2.9

[1]Percent change over prior year.
[2]Percent change in charges per Aged Part B enrollee.
[3]Residual factors are factors other than price, including volume of services, intensity of services, and age/sex changes.

Medicare Enrollment Projections Under Present Law (In Millions)

Non-ESRD

Calendar Year	Part A		Part B	
	Aged	Disabled	Aged	Disabled
2000	33.700	5.222	32.421	4.590
2001	33.904	5.416	32.582	4.747
2002	34.080	5.619	32.713	4.915
2003	34.427	5.929	33.027	5.187
2004	34.837	6.249	33.282	5.458
2005	35.244	6.574	33.584	5.747
2006	35.781	6.820	33.960	5.975
2007	36.361	6.965	34.363	6.128
2008	37.032	7.042	34.927	6.197
2009	37.793	7.178	35.557	6.318
2010	38.503	7.398	36.131	6.496
2011	39.408	7.570	36.833	6.646

ESRD Part A

Calendar Year	Part A			
	Aged	Disabled	299I[1]	Total
2000	0.136	0.109	0.088	0.333
2001	0.144	0.115	0.091	0.349
2002	0.151	0.120	0.094	0.366
2003	0.160	0.126	0.096	0.383
2004	0.167	0.132	0.100	0.399
2005	0.174	0.137	0.104	0.415
2006	0.182	0.141	0.107	0.430
2007	0.190	0.143	0.110	0.443
2008	0.199	0.144	0.113	0.455
2009	0.206	0.146	0.116	0.468
2010	0.213	0.149	0.118	0.480
2011	0.219	0.152	0.120	0.491

ESRD Part B

Calendar Year	Part B			
	Aged	Disabled	299I	Total
2000	0.138	0.104	0.082	0.324
2001	0.145	0.110	0.084	0.338
2002	0.153	0.114	0.087	0.354
2003	0.161	0.120	0.088	0.370
2004	0.168	0.125	0.089	0.382
2005	0.175	0.130	0.092	0.396
2006	0.183	0.133	0.095	0.411
2007	0.190	0.135	0.097	0.422
2008	0.198	0.135	0.100	0.433
2009	0.206	0.137	0.102	0.444
2010	0.212	0.140	0.103	0.455
2011	0.218	0.143	0.105	0.466

[1] Individuals who qualify for Medicare based on ESRD only.

Part A Projections Under Present Law [1]

Calendar Year	Inpatient Hospital		SNF		Home Health		Managed Care		Hospice: Total Reimbursement (in Millions)	
	Aged	Disabled	Aged	Disabled	Aged	Disabled	Aged	Disabled	Aged	Disabled
2000	2,218.26	2,385.85	310.23	104.90	99.05	70.38	593.36	269.74	2,772	146
2001	2,406.91	2,595.76	376.02	129.04	121.53	64.75	571.77	255.43	3,575	188
2002	2,578.76	2,780.67	411.58	145.08	130.36	69.82	523.26	227.72	4,391	231
2003	2,670.88	2,863.47	420.10	149.83	132.99	72.01	522.57	218.64	5,428	286
2004	2,776.44	3,007.09	469.84	173.01	143.45	78.03	569.12	236.84	6,506	342
2005	2,886.98	3,141.22	513.73	193.18	151.58	82.66	675.62	300.03	7,612	401
2006	2,837.70	3,134.52	542.50	206.19	151.98	83.23	823.75	474.01	8,748	460
2007	2,829.10	3,213.58	565.07	221.10	154.92	87.39	984.40	666.45	9,453	498
2008	2,939.56	3,435.57	583.27	235.54	154.64	89.99	1,175.32	805.09	10,113	532
2009	3,029.56	3,601.65	601.50	248.51	155.54	92.45	1,300.70	897.73	10,854	571
2010	3,109.61	3,728.42	619.02	259.56	156.74	94.37	1,405.86	975.24	11,658	614
2011	3,184.88	3,861.11	634.19	271.16	156.90	96.05	1,499.60	1,043.05	12,510	658

[1]Average reimbursement per enrollee on an incurred basis, except where noted.

Part B Projections Under Present Law[1]

Calendar Year	Physician Fee Schedule		Part B Hospital		Durable Medical Equipment	
	Aged	Disabled Non-ESRD	Aged	Disabled Non-ESRD	Aged	Disabled Non-ESRD
2000	1,003.19	951.69	238.98	290.69	118.54	184.47
2001	1,131.47	1,064.17	326.94	400.13	137.14	215.29
2002	1,177.46	1,109.73	333.67	423.49	158.40	261.50
2003	1,263.13	1,190.84	378.19	470.64	182.20	302.52
2004	1,393.46	1,311.26	429.01	545.24	180.98	301.14
2005	1,452.56	1,355.63	472.86	584.41	181.59	304.17
2006	1,457.68	1,335.63	489.78	599.35	185.65	314.41
2007	1,430.16	1,327.52	486.21	613.63	181.03	315.26
2008	1,371.02	1,295.41	496.09	639.55	185.69	333.65
2009	1,279.68	1,222.91	523.40	682.54	179.85	328.19
2010	1,230.21	1,184.36	556.97	731.97	185.64	342.21
2011	1,184.41	1,148.13	591.38	782.77	191.75	357.18

Calendar Year	Carrier Lab		Other Carrier		Intermediary Lab	
	Aged	Disabled Non-ESRD	Aged	Disabled Non-ESRD	Aged	Disabled Non-ESRD
2000	58.89	61.22	201.38	195.17	46.25	59.30
2001	64.86	66.15	239.97	231.14	47.73	64.78
2002	70.96	74.14	286.95	281.69	55.38	74.69
2003	76.42	79.72	337.18	349.92	60.27	80.00
2004	82.37	86.53	362.42	395.20	65.27	88.18
2005	86.79	91.26	371.40	422.84	67.49	91.92
2006	89.80	95.03	376.42	387.94	67.83	92.96
2007	92.25	105.97	381.02	397.92	63.98	90.82
2008	94.33	113.32	413.89	446.22	62.72	90.94
2009	100.76	122.32	452.17	489.48	64.52	94.60
2010	106.57	130.27	492.00	532.51	66.92	98.85
2011	112.57	138.55	535.41	580.30	69.81	103.84

Calendar Year	Other Intermediary		Home Health		Managed Care	
	Aged	Disabled Non-ESRD	Aged	Disabled Non-ESRD	Aged	Disabled Non-ESRD
2000	117.91	108.13	129.45	99.19	531.83	221.42
2001	138.59	114.61	125.20	104.59	498.03	189.91
2002	173.74	143.90	131.98	110.78	494.67	205.08
2003	179.80	138.02	139.32	117.10	481.20	199.56
2004	205.83	165.80	159.56	133.66	537.12	233.86
2005	227.89	178.59	183.06	154.29	624.54	291.73
2006	225.97	187.06	206.98	176.21	836.07	531.56
2007	222.49	187.29	241.42	206.61	1,017.79	683.90
2008	226.83	198.19	257.46	225.22	1,216.35	825.41
2009	225.11	199.81	268.08	238.03	1,333.73	884.49
2010	233.98	210.00	275.19	247.02	1,430.58	956.74
2011	243.47	220.94	276.61	251.43	1,523.40	1,024.61

[1]Average reimbursement per enrollee on an incurred basis.

Claims Processing Costs as a Fraction of Benefits

Calendar Year	Part A	Part B
2000	0.002195	0.014790
2001	0.001862	0.013223
2002	0.001496	0.011708
2003	0.001849	0.011194
2004	0.001676	0.010542
2005	0.001515	0.009540
2006	0.001245	0.007126
2007	0.000968	0.006067
2008	0.000968	0.006067
2009	0.000968	0.006067
2010	0.000968	0.006067
2011	0.000968	0.006067

Approximate Calculation of the USPCC and the National MA Growth Percentage for Aged Beneficiaries

The following procedure will approximate the actual calculation of the USPCCs from the underlying assumptions for the contract year for both Part A and Part B.

Part A:
The Part A USPCC for aged beneficiaries can be approximated by using the assumptions in the tables titled "Part A Projections Under Present Law" and "Claims Processing Costs as a Fraction of Benefits." Information in the "Part A Projections" table is presented on a calendar year per capita basis. First, add the per capita amounts for the aged over all types of providers (excluding hospice). Next, multiply this amount by 1 plus the loading factor for administrative expenses from the "Claims Processing Costs" table. Then, divide by 12 to put this amount on a monthly basis. The last step is to multiply by .97612 to get the USPCC for the aged non-ESRD. This final factor of .97612 is the relationship between the total and non-ESRD per capita reimbursements in 2009. This factor does not necessarily hold in any other year.

Part B:
The Part B USPCC can be approximated by using the assumptions in the tables titled "Part B Projections Under Present Law" and "Claims Processing Costs as a Fraction of Benefits." Information in the "Part B Projections" table is presented on a calendar year per capita basis. First, add the per capita amounts for the aged over all types of providers. Next, multiply by 1 plus the loading factor for administrative expenses and divide by 12 to put this amount on a monthly basis. Then multiply by .96457 to get the USPCC for the aged non-ESRD.

The National Per Capita MA Growth Percentage:

The National Per Capita MA Growth Percentage for 2009 (before adjustment for prior years' over/under estimates) is calculated by adding the USPCCs for Part A and Part B for 2009 and then dividing by the sum of the current estimates of the USPCCs for Part A and Part B for 2008.

Attachment III. Responses to Public Comments

Key Policy Changes from the Advance Notice

Attachment I provides the final estimates of the National MA Growth Percentages (growth trends) and information on deductibles for MSA standard and demonstration plans, and on the maximum out-of-pocket amount for MSA demonstrations plans.

Attachment III, Section E announces the policy decision on the MA coding intensity adjustment for 2009.

Attachment III, Section F provides information on upcoming audit activities.

Attachment III, Section G announces that the CMS is unable to determine for CY 2009 whether an adjustment other than zero to the FFS rates is appropriate to reflect the cost of services obtained by MA enrollees at VA and DoD facilities.

Attachment III, Section I announces that CMS is still preparing the final rule concerning the reporting of drug costs for Part D sponsors that contract with PBMs, and discusses Part D sponsors' options for pricing.

Attachment III, Section J announces that the proposal in the Advance Notice on calculation of the low-income benchmark premium amount is replaced by the approach announced in the final rule CMS-4133-F, titled "Modification to the Weighting Methodology Used to Calculate the Low-income Benchmark Amount," published on April 3, 2008.

As in past years, policies proposed in the Advance Notice that are not modified or retracted in the Rate Announcement become effective in the upcoming payment year, as set forth in the Advance Notice. Clarifications in the Announcement supersede materials in the Advance Notice.

Key Policies Adopted as Proposed in the Advance Notice

Recalibration of the CMS-HCC model. In 2009, CMS will implement an updated version of the aged-disabled CMS-HCC risk adjustment model, including community, institutional, and new enrollee segments of the model. See Section B below for comments and responses regarding the recalibrated model. See Attachment IV, Tables 1, 2, and 3 for the final 2009 model coefficients.

Recalibrated frailty factors. CMS will implement recalibrated frailty factors for CY 2009. See Attachment IV, Table 4 for the final factors.

Frailty Adjustment Transition for PACE organizations. Frailty adjustment factors will be applied to payment to PACE organizations using the transition schedule published in the 2008 Announcement (published April 2, 2007). PACE frailty scores for payment year 2009 will be calculated at a blend of 70% of the frailty factors in use prior to 2008 and 30% of the recalibrated frailty factors implemented in 2009.

Frailty Adjustment Transition for Certain Demonstrations. Frailty adjustment factors will be applied to payment to the following MA plan types using the phase-out schedule published in the 2008 Announcement (published April 2, 2007): Social Health Maintenance Organizations (S/HMOs), Minnesota Senior Health Options (MSHO)/ Minnesota Disability Health Options (MnDHO), Wisconsin Partnership Program (WPP) and Massachusetts Senior Care Options (SCO) plans. The phase out schedule for 2009 is 50% of the pre-2008 frailty factors.

Normalization Factors. Normalization factors for 2009 are as follows:

- The final 2009 normalization factor for the aged-disabled model is 1.030.
- The final 2009 normalization factor for the ESRD dialysis model is 1.019.
- The final 2009 normalization factor to be applied to the risk scores of enrollees in functioning graft status is 1.058.
- The final 2009 normalization factor for the RxHCC model is 1.085.

Budget Neutrality. For 2009, 25 percent of the BN factor will be applied to the risk rates.

Medicare as Secondary Payer (MSP) Adjustment Factor for Aged & Disabled Enrollees. CMS has recalculated the MSP adjuster for working aged and working disabled beneficiaries. The adjuster will be 0.174 in the 2009 payment year.

ESRD Bidding and Payment. For 2009, CMS will continue the policy of excluding costs for ESRD enrollees in the plan A/B bid.

For payment year 2009, CMS' payments for ESRD dialysis and transplant enrollees will be based on State rates calculated using a blend of 50% of the old State ratebook (in use through 2007) and 50% of the revised State ratebook (implemented in 2008).

For 2009 CMS will continue to use the functioning graft coefficients published in the April 7, 2007 Advance Notice for 2008, when the ESRD dialysis model was last recalibrated. (See above for the 2009 normalization factor to be used with the functioning graft risk scores.)

Regional Plan Stabilization Fund. Section 101 of the Medicare, Medicaid, and SCHIP Extension Act of 2007 – enacted December 18, 2007 – delayed Stabilization Fund payments until January 1, 2013.

Continuation of Clinical Trial Policy. In 2009, we will continue the policy of paying on a fee-for-service basis for clinical trial items and services provided to MA plan members that are covered under the relevant National Coverage Determinations on clinical trials.

Reporting of Medicaid Status for Part C Payment. In CY 2009, CMS will complete the transition to using the MMA Medicare/Medicaid Dual Eligible monthly submission file (MMA State files) as the main source of Medicaid status for Part C plan payments. The data sources for the assignment of Medicaid status can be found in Attachment IV, Table 5.

Standard Set of ICD-9 Diagnosis Codes for Risk Adjustment. Starting with payment year 2009, RAPS will only accept valid ICD-9-CM codes for two fiscal years -- the fiscal year that begins prior to the payment year and the fiscal year that begins during the payment year -- for the CMS-HCC, ESRD, and RxHCC risk adjustment models. For example, for diagnoses codes to be used

in 2009 final payment, i.e., for diagnoses from service dates between January 1, 2008 and December 31, 2008, RAPS will only accept codes that are valid for Fiscal Year 2008 and Fiscal Year 2009. See Attachment IV, Table 6 for the acceptable codes.

Medicare Part D Benefit Parameters: Annual Adjustments for Defined Standard Benefit in 2009. In accordance with section 1860D-2(b) of the Social Security Act (the Act), CMS must update the statutory parameters for the defined standard Part D prescription drug benefit each year. See Attachment IV, Table 7 for the 2009 updated Part D benefit parameters for the defined standard benefit, low-income subsidy, and retiree drug subsidy.

Calculation of the Part D National Average Monthly Bid Amount. CMS will complete the transition to the weighted average method based on actual plan enrollments in 2009. Thus for contract year 2009, 100% of the national average monthly bid amount will be based on the enrollment-weighted average.

Coordination of Benefits (COB) User Fees. Upon review of the anticipated costs of COB activities in 2009, the Part D COB user fee will increase to $2.52 per enrollee per year for contract year 2009. This COB user fee will be collected at a rate of $0.28 per enrollee per month from January to September (for an annual rate of $0.21 per enrollee per month) for a total user fee of $2.52 per enrollee per year. Part D sponsors should account for this COB user fee when developing their 2009 bids.

Budget Neutrality Offsets for Reinsurance Payment Demonstration Plans in 2009. The budget neutrality offsets applied to the capitated reinsurance payments for flexible capitated, fixed capitated, and Medicare Advantage rebate option plans will remain at $10.00 per member per year for contract year 2009.

Payment Reconciliation. The 2009 risk percentages and payment adjustments for Part D risk sharing are unchanged from contract year 2008. The risk percentages for the first and second thresholds remain at 5% and 10% of the target amount respectively for 2009. The payment adjustments for the first and second corridors are 50% and 80% respectively.

As in past years, policies proposed in the Advance Notice that are not modified or retracted in the Rate Announcement become effective in the upcoming payment year, as set forth in the Advance Notice. Clarifications in the Announcement supersede materials in the Advance Notice.

Section A. Estimate of the National Per Capita MA Growth Percentage for Calendar Year 2009

As mentioned in Attachment I, the final estimate of the 2009 MA growth trend for combined aged and disabled beneficiaries is 4.24 percent, which is a little lower than the preliminary estimate of 4.8 percent announced February 22, 2008 in the Advance Notice. The President's Budget baseline was used for the preliminary estimate, and the 2008 Trustees Report baseline was used for the final estimate. The primary reason for the lower final estimate is that cash expenditure data for the remainder of 2007 was available which indicated that the actual expenditures for 2007 were lower than previously estimated.

The manner in which the Tax Relief and Health Care Act (TRHCA) of 2006 and the Medicare, Medicaid, and SCHIP Extension Act (MMSEA) of 2007 structured the physician fee schedule increase affects both the adjustment to the 2008 growth rate and the 2009 trend as compared to the 2009 trend reported in the 2007 Trustees Report. About 1 percentage point of the 1.9 percent increase in the 2008 trend is due to legislative changes in the physician fee schedule update, because the previously expected -10 percent adjustment for 2008 was eliminated for half of the year and replaced with a 0.5 percent update. For the second half of the 2008, the update will revert to the current law update of -10 percent, as required by the MMSEA of 2007. Hence, the average for the year is approximately a -5 percent update. The -5 percent update compared to the previously expected -10 percent update increases the overall USPCC growth rate for 2008 by about 1 percent.

However, this revision to the prior 2008 estimate of about a 1 percent increase is offset by a reduction in the 2009 trend change. That is because, under the MMSEA, the 2008 increase has no effect on the calculation of the 2009 physician fee schedule update. As a result, the current law baseline for 2009 reflects a -10 percent update for physician fees. The net impact on the overall 2009 USPCC of this -10 percent update compared to the -5 percent for 2009 as reported last year is about a 1 percent decrease in the trend.

Comment: One commenter believes that the proposed 2009 trend change in the Advance Notice of 3.4% is too low and does not reflect the underlying increases in Medicare health care costs. This commenter feels that CMS should increase the 2009 trend change in the final notice to at least 4.5 percent to be aligned with other CMS estimates of Medicare growth. In addition, this commenter was concerned with the downward adjustments in the growth percentage for 2005 and 2007 and recommended that CMS increase these adjustments to previous years' trend changes and provide a detailed explanation for these proposed changes. Finally, the same commenter recommended that CMS recalculate the estimate of 100% FFS costs for previous years to account for increased Medicare physician payments and trend forward to the 2009 rates.

Response. By law, CMS must release the national MA growth percentage for the upcoming year by the first Monday in April. In years when legislative changes to the physician fee schedule updates are passed after April, such changes are not incorporated into the MA growth trend until the following year, when they are reflected as adjustments to the prior years' estimates. The Tax Relief & Health Care Act (THRCA) of 2006 and the Medicare, Medicaid, and SCHIP Extension Act (MMSEA) of 2007 explicitly limited the increased physician fee schedule updates—for 2007 and for the first half of 2008, respectively, to specific time periods. Moreover, the TRHCA required that the physician fee schedule update for 2008 must be calculated as if the 2007 increase did not occur. Similarly, the MMSEA requires that the physician fee schedule update for the last six months of 2008 and 2009 must be calculated as if the increase for the first six months of 2008 did not occur. As a result, in 2007 and 2008, OACT had to estimate underlying trends for CYs 2008 and 2009, respectively, based on current law updates of approximately -10%.

Regarding the commenter's question about prior years' estimates, the additional adjustments to the 2004 to 2006 growth rates are fairly insignificant and for the three years combined are slightly positive. Since the Medicare growth rates are tabulated on an incurred basis, it can take several years before all bills for a given year are tabulated through the claims history file. This is

why we can still see small changes for years back to 2004. The latest estimates for 2007 were based on incurred data reported through June of 2007. Hence, the claims history for 2007 is relatively incomplete. CMS has cash data through December 2007 from the U.S. Treasury, which indicates that outlays for 2007 were lower than expected. Therefore, the expected increase for 2007 was lowered. As more incurred data is received for 2007, adjustments will be made to account for the actual 2007 trend rates as allowed by law in future payment updates.

Regarding the commenter's recommendation that CMS recalculate the estimate of 100% FFS costs for previous years to account for increased Medicare physician payments and trend forward to the 2009 rates, this is not necessary. The law already allows for adjustments to the growth percentage for prior years' over/underestimates. Therefore, increased payments due to the prior legislative physician updates are already accounted for. In addition, the historical data which is used for calculating the geographic indices for the 100% FFS costs also reflect all prior legislative changes.

Section B. Recalibration of the CMS-HCC Model

Comment. One commenter stated that recalibrating on a biannual basis adds significant uncertainty for MA organizations because of the complexity of estimating the impact of recalibration as they engage in the bid development process and consider strategies for continuing to provide comprehensive and stable benefit packages to enrollees. The commenter recommended that CMS recalibrate the model once every three years, instead of biannually, in order to provide MA organizations with more predictability, while also ensuring the risk adjustment model continues to be based upon regularly updated data. Another commenter was concerned about significant year-to-year variations in MA payments accompanying the recalibration of the CMS-HCC risk adjustment model, and requested that CMS explore opportunities to reduce such variations. In particular, this commenter was concerned that plans in certain geographic areas not be disadvantaged over other plans in other geographic areas.

Response. CMS' policy goal is to recalibrate every two years to strike a balance between updating the model to reflect recent shifts in average relative expenditures among disease groups and reducing the burden of annual model changes. Recalibrating every three instead of every two years could generate more significant shifts in the relative cost factors for each HCC grouping, which could increase the relative level of changes in payments and the degree of uncertainty for the industry. Moreover, CMS seeks to align recalibration of the CMS-HCC model with rebasing of the FFS rates.

In terms of the commenter's request that CMS consider ways to reduce differential geographic impacts, CMS recalibrates the CMS-HCC model using actual FFS diagnoses and claims expenditures. We are not clear what options we could explore to reduce actual geographic variation.

Comment. Two commenters requested that CMS post to the Health Plan Management System (HPMS) as soon as possible the recalibrated risk scores for plans. The commenters noted that this information is critical in order to develop accurate bids. One commenter also noted that it is

difficult to comment on a new model without knowledge of how that model could impact their plan.

Response. Plan-specific recalibrated risk scores will be available through HPMS the week of April 7, 2008, in conjunction with the final bid instructions. In addition, the 2009 CMS-HCC model software reflecting the model recalibrated risk factors was posted March 7, 2008 on the CMS website at http://www.cms.hhs.gov/MedicareAdvtgSpecRateStats/06_Risk_adjustment.asp#TopOfPage.

Comment. One commenter requested that CMS publish frequency tables that show the estimated number of beneficiaries who fall into each HCC category under the existing and recalibrated models (e.g., the percent of members with HCC1 in 2004 and also in 2005) in the 2009 Rate Announcement, and in future Advance Notices. The commenter indicated that this information will assist plans in evaluating the impact of the recalibration as they develop their bids.

Response. This information is available through analysis of the 5 percent Standard Analytic File (SAF). CMS provides the CMS-HCC model software, as mentioned above, to facilitate the analysis described by the commenter.

Comment. One commenter expressed concern that the recalibrated risk factors could result in plan risk score reductions that would drop risk adjusted payments below the level of budget neutrality. The commenter requested that CMS publish the math and supporting documentation for the recalibration of the CMS-HCC coefficients.

Response. In terms of the relationship of recalibrated model factors to the budget neutrality factor, CMS determined the budget neutrality factor for 2009 using the recalibrated risk scores for each plan. Specifically, the BN factor is calculated as the estimated difference between payments to MA organizations at 100 percent of the demographic rates and payments at 100 percent of the risk rates. The size of the total BN factor is determined by the difference in aggregate payments made to MA organizations under the recalibrated risk model and aggregate payments made under the demographic model. Therefore, the effect of the recalibrated model is taken into account when the BN factor is calculated. As we noted in the Advance Notice, for 2009, 25 percent of the BN factor is applied to the risk rates that have been released with this Announcement.

Comment. One commenter expressed concern that their preliminary estimates of the impact of the recalibrated CMS-HCC model leads to a reduction in risk scores.

Response. . At the aggregate level, model recalibration has a neutral effect on the MA risk scores. When we recalibrate, the relative payment weights (risk factors) in the model can change, potentially affecting plan-specific average risk scores. The plan-specific impact will depend on the disease profile of the beneficiaries enrolled in the plan.

Section C. Normalization Factors

Comment. One commenter expressed appreciation that CMS released preliminary estimates of the normalization factors. The commenter also expressed concern that the CMS-HCC factor

represents a 3 percent reduction to risk scores, which will offset any increase in the MA capitation rates. The commenter recommended that CMS reduce the normalization factor and continue to do so as the BN factor is phased-out because continuing high negative adjustments will negatively impact MA payments as budget neutral risk-adjustment is phased out.

Response. CMS is required by the Deficit Reduction Act of 2005 to phase-out the implementation of budget neutral risk-adjusted payments (i.e., budget neutral to payments based on 100 percent of the demographic rates). Application of the normalization factors addresses an unrelated issue, which is that CMS must correct for population and coding changes between the data years used in calculating the model relative factors (the "denominator year") and the payment year. CMS cannot phase-out application of normalization factors because there will always be a lag between denominator and payment years.

Comment. One commenter requested additional information regarding how the 2009 normalization factor for the RxHCC model was determined because the factor of 1.085 appears to be a significant recalibration of Rx risk scores. The commenter requested additional explanation of how the annual trend is calculated and how it is applied for the two years between the calculation of actual average Part D risk score and the payment year (2007-2009). In addition, the commenter asked what prescription drug data was used before Part D began in 2006.

Response. The Part D normalization factor was 1.065 for 2008, and will be 1.085 for 2009. To calculate the 2009 Part D normalization factor, which will adjust for coding trends from the calibration year (2004) to the payment year (2009), we first obtained the actual trend in Part D risk scores by using the actual 2007 average Part D risk score for all potential Part D enrollees. We then projected the trend from 2007 to 2009 using an annual trend calculated on five years of risk score data (2003-2007). We calculated this trend the same way we calculated the trends for the CMS-HCC and the ESRD dialysis factors: we first calculate average predicted costs using the most recent model (in the case of the Rx-HCC model, we have only one model) for the most recent five years for which we have complete diagnosis data. We then use these data points to estimate the annual average trend in predicted costs. We applied this annual trend for the years between 2007 to 2009 and added it to the actual trend identified by the 2007 average Part D risk score. This downward adjustment, which helps ensure that the average risk score across all Part D plans equals 1.0, will not affect total plan revenue.

For information on what prescription drug data was used for initial calibration of the Part D Rx-HCC model, see the 2006 Advance Notice, Attachment III (pages 43-48), released on February 18, 2005 on the CMS website at http://www.cms.hhs.gov/MedicareAdvtgSpecRateStats/AD/list.asp#TopOfPage.

Section D. Budget Neutrality

The final estimate of the National Per Capita MA Growth Percentage is not the only factor that determines the final capitation rates for a year. The DRA specifies the components that CMS must include in the estimate of budget neutral (BN) risk adjustment factor, and codifies the phase-out of the BN factor. As in prior years, the BN factor was estimated as the difference

between aggregate payments to plans using 100 percent demographic payments and aggregate payments to plans using 100 percent risk adjustment payments, expressed as a percent of risk adjusted payments. For purposes of the calculation, CMS assumes that risk payments to plans will be at the local benchmarks, adjusted for each plan's risk score. CMS calculates a single BN factor for all MA plan enrollees.

The BN factor estimate for 2009 is 1.009. This factor was calculated based on a full BN factor of 1.038, multiplied by the BN phase-out percentage of 25 percent. As 2009 is the third year of the phase-out required by the DRA of 2005, 25 percent of the full BN factor is applied to the rates, as the same percentage for all counties.

Comment. One commenter requested that CMS release the BN factor before the Rate Announcement is released because of the shortened time frame in 2008 between release of the Announcement and the bid due date.

Response: Since CMS cannot calculate the BN factor until the final capitation rates are determined, and the final capitation rates are not determined until the National Per Capita MA Growth Percentage is determined (using the 2008 Trustees Report baseline), it is not possible for CMS to release the BN factor prior to the April 7 release of the Rate Announcement and final capitation rates.

Section E. Adjustment for MA Coding Intensity

In the 2009 Advance Notice, CMS summarized findings from our analysis of risk scores in FFS and Medicare Advantage over the 2004-2006 time period and proposed to apply a coding difference adjustment to contracts whose disease scores for stayers exceeded FFS by twice the industry average. We proposed to apply an adjustment calculated based on those contracts that fell above our threshold.

In response to the Advance Notice, CMS received a significant number of comments on the proposed adjustment for MA coding differences, most of which disagreed with our view that we had identified differences in coding patterns between MA and FFS Medicare. Based on our analysis of the comments received, and our further consideration of the question of whether differences in risk scores can be attributed to differences in coding patterns, we have again decided not to make a coding intensity adjustment for 2009.

We hope to be able to reach a more definitive conclusion as to whether differences in risk scores are attributable to differences in coding patterns prior to the Rate Announcement for 2010. In the Advance Notice, we identified differences between the risk scores of MA and FFS Medicare enrollees. However, we did not have available comprehensive information from medical records to support our hypothesis that risk score differences were driven by coding pattern differences, rather than by the health status of MA enrollees. For 2010, we intend to use the results of the first year of plan-level annual MA plan audits (see section F below) to further inform our study of coding pattern differences. .Moreover, CMS will collect additional utilization data from MA organizations to increase the accuracy of our risk-adjusted payments.

Below, we summarize and respond to the comments received on the proposed coding intensity adjustment.

(1) Legal Justification for the MA Coding Intensity Adjustment

Comment. Twenty-nine of the 30 commenters on the Advance Notice expressed views on our coding intensity proposal, and all but one of these 29 commenters opposed the adjustment as proposed. The commenter who supported the adjustment was encouraged by CMS' efforts to implement the Deficit Reduction Act (DRA) provision, but argued that CMS had too narrowly defined the subset of plans targeted to have their risk scores adjusted, and felt that CMS' effort to correct upcoding was minimal and unacceptable. Twenty eight commenters opposed the adjustment. Many contended that CMS has not demonstrated that conclusive evidence of coding differences exists, and contended that CMS had not met the requirement in the Deficit Reduction Act (DRA) that the Secretary must identify differences in coding patterns in order to adjust capitation payments to "reflect […] differences in coding patterns between Medicare Advantage plans and providers under part A and B…" Some commenters suggested that CMS defer implementation of the DRA provision pending completion of further research and analysis to determine the extent of coding inaccuracies by MA organizations.

Response. As noted above, CMS has determined that for CY 2009, we will not make an adjustment to risk scores when calculating 2009 plan payments. We believe that the results of the Audits discussed below in Section F will result in an ability to determine more conclusively whether the differences in risk scores we have identified are attributable to differences in coding patterns.

Comment. Authority under the DRA. Many commenters cited the Deficit Reduction Act (DRA) requirement directing CMS to adjust capitation payments to "reflect [ ] differences in coding patterns between Medicare Advantage plans and providers under part A and B to the extent that the Secretary has identified such differences" and contended that CMS has not demonstrated that evidence of such differences exists. Further, numerous commenters also cited the Conference Report for the DRA, which states that "The conferees intend that any adjustments made for the differences in coding patterns be made for differences resulting from inaccurate coding." These commenters interpret the conferees' use of the term "inaccurate" to refer to "improper" or fraudulent coding, and noted that, in the 2009 Advance Notice, CMS stated that "We do not assume that the coding pattern differences that we found in our study are the result of improper coding." The commenters thus argued that CMS does not have the authority to make adjustments based on the coding pattern differences that CMS found. Some commenters suggested that CMS defer implementation of the DRA provision pending completion of further research and analysis to determine the extent of coding inaccuracies by MA organizations.

Response. CMS believes that the statutory language in the DRA provision at issue provides for a payment adjustment if CMS establishes that there are "differences in coding patterns between Medicare Advantage plans and providers under part A and B." The Conference Report language necessarily must be read in light of the statutory language that Congress actually enacted.

Given the fact that the MA payment methodology is based on fee-for-service payments, and that the risk adjustment methodology is designed to compare the risk scores of MA plan enrollees to other plan enrollees and beneficiaries not enrolled in MA plans, for this comparison to be valid, MA plans must code the way Medicare Part A and B does. This would result in the MA plans' coding "accurately" reflecting the fee-for-service coding used on the beneficiaries to whom MA plan enrollees are being compared. In this sense, "differences" in coding patterns, regardless of the source, would make the MA plan coding "inaccurate" for purposes of implementing risk adjustment.

This reading of the word "inaccurate" is supported by floor statements made by Senator Grassley, Congressman Barton, and Congressman Thomas. Senator Grassley made the following floor statement; the other two committee chairs made very similar statements:

> Section 5301 and the joint statement which accompanied the conference report in the Senate requiring adjustments for differences in coding patterns is intended to include adjustments for coding that is inaccurate or incomplete for the purpose of establishing risk scores that are consistent across both fee-for-service and Medicare Advantage settings, even if such coding is accurate or complete for other purposes. This will ensure that the goal of risk adjustment—to pay plans accurately—is met.

Comment. Several commenters contended that the DRA provision requiring a coding intensity adjustment did not provide for an adjustment that would be applied to a subset of plans, as opposed to the MA program generally.

Response. The DRA requires that, in "applying the adjustment under [section 1853(a)(1)(C)(i)] for health status to payment amounts, the Secretary shall ensure that such adjustment reflects. . .differences in coding patterns between the Medicare Advantage plans and providers under Part A and B to the extent that the Secretary has identified such differences." Section 1853(a)(1)(C)(ii)(I). The adjustments to capitation rates made under section 1853(a)(1)(C)(i) generally are specific to a particular MA organization. In the case of adjustments based on an enrollee's risk score, they are specific to the plan's individual enrollees. In the case of adjustments made to reflect working aged enrollees, they are made at the plan level based on that plan's enrollees.

We believe, therefore, that if we had made a final determination that an adjustment for 2009 was justified, we would have had the authority to make adjustments where we found the greatest differences in coding patterns (and where such adjustments arguably would be more necessary in order for risk scores to have the same meaning for MA enrollees and original Medicare enrollees), while not doing so where there are no such differences, or where the difference is of a smaller magnitude.

(2) Purpose of coding differences adjustment and informing of public of final methodology

Comment. One commenter contended that the Advance Notice did not make clear precisely the purpose of the proposed coding intensity adjustment, other than citing the Deficit Reduction Act (DRA). Other commenters felt that CMS had not adequately demonstrated the need for such an adjustment for coding pattern differences, and had not identified with any certainty the reasons

for the difference. Commenters suggested that there were other explanations of coding pattern differences, such as regional coding pattern differences, other than those identified by CMS.

Response. The DRA requires that CMS adjust payments to reflect "differences in coding patterns between Medicare Advantage plans and providers under part A and B to the extent that the Secretary has identified such differences." While we have reconsidered our view that the differences that we found were conclusively the result of coding pattern differences, if we had reached such a conclusion, an adjustment would have been appropriate without regard to the findings cited by commenters.

(3) Impact of plans, markets, beneficiaries

Comment. While some commenters felt that CMS too narrowly limited the number of contracts to which the adjustment would be applied, and a few others agreed with the CMS proposal to apply the adjustment to plans whose risk score change relative to FFS Medicare is significantly above the average change relative to FFS Medicare, many commenters expressed concerns that applying an adjustment to a subset of contracts was inequitable and had anti-competitive implications.

Several commenters felt that the adjustment penalized MA organizations that have been in the program longer and are now operating more efficiently. A number of commenters posited that the coding adjustment could discourage providers from contracting with plans that received the coding intensity adjustment, since MA organizations, especially those that pay providers a percent of revenue, may have to lower provider payments, which might lead to difficulty in maintaining provider networks and accessibility of care, instability in beneficiary access to care, and consumer dissatisfaction if their physicians leave the plan. Commenters also expressed concern that a coding intensity adjustment would lead to increased premiums and cost sharing and decreased benefits, and possibly cause disruption for beneficiaries who may then feel that they have to disenroll from their plan, and who may then have to switch providers. One commenter suggested that plans will lack incentive to enroll sicker, higher-risk patients. Several commenters expressed concern about the ability of plans to continue to provide appropriate care.

Response. We appreciate commenters' concerns regarding their perceptions of inequity in applying a coding differences adjustment to a subset of contracts and the market implications of such a targeted approach. Because we have decided not to make an adjustment for 2009, the above issues are moot for the 2009 bidding process.

(4) Methodological Questions and Concerns

Comment. Commenters disagreed with CMS's proposal to use the average stayer percentage to adjust the adjustment factor, in order to apply it to all enrollees, noting changes in enrollment over the time period of the study, and variations in stayer percentages among contracts as a result of different enrollee populations. Other commenters felt that an adjustment would disadvantage MA organizations with sicker enrollees. Several commenters suggested that an adjustment for coding pattern differences would discourage initiatives to improve coding, or to maintain thorough coding, since increased coding might risk a revenue reduction in future years. Several

commenters disagreed that CMS had taken into full account the degree of "catch up" and felt that a number of MA organizations would face the possibility of being penalized for these efforts.

Response. We appreciate commenters' concerns about the methodology of our approach to calculating and applying an MA coding differences adjustment. Because we are not making an adjustment for 2009, these comments are moot for this year.

Comment. One commenter suggested that CMS identify strategies for improving coding accuracy in FFS to reduce the variance in coding patterns directly related to differences in financial incentives between MA and FFS – strategies such as risk-adjusting FFS payments.

Response. CMS does make adjustments to FFS payments for diagnosis coding that is not in synchronization with a provider's case mix. We have applied an adjustment to long term hospitals that is projected to total $430 million over five years (FY 2009-FY 2013) and to home health providers that is projected to total $6.53 billion from 2008-2012.

Section F. CMS Audits

In CY 2007, CMS' payments to MA plans were 100 percent risk-adjusted for the first time because the transition from demographic-only to risk-adjusted payments was completed. Given this milestone, CMS has determined that our Risk Adjustment Data Validation, starting with CY 2007 payments, will be conducted using a sampling frame that generates statistically valid plan-level payment error estimates for those plans selected for review.

CMS will audit a subset of MA plans each year. The audit will include randomly-selected plans and targeted plans. Targeted plans will be selected based on how their risk score growth compared to FFS.

Findings from our validation studies from CY 2007 onward may inform CMS why plan average risk scores did or did not grow rapidly. This analysis will allow us to further refine our MA coding intensity adjustment. In addition, because we will have statistically-valid plan-level error estimates, we will make plan-level payment adjustments rather than adjustments to payments for specific beneficiaries whose risk scores were not supported by the medical record reviews, as we have done previously.

Section G. Adjustment to FFS Capitation Rates for VA-DOD Costs

In the Advance Notice, CMS proposed to adjust to the extent appropriate the 2009 FFS rates to reflect CMS' "estimate, on a per capita basis, of the amount of additional payments that would have been made in the area involved under this title if individuals entitled to benefits under this title had not received services from facilities of the Department of Defense or the Department of Veterans Affairs." Specifically, the Office of the Actuary (OACT) proposed to compare the risk-adjusted Medicare reimbursements of dual-eligible individuals — those entitled to benefits under this title and entitled to benefits from the Department of Defense (e.g., DoD TRICARE for Life and DoD US Family Health Plan) or the Department of Veterans Affairs (VA) — with individuals entitled only under this title. In cases where groupings of dual-eligible individuals

(who would possibly have services provided in VA or DoD facilities not reimbursed by Medicare) have risk-adjusted Medicare reimbursements significantly different from other Medicare-eligible individuals, we propose to adjust the MA FFS rates by excluding these individuals from the calculation.

For 2009, CMS will not make the proposed adjustment to the FFS rates. While analysis is underway on VA data, CMS has not yet received the necessary data from DoD. For this reason, CMS is unable at this time to determine the extent to which an adjustment other than zero is appropriate. CMS will continue to work on acquiring the data to support the necessary analysis.

Comment. One commenter commended CMS for moving forward with this analysis and requested an opportunity to obtain a detailed understanding of the methodology that is developed and its anticipated impact as CMS proceeds with this effort.

Response. Over the coming year, CMS is open to discussions with interested parties about the proposed methodology.

Comment. One commenter expressed appreciation that CMS is proceeding to incorporate this adjustment into the FFS rates, but expressed concern that some county capitation rates would be reduced as a result. The commenter recommended that CMS phase-in any VA-DoD-related adjustments that would reduce MA county rates to limit the negative impact on beneficiaries.

Response. As noted above, CMS is unable to determine whether an adjustment other than zero is appropriate for CY 2009. We will take the commenter's concern into account as we continue our analysis.

Section H. Standard Set of ICD-9 Diagnosis Codes for Risk Adjustment

Comment. One commenter supported CMS's adoption of a standardized list of diagnosis codes for risk adjustment and asked if CMS would provide a crosswalk to plans between the old and new codes. The commenter also asked if CMS had done any analysis on the impact of establishing this change (e.g., estimates of increases in rejection rates and/or associated financial impact).

Response. ICD-9 codes are updated on an annual basis. You can find additional information on this process at: www.cdc.gov/nchs/icd9.htm. CMS has been monitoring rejection rates for invalid ICD-9 codes since January 2008 when edits against the standardized code set were implemented in the Risk Adjustment Processing System. CMS has seen no evidence of an increase in error rates for invalid ICD-9 codes, strongly suggesting that MA organizations were themselves operating under this standard before CMS implemented the edits. A complete listing of the risk adjustment diagnosis codes acceptable for risk adjustment prior to January 2008 and after implementation of the change in editing rules is available on the CMS website at http://www.cms.hhs.gov/MedicareAdvtgSpecRateStats/06_Risk_adjustment.asp#TopOfPage .

Section I. Part D – Reporting Drug Costs When Contracting with a Pharmacy Benefit Manager (PBM)

In the Advance Notice, we stated that we intended to issue a final rule this Spring concerning the reporting of drug costs for Part D sponsors that contract with PBMs. We are still preparing this final rule and therefore are unable to issue the final rule this Spring as expected. As a result, Part D sponsors will not have sufficient time after the release of the final rule to prepare their 2009 bids in accordance with the policies that will be established in this rule. Therefore, for plan year 2009, as in 2006, 2007, and 2008, Part D sponsors that use a PBM may apply either the pass through or lock-in pricing approach when calculating cost-sharing and reporting drug costs. Part D sponsors must choose only one approach and cannot switch between them for purposes of calculating cost-sharing and reporting drug costs. Thus, the chosen pricing approach must be used consistently as a basis for: (i) calculating beneficiary cost-sharing; (ii) accumulating gross covered drug costs; (iii) calculating TrOOP; (iv) reporting drug costs on the Prescription Drug Event (PDE) records; and (v) developing bids submitted to CMS.

To ensure transparency in bid development, all plans will be required to submit an actuarial attestation, through HPMS and in hardcopy, which identifies the pricing approach (lock-in or pass through) that was used in the development of each 2009 bid. Additional information regarding this attestation will be issued in future guidance.

Section J. Part D - Calculation of the Low-Income Benchmark Premium Amount.

In Attachment III, Section B2 of the Advance Notice, CMS proposed to extend to 2009 the regional benchmark weighting component of the "Medicare Demonstration to Transition Enrollment of Low Income Subsidy Beneficiaries." We also noted in this same section that the de minimis component of the demonstration would be replaced by the final version of the proposed rule titled "Option for Prescription Drug Plans to Lower Their Premiums for Low-Income Subsidy Beneficiaries" which was published on January 8, 2008. The objective of both extending the demonstration an additional year and codifying a variation of the de minimis policy in regulation was to reduce the number of LIS beneficiaries who are reassigned to new Part D sponsors because their current plan's premium exceeds the regional LIS benchmark.

A final version of the rule was published on April 3, 2008. The final rule CMS-4133-F is titled "Modification to the Weighting Methodology Used to Calculate the Low-income Benchmark Amount." The final rule changes how the regional benchmarks are calculated and eliminates the need to extend the LIS transition demonstration. Therefore, CMS will not extend the LIS transition demonstration to 2009.

Section K. Part D - Coordination of Benefits (COB) User Fee

Comment: One commenter asked CMS to provide more information on why the COB user fee increased over 85%.

Response: The increase in the COB user fee is due to several new CMS initiatives to improve the coordination of benefits. For example, CMS is replacing the current manual TrOOP balance

transfer process with a streamlined automated transfer process. The increase in the COB user fee reflects, in part, the costs associated with developing and implementing this new automated process. CMS is also working with States to permit more frequent reporting of information regarding low-income status (full dual and LIS files for Medicare Part D). This initiative will enhance the accuracy of LIS data at point-of-sale, thus reducing Part D sponsors' reliance on Best Available Evidence. Recent legislation has mandated that all third party insurers that are secondary to Medicare provide CMS with information regarding other health insurance coverage. The COB user fee also has been increased to reflect the costs associated with receiving and subsequently providing this additional information to Part D sponsors and the TrOOP Facilitator.

Attachment IV 2009 Risk Adjustment Factors, Part D Benefit Parameters, and Other Information

The tables in this enclosure are identical to those published in the February 22, 2008 Advance Notice.

Table IV-1. 2009 Community and Institutional Factors for the CMS-HCC Model

Variable	Disease Group	Community Factors	Institutional Factors
Female			
0-34 Years		0.187	1.026
35-44 Years		0.206	0.884
45-54 Years		0.275	0.888
55-59 Years		0.333	0.943
60-64 Years		0.411	0.943
65-69 Years		0.299	0.971
70-74 Years		0.368	0.931
75-79 Years		0.457	0.835
80-84 Years		0.544	0.775
85-89 Years		0.637	0.704
90-94 Years		0.761	0.614
95 Years or Over		0.771	0.457
Male			
0-34 Years		0.120	1.030
35-44 Years		0.164	0.871
45-54 Years		0.217	0.871
55-59 Years		0.249	0.978
60-64 Years		0.389	1.015
65-69 Years		0.328	1.221
70-74 Years		0.413	1.154
75-79 Years		0.517	1.143
80-84 Years		0.597	1.087
85-89 Years		0.692	1.001
90-94 Years		0.834	0.932
95 Years or Over		0.980	0.743
Medicaid and Originally Disabled Interactions with Age and Sex			
Medicaid_Female_Aged		0.179	0.091
Medicaid_Female_Disabled		0.131	0.091
Medicaid_Male_Aged		0.166	0.091
Medicaid_Male_Disabled		0.077	0.091
Originally Disabled_Female		0.204	0.023
Originally Disabled_Male		0.168	0.023
Disease Coefficients	**Description Label**		
HCC1	HIV/AIDS	0.945	0.967
HCC2	Septicemia/Shock	0.759	0.764
HCC5	Opportunistic Infections	0.300	0.288
HCC7	Metastatic Cancer and Acute Leukemia	2.276	0.824

Variable	Disease Group	Community Factors	Institutional Factors
HCC8	Lung, Upper Digestive Tract, and Other Severe Cancers	1.053	0.470
HCC9	Lymphatic, Head and Neck, Brain, and Other Major Cancers	0.794	0.368
HCC10	Breast, Prostate, Colorectal and Other Cancers and Tumors	0.208	0.182
HCC15	Diabetes with Renal or Peripheral Circulatory Manifestation[1]	0.508	0.459
HCC16	Diabetes with Neurologic or Other Specified Manifestation[1]	0.408	0.459
HCC17	Diabetes with Acute Complications[1]	0.339	0.459
HCC18	Diabetes with Ophthalmologic or Unspecified Manifestation[1]	0.259	0.459
HCC19	Diabetes without Complication[1]	0.162	0.248
HCC21	Protein-Calorie Malnutrition	0.856	0.374
HCC25	End-Stage Liver Disease	0.978	0.654
HCC26	Cirrhosis of Liver	0.406	0.384
HCC27	Chronic Hepatitis	0.406	0.384
HCC31	Intestinal Obstruction/Perforation	0.311	0.345
HCC32	Pancreatic Disease	0.403	0.309
HCC33	Inflammatory Bowel Disease	0.241	0.205
HCC37	Bone/Joint/Muscle Infections/Necrosis	0.535	0.497
HCC38	Rheumatoid Arthritis and Inflammatory Connective Tissue Disease	0.346	0.215
HCC44	Severe Hematological Disorders	1.015	0.493
HCC45	Disorders of Immunity	0.912	0.427
HCC51	Drug/Alcohol Psychosis[3]	0.274	0.000
HCC52	Drug/Alcohol Dependence[3]	0.274	0.000
HCC54	Schizophrenia	0.524	0.351
HCC55	Major Depressive, Bipolar, and Paranoid Disorders	0.353	0.293
HCC67	Quadriplegia, Other Extensive Paralysis	1.011	0.434
HCC68	Paraplegia	0.993	0.434
HCC69	Spinal Cord Disorders/Injuries	0.558	0.225
HCC70	Muscular Dystrophy[3]	0.395	0.000
HCC71	Polyneuropathy	0.327	0.225
HCC72	Multiple Sclerosis	0.599	0.145
HCC73	Parkinson's and Huntington's Diseases	0.592	0.092
HCC74	Seizure Disorders and Convulsions	0.267	0.177
HCC75	Coma, Brain Compression/Anoxic Damage[3]	0.415	0.000
HCC77	Respirator Dependence/Tracheostomy Status	1.867	1.559
HCC78	Respiratory Arrest	1.082	1.235
HCC79	Cardio-Respiratory Failure and Shock	0.578	0.445
HCC80	Congestive Heart Failure	0.410	0.228
HCC81	Acute Myocardial Infarction	0.359	0.424
HCC82	Unstable Angina and Other Acute Ischemic Heart Disease	0.284	0.424
HCC83	Angina Pectoris/Old Myocardial Infarction	0.244	0.290
HCC92	Specified Heart Arrhythmias	0.293	0.207
HCC95	Cerebral Hemorrhage	0.324	0.179
HCC96	Ischemic or Unspecified Stroke	0.265	0.179
HCC100	Hemiplegia/Hemiparesis	0.437	0.039
HCC101	Cerebral Palsy and Other Paralytic Syndromes[3]	0.180	0.000

Variable	Disease Group	Community Factors	Institutional Factors
HCC104	Vascular Disease with Complications	0.610	0.482
HCC105	Vascular Disease	0.316	0.165
HCC107	Cystic Fibrosis	0.399	0.631
HCC108	Chronic Obstructive Pulmonary Disease	0.399	0.359
HCC111	Aspiration and Specified Bacterial Pneumonias	0.703	0.573
HCC112	Pneumococcal Pneumonia, Emphysema, Lung Abscess	0.249	0.181
HCC119	Proliferative Diabetic Retinopathy and Vitreous Hemorrhage	0.252	0.497
HCC130	Dialysis Status	1.349	1.718
HCC131	Renal Failure	0.368	0.388
HCC132	Nephritis	0.125	0.253
HCC148	Decubitus Ulcer of Skin	1.153	0.485
HCC149	Chronic Ulcer of Skin, Except Decubitus	0.449	0.241
HCC150	Extensive Third-Degree Burns[3]	1.416	0.000
HCC154	Severe Head Injury[3]	0.415	0.000
HCC155	Major Head Injury[3]	0.106	0.000
HCC157	Vertebral Fractures without Spinal Cord Injury	0.443	0.161
HCC158	Hip Fracture/Dislocation[3]	0.429	0.000
HCC161	Traumatic Amputation	0.678	0.260
HCC164	Major Complications of Medical Care and Trauma	0.296	0.309
HCC174	Major Organ Transplant Status	0.705	0.920
HCC176	Artificial Openings for Feeding or Elimination	0.662	0.841
HCC177	Amputation Status, Lower Limb / Amputation Complications	0.678	0.260
Disabled/Disease Interactions			
D_HCC5	Disabled_Opportunistic Infections	0.623	1.016
D_HCC44	Disabled_Severe Hematological Disorders	1.036	0.362
D_HCC51	Disabled_Drug/Alcohol Psychosis	0.729	0.299
D_HCC52	Disabled_Drug/Alcohol Dependence	0.310	0.299
D_HCC107	Disabled_Cystic Fibrosis[3]	1.097	-
Disease Interactions			
INT1	DM_CHF[2]	0.154	0.125
INT2	DM_CVD	0.102	0.028
INT3	CHF_COPD	0.219	0.194
INT4	COPD_CVD_CAD	0.173	0.071
INT5	RF_CHF[2,3]	0.231	-
INT6	RF_CHF_DM[2]	0.477	0.358

NOTES:

[1] Includes Type I or Type II Diabetes Mellitus.

[2] Beneficiaries with the three-way interaction RF*CHF*DM are excluded from the two-way interactions DM*CHF and RF*CHF. Thus, the three-way interaction term RF*CHF*DM is not additive to the two-way interaction terms DM*CHF and RF*CHF. Rather, it is hierarchical to, and excludes these interaction terms. A beneficiary with all three conditions is not "credited" with the two-way interactions. All other interaction terms are additive.

[3] HCC or disease interaction excluded from institutional model because estimated coefficient less than 0 or t-statistic less than 1.0.

The 2007 denominator of $7,463.14 used to calculate both the community and institutional factors is the national predicted average annual cost under the model.

DM is diabetes mellitus (HCCs 15-19).
CHF is congestive heart failure (HCC 80).
COPD is chronic obstructive pulmonary disease (HCC 108).
CVD is cerebrovascular disease (HCCs 95, 96, 100, and 101).
CAD is coronary artery disease (HCCs 81-83).
RF is renal failure (HCC 131).

SOURCE: RTI International analysis of 2004/2005 Medicare 5% sample.
SOURCE: RTI International analysis of 2004/2005 Medicare 100% institutional sample.

Attachment IV-2. Disease Hierarchies for the CMS-HCC Model

Hierarchical Condition Category (HCC)	If the Disease Group is Listed in This Column…	…Then Drop the Associated Disease Group(s) Listed in This Column
	Disease Group Label	
5	Opportunistic Infections	112
7	Metastatic Cancer and Acute Leukemia	8, 9, 10
8	Lung, Upper Digestive Tract, and Other Severe Cancers	9, 10
9	Lymphatic, Head and Neck, Brain and Other Major Cancers	10
15	Diabetes with Renal Manifestations or Peripheral Circulatory Manifestation	16, 17, 18, 19
16	Diabetes with Neurologic or Other Specified Manifestation	17, 18, 19
17	Diabetes with Acute Complications	18, 19
18	Diabetes with Ophthalmologic or Unspecified Manifestations	19
25	End-Stage Liver Disease	26, 27
26	Cirrhosis of Liver	27
51	Drug/Alcohol Psychosis	52
54	Schizophrenia	55
67	Quadriplegia/Other Extensive Paralysis	68, 69, 100, 101, 157
68	Paraplegia	69, 100, 101, 157
69	Spinal Cord Disorders/Injuries	157
77	Respirator Dependence/ Tracheostomy Status	78, 79
78	Respiratory Arrest	79
81	Acute Myocardial Infarction	82, 83
82	Unstable Angina and Other Acute Ischemic Heart Disease	83
95	Cerebral Hemorrhage	96
100	Hemiplegia/Hemiparesis	101
104	Vascular Disease with Complications	105, 149
107	Cystic Fibrosis	108
111	Aspiration and Specified Bacterial Pneumonias	112
130	Dialysis Status	131, 132
131	Renal Failure	132
148	Decubitus Ulcer of Skin	149
154	Severe Head Injury	75, 155
161	Traumatic Amputation	177

How Payments are Made with a Disease Hierarchy -- EXAMPLE: If a beneficiary triggers HCCs 148 (Decubitus Ulcer of the Skin) and 149 (Chronic Ulcer of Skin, Except Decubitus), then HCC 149 will be dropped. In other words, payment will always be associated with the HCC in column 1 if a HCC in column 3 also occurs during the same collection period. Therefore, the MA organization's payment will be based on HCC 148 rather than HCC 149.

Attachment IV-3. 2009 CMS-HCC Model for New Enrollees

	Non-Medicaid & Non-Originally Disabled	Medicaid & Non-Originally Disabled	Non-Medicaid & Originally Disabled	Medicaid & Originally Disabled
Female				
0-34 Years	0.496	0.807	0.000	0.000
35-44 Years	0.652	0.963	0.000	0.000
45-54 Years	0.841	1.152	0.000	0.000
55-59 Years	0.969	1.280	0.000	0.000
60-64 Years	1.094	1.404	0.000	0.000
65 Years	0.497	0.958	1.096	1.557
66 Years	0.554	0.987	1.153	1.587
67 Years	0.595	1.028	1.194	1.628
68 Years	0.619	1.052	1.218	1.651
69 Years	0.652	1.085	1.251	1.684
70-74 Years	0.759	1.208	1.320	1.769
75-79 Years	0.955	1.357	1.430	1.832
80-84 Years	1.118	1.520	1.593	1.995
85-89 Years	1.255	1.657	1.730	2.132
90-94 Years	1.358	1.760	1.834	2.236
95 Years or Over	1.232	1.634	1.707	2.109
Male				
0-34 Years	0.344	0.675	0.000	0.000
35-44 Years	0.583	0.914	0.000	0.000
45-54 Years	0.729	1.060	0.000	0.000
55-59 Years	0.827	1.158	0.000	0.000
60-64 Years	1.033	1.365	0.000	0.000
65 Years	0.550	1.022	1.116	1.587
66 Years	0.586	1.058	1.117	1.589
67 Years	0.664	1.136	1.195	1.667
68 Years	0.664	1.136	1.195	1.667
69 Years	0.723	1.195	1.254	1.726
70-74 Years	0.855	1.322	1.392	1.859
75-79 Years	1.113	1.484	1.521	1.893
80-84 Years	1.299	1.670	1.707	2.078
85-89 Years	1.468	1.839	1.876	2.247
90-94 Years	1.630	2.001	2.038	2.409
95 Years or Over	1.638	2.009	2.046	2.417

NOTES:
The 2007 denominator of $7,463.14 used to calculate the new enrollee factors is the national predicted average annual cost under the model.

Three sets of interaction coefficients were constrained to be equal (Male, Age 67 & Male, Age 68; Medicaid, Male, Age 65 & Medicaid, Male, Ages 66 to 69; Originally Disabled, Female, Age 65 & Originally Disabled, Female, Ages 66 to 69). These constraints are necessary so that predicted expenditures, and risk scores for all demographic groups, vary in a reasonable way, as shown in the table of mutually exclusive demographic groups.

SOURCE: RTI International analysis of 2004/2005 Medicare 5% sample.

Table IV-4. Final Recalibrated Frailty Factors for CY 2009

ADL	2008 Factors (Non-Medicaid)	2009 Recalibrated Factors (Non-Medicaid)	2008 Factors (Medicaid)	2009 Recalibrated Factors (Medicaid)
0	-0.089	-0.093	-0.183	-0.180
1-2	+0.110	+0.112	+0.024	+0.035
3-4	+0.200	+0.201	+0.132	+0.155
5-6	+0.377	+0.381	+0.188	+0.200

Table IV-5. Data sources for the assignment of Medicaid status

	Payment year 2007	**Payment year 2008**	**Payment year 2009**
New enrollees	1. Third Party Buy-In file 2. Plan-reported Medicaid • Batch "01" transactions • Retroactive "01s" through IntegriGuard	1. MMA State files 2. Plan-reported • Retroactive "01s" through IntegriGuard	1. MMA State files 2. Plan-reported • Retroactive "01s" through IntegriGuard
Full risk enrollees		1. MMA State files 2. Third Party Buy-In file 3. Plan-reported Medicaid • Batch "01" transactions • Retroactive "01s" through IntegriGuard	

Notes: Full risk enrollees. CMS considers full risk Medicare beneficiaries as dually-eligible if they were eligible for title XIX during any month in the year prior to the payment year. Full risk Medicare beneficiaries have 12 months of Part B in the year prior to the payment year.
New enrollees. CMS assigns Medicaid status for new enrollees on a concurrent basis, i.e., if a newly-enrolled Medicare beneficiary is eligible for title XIX during any month during the payment year, they are considered Medicaid for that year.

Table IV-6. Acceptable diagnoses codes

Year of Payment	**Date of Service**	**Source of codes**
2007	1/06 – 12/06	The list of codes published on our website at http://www.cms.hhs.gov/MedicareAdvtgSpecRateStats/06_Risk_adjustment.asp#TopOfPage (which lists acceptable codes by year)
2008	1/07 – 12/07	The list of codes published on our website at http://www.cms.hhs.gov/MedicareAdvtgSpecRateStats/06_Risk_adjustment.asp#TopOfPage (which lists acceptable codes by year)
2009	1/08 – 12/08	Valid diagnoses in Fiscal Years 2008, 2009
2010	1/09 – 12/09	Valid diagnoses in Fiscal Years 2009, 2010
2011	1/10 – 12/10	Valid diagnoses in Fiscal Years 2010, 2011

Table IV-7. Updated Part D Benefit Parameters for Defined Standard Benefit, Low-Income Subsidy, and Retiree Drug Subsidy

Annual Percentage Increases	Annual percentage trend for 2008	Prior year revisions	Annual percentage increase for 2008
Applied to all parameters but (1)	5.97%	1.48%	7.54%
CPI (all items, U.S. city average): Applied to (1)	2.60%	0.57%	3.18%

Part D Benefit Parameters	2008	2009
Standard Benefit Design Parameters		
Deductible	$275	$295
Initial Coverage Limit	$2,510	$2,700
Out-of-Pocket Threshold	$4,050	$4,350
Total Covered Part D Drug Spend at OOP Threshold (2)	$5,726.25	$6,153.75
Minimum Cost-sharing in Catastrophic Coverage Portion of Benefit		
Generic/Preferred Multi-Source Drug	$2.25	$2.40
Other	$5.60	$6.00
Part D Full Benefit Dual Eligible Parameters		
Copayments for Institutionalized Beneficiaries	$0.00	$0.00
Maximum Copayments for Non-Institutionalized Beneficiaries		
Up to or at 100% FPL		
Up to Out-of-Pocket Threshold (1)		
Generic/Preferred Multi-Source Drug (3)	$1.05	$1.10
Other (3)	$3.10	$3.20
Above Out-of-Pocket Threshold	$0.00	$0.00
Over 100% FPL		
Up to Out-of-Pocket Threshold		
Generic/Preferred Multi-Source Drug	$2.25	$2.40
Other	$5.60	$6.00
Above Out-of Pocket Threshold	$0.00	$0.00
Part D Non-Full Benefit Dual Eligible Full Subsidy Parameters		
Resources ≤ $6,290 (individuals) or ≤ $9,440 (couples) (4)		
Maximum Copayments up to Out-of-Pocket Threshold		
Generic/Preferred Multi-Source Drug	$2.25	$2.40
Other	$5.60	$6.00
Maximum Copayments above Out-of-Pocket Threshold	$0.00	$0.00
Resources bet $6,290-$10,490 (ind) or $9,440-$20,970 (couples) (4)		
Deductible (3)	$56.00	$60.00
Coinsurance up to Out-of-Pocket Threshold	15%	15%
Maximum Copayments above Out-of-Pocket Threshold		
Generic/Preferred Multi-Source Drug	$2.25	$2.40
Other	$5.60	$6.00
Part D Non-Full Benefit Dual Eligible Partial Subsidy Parameters		
Deductible (3)	$56.00	$60.00
Coinsurance up to Out-of-Pocket Threshold	15%	15%
Maximum Copayments above Out-of-Pocket Threshold		
Generic/Preferred Multi-Source Drug	$2.25	$2.40
Other	$5.60	$6.00
Retiree Drug Subsidy Amounts		
Cost Threshold	$275	$295
Cost Limit	$5,600	$6,000

(1) CPI adjustment applies to copayments for non-institutionalized beneficiaries up to or at 100% FPL.
(2) Amount of total drug spending required to attain out-of-pocket threshold in the defined standard benefit if beneficiary does not have prescription drug coverage through a group health plan, insurance, government-funded health program or similar third party arrangement.
(3) The increases to the LIS deductible, generic/preferred multi-source drugs and other drugs copayments are applied to the unrounded 2008 values of $55.91, $1.04, and $3.13 respectively.
(4) The actual amount of resources allowable will be updated for contract year 2009.

Office of the Actuary, Centers for Medicare and Medicaid Services, February 22, 2008

April 6, 2009

NOTE TO: All Medicare Advantage Organizations, Prescription Drug Plan Sponsors, and Other Interested Parties

SUBJECT: Announcement of Calendar Year (CY) 2010 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies

In accordance with section 1853(b)(1) of the Social Security Act (the Act), we are notifying you of the annual Medicare Advantage (MA) capitation rate for each MA payment area for 2010, and the risk and other factors to be used in adjusting such rates. The capitation rate tables for CY 2010 are posted on the Centers for Medicare & Medicaid Services (CMS) web site at http://www.cms.hhs.gov/MedicareAdvtgSpecRateStats/ under Ratebooks and Supporting Data. The spreadsheet that shows the statutory component of the regional benchmarks is also posted at this website.

Attachment I shows the final estimates of the increases in the National Per Capita MA Growth Percentages for 2010. These growth rates will be used to update the 2010 rates, except for the ESRD State rates, which are subject to a 2 percent minimum increase under Section 1853(a)(1)(H). As discussed in Attachment I, the final estimate of the increase in the National Per Capita MA Growth Percentage for combined aged and disabled beneficiaries is 0.81 percent. Attachment II provides a set of tables that summarizes many of the key Medicare assumptions used in the calculation of the National Per Capita MA Growth Percentages.

Section 1853(b)(4) of the Act requires CMS to release county-specific per capita fee-for-service (FFS) expenditure information on an annual basis, beginning with March 1, 2001. In accordance with this requirement, FFS data for CY 2007 are being posted on the above website.

Attachment III presents responses to comments on the Advance Notice of Methodological Changes for CY 2010 MA Capitation Rates and Parts C and Part D Payment Policies (Advance Notice). We received 66 submissions in response to CMS' request for comments on the Advance Notice, published on February 20, 2009. Three of the comments were from advocacy groups, three were from Congress (members or agencies of Congress), seven were from associations, nine were from consultants, and forty-four were from health plans.

Attachment IV contains tables with the Part D benefit parameters.

Key Changes from the Advance Notice

Attachment I provides the final estimates of the National MA Growth Percentages (growth trends) and information on deductibles for MSA standard and demonstration plans, and on the maximum out-of-pocket amount for MSA demonstrations plans.

Attachment III, Section E announces the policy decision on the MA coding pattern differences adjustment for 2010. After consideration of comments, CMS has modified the methodology proposed in the Advance Notice. Section D includes the Budget Neutrality factor for 2010. Attachment IV announces the final version of the update to the Part D Benefit Parameters.

As in past years, policies proposed in the Advance Notice that are not modified or retracted in the Rate Announcement become effective in the upcoming payment year, as set forth in the Advance Notice. Clarifications in the Announcement supersede materials in the Advance Notice.

Proposals Adopted as Issued in the Advance Notice:

Frailty Adjustment Transition for PACE organizations. Frailty adjustment scores will be applied to payment to PACE organizations using the transition schedule published in the 2008 Announcement (published April 2, 2007). PACE frailty scores for payment year 2010 will be calculated using a blend of 50% of the frailty factors in use prior to 2008 and 50% of the recalibrated frailty factors implemented in 2009.

Frailty Adjustment Transition for Certain Demonstrations. Frailty adjustment scores will be applied to payment to the following MA plan types using the phase-out schedule published in the 2008 Announcement (published April 2, 2007): Social Health Maintenance Organizations (S/HMOs), Minnesota Senior Health Options (MSHO)/ Minnesota Disability Health Options (MnDHO), Wisconsin Partnership Program (WPP) and Massachusetts Senior Care Options (SCO) plans. The phase out schedule for 2010 is 25% of the pre-2008 frailty factors. 2010 will be the final year in the phase out for these MA plan types.

Normalization Factors. Normalization factors for 2010 are as follows:

- The final 2010 normalization factor for the aged-disabled model is 1.041.
- The final 2010 normalization factor for the ESRD dialysis model is 1.039.
- The final 2010 normalization factor to be applied to the risk scores of enrollees in functioning graft status is 1.072.
- The final 2010 normalization factor for the RxHCC model is 1.146.

ESRD Payment. For payment year 2010, CMS' payments for ESRD dialysis and transplant enrollees will be based on State rates calculated using a blend of 25% of the old State ratebook (in use through 2007) and 75% of the revised State ratebook (implemented in 2008).

IME Phase Out. For 2010, CMS will begin phasing out indirect medical education (IME) amounts from MA capitation rates (including ESRD).

Location of Network Areas for PFFS Plans in Plan Year 2011. The list of network areas for plan year 2011 can be downloaded from the following website: http://www.cms.hhs.gov/PrivateFeeforServicePlans/ The list has not changed since the publication of the Advance Notice.

Continuation of Clinical Trial Policy. In 2010, we will continue the policy of paying on a fee-for-service basis for clinical trial items and services provided to MA plan members that are covered under the relevant National Coverage Determinations on clinical trials.

Adjustment to FFS Per Capita Costs for VA-DOD Costs. For payment year 2010, OACT concludes that there is insufficient evidence to incorporate any VA adjustment into the rate making process.

Calculation and Source Data of MSP Factor. For payment year 2010, CMS no longer requires that MA organizations conduct, nor will we use the results of, plan surveys conducted in 2009. Rather, CMS will adjust for MSP status using Coordination of Benefits (COB) data.

Reporting Drug Costs When Contracting with a Pharmacy Benefit Manager (PBM). In accordance with the January 12, 2009 Final Rule with Comment, "Medicare Advantage and Prescription Drug Benefit Programs: Negotiated Pricing and Remaining Revisions", Part D sponsors must use the amount paid to the pharmacy (or other dispensing provider) when calculating beneficiary cost sharing, developing their Part D bids, and reporting drug costs to CMS. For Part D sponsors that contract with a PBM, amounts paid to the PBM for Part D drugs that exceed the amounts paid to the pharmacy (or other dispensing provider) must be included in the administrative expense component of the bid. Starting in 2010, Part D sponsors will not be required to submit an Attestation of Pricing Approach.

Reinsurance Payment Demonstration Plans. 2010 is the last scheduled year for the Part D Reinsurance Payment Demonstration. CMS will not accept any new or expanded applications for reinsurance demonstration plans to be offered in 2010. Reinsurance demonstration plans which were offered in 2009 may continue through 2010. The budget neutrality offsets applied to the capitated reinsurance payments for these plans will be $10.77 per member per year for contract year 2010.

Payment Reconciliation. The 2010 risk percentages and payment adjustments for Part D risk sharing are unchanged from contract year 2009. The risk percentages for the first and second thresholds remain at 5% and 10% respectively of the target amount for 2010. The payment adjustments for the first and second corridors are 50% and 80% respectively.

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Attachments

Attachment I. Final Estimate of the Increase in the National Per Capita MA Growth Percentages for 2010

The first table below shows the National Per Capita MA Growth Percentages (NPCMAGP) used to determine the minimum update percentages for 2010. Adjustments of 1.99 percent, 0.64 percent, 1.23 percent and 1.76 percent for aged, disabled, ESRD, and combined aged and disabled, respectively, are included in the NPCMAGP to account for corrections to prior years' estimates as required by section 1853(c)(6)(C). The combined aged and disabled increase is used in the development of the ratebook.

The second table below shows the monthly actuarial value of the Medicare deductible and coinsurance for 2009 and 2010. In addition, for 2010, the actuarial value of deductibles and coinsurance is being shown for non-ESRD only, since the plan bids will not include ESRD benefits in 2010. These data were furnished by the Office of the Actuary.

Increase in the National Per Capita MA Growth Percentages for 2010

	Prior Increases	Current Increases			NPCMAGP for 2010 With §1853(c)(6)(C) adjustment[1]
	2003 to 2009	2003 to 2009	2009 to 2010	2003 to 2010	
Aged	38.97%	41.74%	−0.97%	40.36%	1.00%
Disabled	46.87%	47.81%	−0.67%	46.82%	−0.04%
ESRD[2]	15.44%	16.86%	−0.95%	15.76%	0.28%[3]
Aged+Disabled	39.94%	42.40%	−0.93%	41.07%	0.81%

[1]Current increases for 2003 to 2010 divided by the prior increases for 2003 to 2009.
[2]Starting in 2008, increases for ESRD reflect an estimate of the increase for dialysis-only beneficiaries.
[3]The NPCMAGP for ESRD for 2010 will be the minimum 2 percent increase.

Monthly Actuarial Value of Medicare Deductible and Coinsurance for 2009 and 2010

	2009	2010	Change	2010 non-ESRD
Part A Benefits	$37.94	$40.31	6.2%	$38.34
Part B Benefits[4]	$97.97	$100.01	2.1%	$93.98
Total Medicare	$135.91	$140.32	3.2%	$132.32

[4]Includes the amounts for outpatient psychiatric charges.

Medical Savings Account (MSA) Plans. The maximum deductible for current law MSA plans for 2010 is $10,600. For MSA demonstration plans, the 2010 minimum deductible amount is $2,200, the maximum out-of-pocket amount is $10,600, and the minimum difference between the deductible and deposit is $1,000.

Attachment II. Key Assumptions and Financial Information

The USPCCs are the basis for the National Per Capita MA Growth Percentages. Attached is a table that compares the published United States Per Capita Costs (USPCC) with current estimates for 2003 to 2010. In addition, this table shows the current projections of the USPCCs through 2012. We are also providing an attached set of tables that summarizes many of the key Medicare assumptions used in the calculation of the USPCCs. Most of the tables include information for the years 2003 through 2012.

All of the information provided in this enclosure applies to the Medicare Part A and Part B programs. Caution should be employed in the use of this information. It is based upon nationwide averages, and local conditions can differ substantially from conditions nationwide.

None of the data presented here pertain to the Medicare prescription drug benefit.

Comparison of Current Estimates of the USPCC with Published Estimates

PART A:

Calendar Year	Aged			Disabled			Aged and Disabled		
	Current Estimate	Published Estimate	Ratio	Current Estimate	Published Estimate	Ratio	Current Estimate	Published Estimate	Ratio
2003	$301.42	$290.50	0.964	$250.04	$234.89	0.939	$293.87	$282.50	0.961
2004	$321.21	$326.78	1.017	$268.86	$271.69	1.011	$313.24	$318.43	1.017
2005	$343.27	$348.28	1.015	$286.31	$291.45	1.018	$334.31	$339.49	1.015
2006	$352.70	$351.38	0.996	$309.67	$295.15	0.953	$345.97	$342.67	0.990
2007	$363.56	$370.34	1.019	$317.49	$318.17	1.002	$356.07	$362.06	1.017
2008	$388.02	$385.61	0.994	$342.42	$344.31	1.006	$380.69	$379.02	0.996
2009	$410.78	$414.22	1.008	$362.11	$378.40	1.045	$402.88	$408.50	1.014
2010	$415.28	$415.28	1.000	$366.83	$366.83	1.000	$407.38	$407.38	1.000
2011	$429.04			$380.50			$421.12		
2012	$446.59			$400.33			$439.13		

PART B:

Calendar Year	Aged			Disabled			Aged and Disabled		
	Current Estimate	Published Estimate	Ratio	Current Estimate	Published Estimate	Ratio	Current Estimate	Published Estimate	Ratio
2003	$250.81	$232.24	0.926	$246.76	$211.58	0.857	$250.26	$229.47	0.917
2004	$276.49	$263.39	0.953	$274.57	$252.74	0.920	$276.22	$261.89	0.948
2005	$296.64	$281.90	0.950	$293.34	$272.79	0.930	$296.16	$280.58	0.947
2006	$319.09	$311.28	0.976	$311.80	$316.82	1.016	$318.00	$312.09	0.981
2007	$336.19	$334.02	0.994	$331.91	$343.76	1.036	$335.54	$335.47	1.000
2008	$354.57	$354.44	1.000	$352.88	$343.26	0.973	$354.31	$352.75	0.996
2009	$371.93	$358.03	0.963	$372.21	$357.10	0.959	$371.97	$357.89	0.962
2010	$359.82	$359.82	1.000	$362.57	$362.57	1.000	$360.25	$360.25	1.000
2011	$365.13			$369.74			$365.85		
2012	$375.68			$381.49			$376.58		

PART A & PART B:

Calendar Year	Aged			Disabled			Aged and Disabled		
	Current Estimate	Published Estimate	Ratio	Current Estimate	Published Estimate	Ratio	Current Estimate	Published Estimate	Ratio
2003	$552.23	$522.74	0.947	$496.80	$446.47	0.899	$544.13	$511.97	0.941
2004	$597.70	$590.17	0.987	$543.43	$524.43	0.965	$589.46	$580.32	0.984
2005	$639.91	$630.18	0.985	$579.65	$564.24	0.973	$630.47	$620.07	0.984
2006	$671.79	$662.66	0.986	$621.47	$611.97	0.985	$663.97	$654.76	0.986
2007	$699.75	$704.36	1.007	$649.40	$661.93	1.019	$691.61	$697.53	1.009
2008	$742.59	$740.05	0.997	$695.30	$687.57	0.989	$735.00	$731.77	0.996
2009	$782.71	$772.25	0.987	$734.32	$735.50	1.002	$774.85	$766.39	0.989
2010	$775.10	$775.10	1.000	$729.40	$729.40	1.000	$767.63	$767.63	1.000
2011	$794.17			$750.24			$786.97		
2012	$822.27			$781.82			$815.71		

Comparison of Current Estimates of the USPCC with Published Estimates−continued

PART A:

	All ESRD				Basis for Growth Percentage	
Calendar Year	Current Estimate	Published Estimate	Ratio	Current Cumulative Trend	Adjustment Factor for Dialysis-only*	Adjusted Current Cumulative Trend
2003	1,854.38	1,596.58	0.861			
2004	1,690.26	1,685.25	0.997	0.9115		0.9115
2005	1,735.53	1,759.90	1.014	0.9359		0.9359
2006	1,807.19	1,717.97	0.951	0.9746		0.9746
2007	1,891.18	1,874.54	0.991	1.0198		1.0198
2008	2,015.22	1,843.42	0.915	1.0867	1.0067	1.0940
2009	2,112.67	1,885.71	0.893	1.1393	1.0134	1.1546
2010	2,133.76	2,133.76	1.000	1.1507	1.0202	1.1739
2011	2,200.43			1.1866	1.0271	1.2187
2012	2,299.34			1.2400	1.0340	1.2820

PART B:

	All ESRD				Basis for Growth Percentage	
Calendar Year	Current Estimate	Published Estimate	Ratio	Current Cumulative Trend	Adjustment Factor for Dialysis-only*	Adjusted Current Cumulative Trend
2003	2,021.41	1,847.53	0.914			
2004	2,161.14	2,552.18	1.181	1.0691		1.0691
2005	2,297.12	2,739.99	1.193	1.1364		1.1364
2006	2,297.76	2,454.98	1.068	1.1367		1.1367
2007	2,356.60	2,470.81	1.048	1.1658		1.1658
2008	2,446.23	2,887.38	1.180	1.2102	0.9709	1.1749
2009	2,533.58	2,371.73	0.936	1.2534	0.9426	1.1815
2010	2,523.56	2,523.56	1.000	1.2484	0.9152	1.1426
2011	2,581.94			1.2773	0.8886	1.1350
2012	2,608.15			1.2903	0.8627	1.1131

PART A & PART B:

	All ESRD				Basis for Growth Percentage	
Calendar Year	Current Estimate	Published Estimate	Ratio	Current Cumulative Trend	Adjustment Factor for Dialysis-only*	Adjusted Current Cumulative Trend
2003	3,875.79	3,444.11	0.889			
2004	3,851.40	4,237.43	1.100	0.9937		0.9937
2005	4,032.65	4,499.89	1.116	1.0405		1.0405
2006	4,104.95	4,172.95	1.017	1.0591		1.0591
2007	4,247.78	4,345.35	1.023	1.0960		1.0960
2008	4,461.45	4,730.80	1.060	1.1511	0.9871	1.1362
2009	4,646.25	4,257.44	0.916	1.1988	0.9748	1.1686
2010	4,657.32	4,657.32	1.000	1.2016	0.9633	1.1576
2011	4,782.37			1.2339	0.9523	1.1751
2012	4,907.49			1.2662	0.9430	1.1940

* Starting in 2008, increases for ESRD reflect an estimate of the increase for dialysis-only beneficiaries

Summary of Key Projections Under Present Law[1]

Part A

Year	Calendar Year CPI Percent Increase	Fiscal Year PPS Update Factor	FY Part A Total Reimbursement (Incurred)
2003	2.2	3.0	3.6
2004	2.6	3.4	8.8
2005	3.5	3.3	8.9
2006	3.2	3.7	6.2
2007	2.9	3.4	5.6
2008	4.3	3.3	8.2
2009	−1.0	2.7	9.1
2010	1.7	−0.9	3.1
2011	2.3	2.6	5.3
2012	2.7	4.9	7.4

Part B[2]

Calendar Year	Physician Fee Schedule		Part B Hospital	Total
	Fees	Residual[3]		
2003	1.7	4.5%	5.4%	6.9%
2004	1.5	5.9%	10.0%	9.7%
2005	1.5	3.2%	9.8%	6.9%
2006	0.2	4.6%	4.1%	5.9%
2007	0.0	3.5%	8.4%	4.3%
2008	0.5	3.6%	3.8%	4.4%
2009	1.1	2.6%	6.1%	4.4%
2010	−21.5	8.1%	5.8%	−3.8%
2011	−5.6	2.8%	6.1%	1.7%
2012	−5.3	2.9%	6.3%	2.4%

[1]Percent change over prior year.
[2]Percent change in charges per Aged Part B enrollee.
[3]Residual factors are factors other than price, including volume of services, intensity of services, and age/sex changes.

Medicare Enrollment Projections Under Present Law (In Millions)

Non-ESRD

Calendar Year	Part A		Part B	
	Aged	Disabled	Aged	Disabled
2003	34.428	5.929	33.027	5.187
2004	34.835	6.249	33.282	5.458
2005	35.241	6.576	33.609	5.747
2006	35.892	6.657	33.962	5.987
2007	36.432	7.068	34.445	6.187
2008	37.264	7.133	34.979	6.335
2009	37.768	7.318	35.503	6.485
2010	38.473	7.500	36.065	6.645
2011	39.371	7.679	36.752	6.798
2012	40.657	7.813	37.806	6.922

ESRD Part A

Calendar Year	Part A			
	Aged	Disabled	299I[1]	Total
2003	0.160	0.126	0.096	0.383
2004	0.167	0.132	0.100	0.399
2005	0.174	0.137	0.104	0.415
2006	0.182	0.141	0.107	0.430
2007	0.190	0.143	0.110	0.443
2008	0.198	0.144	0.113	0.455
2009	0.206	0.146	0.116	0.467
2010	0.212	0.149	0.118	0.478
2011	0.218	0.151	0.120	0.489
2012	0.226	0.154	0.121	0.501

ESRD Part B

Calendar Year	Part B			
	Aged	Disabled	299I	Total
2003	0.161	0.120	0.088	0.370
2004	0.168	0.125	0.089	0.382
2005	0.175	0.130	0.092	0.396
2006	0.183	0.133	0.095	0.411
2007	0.190	0.135	0.098	0.423
2008	0.198	0.135	0.100	0.433
2009	0.205	0.137	0.102	0.444
2010	0.211	0.140	0.103	0.454
2011	0.217	0.142	0.105	0.464
2012	0.225	0.144	0.106	0.475

[1] Individuals who qualify for Medicare based on ESRD only.

Part A Projections Under Present Law [1]

Calendar Year	Inpatient Hospital		SNF		Home Health		Managed Care		Hospice: Total Reimbursement (in Millions)	
	Aged	Disabled	Aged	Disabled	Aged	Disabled	Aged	Disabled	Aged	Disabled
2003	2,657.65	2,861.53	419.92	150.13	132.41	71.96	522.55	218.64	5,446	287
2004	2,775.49	3,005.59	469.88	173.01	143.46	78.03	569.16	236.85	6,506	342
2005	2,885.13	3,139.82	513.88	193.18	151.60	82.67	675.68	299.94	7,618	401
2006	2,830.27	3,212.38	541.17	211.94	151.48	85.64	823.25	516.26	8,866	467
2007	2,776.45	3,147.05	574.84	227.61	154.16	87.70	981.74	659.27	9,991	526
2008	2,861.37	3,285.05	608.19	245.18	160.79	93.02	1,160.89	812.33	11,094	584
2009	2,930.10	3,400.83	638.32	261.85	164.90	96.90	1,340.39	922.44	12,032	633
2010	2,904.68	3,413.61	658.25	275.22	165.52	98.95	1,402.32	950.92	12,667	667
2011	3,017.84	3,557.11	678.55	287.01	166.81	100.58	1,437.67	965.70	13,515	711
2012	3,154.87	3,743.18	693.61	298.78	171.29	104.73	1,498.52	1,014.58	14,480	762

[1]Average reimbursement per enrollee on an incurred basis, except where noted.

Part B Projections Under Present Law[1]

Calendar Year	Physician Fee Schedule		Part B Hospital		Durable Medical Equipment	
	Aged	Disabled Non-ESRD	Aged	Disabled Non-ESRD	Aged	Disabled Non-ESRD
2003	1,263.11	1,190.84	378.19	470.64	182.20	302.52
2004	1,393.34	1,311.08	429.21	545.45	180.99	301.09
2005	1,451.27	1,354.77	482.59	602.99	181.31	303.92
2006	1,456.82	1,327.97	498.14	614.52	181.80	307.02
2007	1,428.28	1,313.39	527.81	655.89	178.26	305.51
2008	1,430.09	1,329.54	536.91	678.15	184.97	323.44
2009	1,459.42	1,364.59	561.03	716.66	188.65	336.77
2010	1,200.72	1,134.42	589.34	759.93	190.54	344.55
2011	1,158.11	1,095.03	632.20	815.49	200.34	364.09
2012	1,123.10	1,048.67	677.78	874.11	212.59	387.26

Calendar Year	Carrier Lab		Other Carrier		Intermediary Lab	
	Aged	Disabled Non-ESRD	Aged	Disabled Non-ESRD	Aged	Disabled Non-ESRD
2003	76.42	79.72	337.18	349.92	60.27	80.00
2004	82.36	86.53	362.39	394.84	65.27	88.18
2005	86.70	91.41	370.65	416.71	67.44	91.99
2006	89.75	94.92	375.76	379.88	67.62	92.56
2007	94.76	104.06	378.16	389.56	67.22	95.21
2008	97.95	113.14	374.00	405.60	66.12	96.53
2009	106.24	124.29	389.94	436.29	69.37	102.38
2010	109.81	129.63	399.97	448.65	67.96	101.27
2011	110.54	130.59	425.25	476.82	67.19	100.23
2012	117.25	138.33	452.30	505.73	70.51	105.07

Calendar Year	Other Intermediary		Home Health		Managed Care	
	Aged	Disabled Non-ESRD	Aged	Disabled Non-ESRD	Aged	Disabled Non-ESRD
2003	179.80	138.02	139.32	117.11	481.20	199.56
2004	205.81	165.80	159.56	133.66	537.12	233.86
2005	227.10	178.95	183.00	154.37	624.09	291.73
2006	232.17	193.37	206.78	175.63	835.76	529.27
2007	241.88	213.35	236.25	205.17	1,006.33	676.72
2008	245.10	220.65	252.04	217.40	1,197.45	823.14
2009	259.41	240.62	258.15	226.98	1,308.34	889.44
2010	246.99	240.31	259.86	231.77	1,392.73	932.58
2011	263.00	259.80	263.03	235.76	1,406.65	930.81
2012	278.68	278.67	271.14	245.27	1,451.31	965.53

[1]Average reimbursement per enrollee on an incurred basis.

Claims Processing Costs as a Fraction of Benefits

Calendar Year	Part A	Part B
2003	0.001849	0.011194
2004	0.001676	0.010542
2005	0.001515	0.009540
2006	0.001245	0.007126
2007	0.000968	0.006067
2008	0.000944	0.006414
2009	0.000944	0.006414
2010	0.000944	0.006414
2011	0.000944	0.006414
2012	0.000944	0.006414

Approximate Calculation of the USPCC and the National MA Growth Percentage for Aged Beneficiaries

The following procedure will approximate the actual calculation of the USPCCs from the underlying assumptions for the contract year for both Part A and Part B.

Part A:
The Part A USPCC for aged beneficiaries can be approximated by using the assumptions in the tables titled "Part A Projections Under Present Law" and "Claims Processing Costs as a Fraction of Benefits." Information in the "Part A Projections" table is presented on a calendar year per capita basis. First, add the per capita amounts for the aged over all types of providers (excluding hospice). Next, multiply this amount by 1 plus the loading factor for administrative expenses from the "Claims Processing Costs" table. Then, divide by 12 to put this amount on a monthly basis. The last step is to multiply by .97035 to get the USPCC for the aged non-ESRD. This final factor of .97035 is the relationship between the total and non-ESRD per capita reimbursements in 2010. This factor does not necessarily hold in any other year.

Part B:
The Part B USPCC can be approximated by using the assumptions in the tables titled "Part B Projections Under Present Law" and "Claims Processing Costs as a Fraction of Benefits." Information in the "Part B Projections" table is presented on a calendar year per capita basis. First, add the per capita amounts for the aged over all types of providers. Next, multiply by 1 plus the loading factor for administrative expenses and divide by 12 to put this amount on a monthly basis. Then multiply by .96240 to get the USPCC for the aged non-ESRD.

The National Per Capita MA Growth Percentage:
The National Per Capita MA Growth Percentage for 2010 (before adjustment for prior years' over/under estimates) is calculated by adding the USPCCs for Part A and Part B for 2010 and then dividing by the sum of the current estimates of the USPCCs for Part A and Part B for 2009.

Attachment III. Responses to Public Comments

Section A. Estimate of the National Per Capita MA Growth Percentage for Calendar Year 2010

As mentioned in Attachment I, the final estimate of the 2010 MA growth trend for combined aged and disabled beneficiaries is 0.81 percent, which is 0.3 higher than the preliminary estimate of 0.5 percent announced February 20, 2009 in the Advance Notice. The President's Budget current-law baseline was used for the preliminary estimate, and a more recent baseline was used for the final estimate. The primary reason for the higher final estimate is that the more recent baseline is based on a different set of economic assumptions. In addition, some additional program data and assumption modifications had nearly offsetting impacts.

Comment: Many commenters contend that, if rates are reduced, MA organizations will have trouble maintaining their provider networks, because they will have to pay providers less, and will have to raise premiums, increase copays and deductibles, especially in rural areas, Puerto Rico, in the case of Special Needs Plans (SNPs), PACE plans, and plans that are in direct competition with cost plans.

Response: Plans prepare bids that reflect their revenue requirements. If plan costs grow at a faster rate than increases in benchmarks, plans may choose to reduce their margins or benefits or increase premiums and copays from prior levels. Our intent here is not to hurt providers, beneficiaries or plans, but to update the rates in a way that is consistent with longstanding practice and current law.

Comment: Many commenters felt that the growth trend was underestimated, especially compared to other recent estimates. Some commenters argued that, based on the USPCCs published in the 2009 Payment Rate Announcement and the trend restatements published in the 2010 Advance Notice, trends have been running approximately 5% for the past 4 years. The −1.1% trend for 2010, they say, is materially lower than these trends.

Other commenters contended that the estimate of the Medicare growth in the Advance Notice does not track with other estimates of healthcare cost increases. On average, over the last decade, they say, Medicare spending has increased 5.8 percent annually. CMS' estimate of negative growth in the Advance Notice is significantly lower than other estimates, including other CMS estimates, such as the April 2008 announcement of MA rates (3.8%), the 2008 Medicare Trustees Report (4.6%), and a 2/24/09 *Health Affairs* Article (2.5%) written by CMS actuaries among others.

Therefore, commenters asked for more information on the calculation of the growth trend, especially in terms of projected trends in other Medicare expenditures (hospital inpatient and imaging, for instance), as well as utilization projections that may be relevant to explaining the low growth percentage.

Response: While the estimate for the national growth percentage has been succeeded by the final national growth percentage as announced in this notice, we provide the following rough derivation of the estimate announced in the Advance Notice.

In last year's rate announcement, we provided an estimate of the 2010 per capita growth rate of 3.8 percent. At that time, the relative reduction in physician fees for 2010 was expected to be 5 percent. Subsequent legislation amended the law to provide for roughly a 20 percent cut in physician fees beginning in January 2010. The difference between the originally expected cut of 5 percent and the cut of approximately 21 percent provided for under current law accounts for roughly a 3 percentage point reduction in the USPCC growth rate.

In addition, OACT has updated their databases since last year's estimates to account for new utilization and intensity trends. The updating of historical databases accounts for roughly another 1 percent change in the USPCC growth rate. The remainder of the difference between last year's estimate of 3.8 percent and the estimate of −1.1 percent is due to different economic assumptions which lead to lower provider market baskets, CPI, and other price indices used for updating payments to Medicare providers.

Some commenters pointed out what they suggested were inconsistencies in various published CMS growth rates for 2010. The 3.8 percent per capita growth rate in last year's announcement was based on the 2008 Trustees Report. The 4.6 percent cited in some comments was also from the 2008 Trustees Report. However, the 4.6 percent includes Part D expenditures whereas the 3.8 percent includes just Parts A and B. The 2.5 percent cited from the 2/24/09 Health Affairs article is also based on the 2008 Trustees Report. The 2.5 percent is growth in total expenditures, not per capita. In addition, the 2.5 percent was adjusted to account for the legislation that modified the physician fee increase for 2010, but it does not include any of the changes made from the updating of the historical data bases.

Some commenters have asked for more information on the growth trend. As has always been the practice, CMS provides detailed information on assumptions and trends in the final announcement of the payment rate update. See attachment II of this Notice.

Comment: Several commenters asked that OACT revisit several assumptions used in the growth trend. Commenters asked CMS to review economic assumptions that are utilized in the preliminary estimates in light of continuing increases in health care spending as well as the projected economic impact of the stimulus package. Other commenters wanted to better understand the analytic support behind the suggested lagged effect of a slowing economy on medical trends, specifically in the Medicare environment. Commenters said they did not believe that the slowing economy would result in reduced utilization of medical services by the Medicare population. Two commenters indicated that their MA plans have not experienced a drop in utilization of Part B drugs. One questioned whether the change in the trend is driven by a real decrease in part B drug utilization across Medicare or if it is an artifact of enrollment shifts from traditional FFS into MAPD plans, where hospital cost sharing is limited. Another has found that while unit costs are falling, utilization has continued to grow at a high rate. As a result, this commenter says, cost trends overall appear to have moderated in the past several years, but there have been no significant decreases in per member Part B drug costs.

Response: When OACT stated that new economic assumptions are one reason for a lower estimated per capita growth rate for 2010, they were specifically referencing the effect of the economic assumptions on projected unit costs. The lower economic growth rates affect various price indices such as the CPI, the hospital market basket, etc., which in turn affect projected unit costs. Utilization and intensity trends are developed from historical trends using the latest Medicare claims data available. For the latest budget baseline projections, OACT had fairly complete data for 2007 and about one-half year's data for 2008. For one service in particular, Part B physician administered drugs, the latest data showed much lower utilization compared to prior estimates. Our current data shows residual growth rates of about 7 percent per capita compared to prior estimates of about 16 percent per capita. We used this later data in developing the historical base and in developing the lower projected trend rates. Prior projections graded the trend down to about 7 percent. We now project a flat 7 percent residual factor. These trends are measured on a per capita basis, so they are not an artifact of enrollment shifts from traditional FFS into managed care plans as one commenter suggested.

Comment: Several commenters thought that CMS should follow what the commenters believed to be the assumptions in the President's Budget, and in the *Health Affairs* online article published 2/24/09, and assume in its estimate of the Medicare growth percentage that the 21% reduction in the physician fee schedule will not be implemented as provided for under current law. The assumptions in the President's Budget and the *Health Affairs* article would, in the opinion of these commenters, be a more reasonable predictor of the actual growth in Medicare expenditures considering Congress's historical actions on the issue of physician rates. Commenters suggested that CMS take historical patterns into account in making its estimate for the current year. Alternatively, commenters asked that CMS provide a citation to any provision of law that would prevent CMS from reflecting assumptions other than the reduction in the SGR provided for under current law in the development of the trend. One commenter recommends that OACT adjust utilization and coding factors in their model so that total physician reimbursement per beneficiary would be the same as if the physician schedule were increased as the commenter believes will happen, even while incorporating the reduction in the SGR provided for under current law. Other commenters suggested a transition to ensure a smooth transition to the new rates.

Response: The President's Budget and the *Health Affairs* online article both show current law projections that assume roughly a 21 percent cut in physician fees. While it is true that each shows an additional illustration of an adjustment to current law if physician fees were held constant, this is not the current law scenario. CMS's consistent interpretation and longstanding practice has been to base the projected growth percentage on the law as it exists on the date of the announcement of the payment rate update. The statute requires that the growth percentage reflect the Secretary's estimate of the projected per capita rate of growth in expenditures "under this title." We believe that the best read of this statutory language is that the growth percentage should be based on the provisions of "this title" (Title XVIII) as of the date that the rates are announced. As a result, every ratebook to date has been based on a USPCC increase estimated under the then current law. Changes to the Medicare statute are a fairly common occurrence. There have been a number of years where Medicare expenditures were expected to be reduced by pending legislative action. In those years, if we had anticipated the legislative changes in the projections, payments to Medicare Advantage plans would have been reduced. By following current law as the basis for the projection, any judgment regarding the likelihood or implications

of unknown possible law changes is removed. Plans have sometimes benefited from this practice and other times been disadvantaged by it. In each case, the advantage or disadvantage has been temporary, affecting only the first contract year following the change in law.

Comment: One commenter asked how the 2010 rates will be adjusted if Congress acts to stop the 21% physician pay cut. Commenters asked that we make efforts to incorporate the approach at another time before the 2010 contract year, such as through the bidding process. Forecasting a decrease in the current year and allowing for a correction in the future will cause unnecessary benefit cuts or premium increases.

Response: We are required by law to release the CY2010 ratebook on April 6, 2009. We expect that this will be the ratebook that will be used in the CY2010 bid preparation and plan payment. If Congress acts to override the physician pay cut, CMS will work with Congress to explore viable options for incorporating any changes in physician pay into the MA payments for CY 2010.

Comment: Several commenters asked for our legal basis for not giving MA organizations a 2% minimum increase.

Response: Section 5301 of the Deficit Reduction Act of 2005 (DRA) added §1853(k) of the Act to create a single rate book for calculating Medicare Advantage (MA) payments and applicable adjustments. The DRA also modified the methodology for updating the MA payment rates by adding §1853(k)(1)(B) of the Act. Beginning in 2007, the statute requires that the previous year's benchmarks be updated annually using the national per capita MA growth percentage as described in §1853(c)(6) of the Act. Since the statute, as revised by the DRA, no longer provides for the 2 percent minimum update, CMS cannot apply it to the 2010 MA rates. The 2 percent minimum update still applies to the end stage renal disease MA update because the statute at §1853(a)(1)(H) provides that ESRD rates are to be calculated in a manner consistent with the way those rates were calculated "under the provisions of [section 1853] as in effect before the date of enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003." The pre-2003 version of section 1853 of the Act included the 2 percent minimum update.

Comment: One commenter suggested that PACE needs its own rate book because it cannot charge premiums or deductibles and therefore cannot respond to a decrease in the rate book.

Response: PACE rates are determined in accordance with §1894(d) of the Act. PACE plans already have their own rate book in the sense that, unlike all other MA plan payment rates, IME payments are not carved out of PACE rates. Under current law, CMS does not have authority to apply a different growth percentage to the rates for PACE plans.

Comment: One commenter asked that we publish an explanation of how each kind of payment amount is determined. The commenter would especially like an explanation of which fields on the MMR are used to establish payment for an ESRD case, which fields in the bid tool are the drivers for the fields in the MMR, etc.

Response: CMS is in the process of drafting a Medicare Manual Chapter with this information. We will seek comment on the revision in the near future.

Comment: We received two comments on the Bid Pricing Tool and one regarding payments to physicians.

Response: The subject of the Advance Notice is payment to Medicare Advantage organizations. These comments are not relevant to the subject of the Advance Notice. We will respond to these comments in the appropriate forums. We will respond to comments on the Bid Pricing Tool during our Actuarial Bidding Calls this Spring.

Section B. Frailty Adjustment

Comment: One commenter believed that the current risk adjustment system does not adequately account for limitations of daily living for those MA enrollees who live in the community despite being at an institutional level of care. The commenter encouraged CMS to make changes to address payment adequacy for this population. One commenter was concerned that the revised frailty adjustment model in combination with the CMS-HCC risk adjustment model does not fully account for Medicare costs for beneficiaries comparable to those enrolled in PACE. The commenter encouraged CMS to accelerate efforts to assure that the risk adjustment model and frailty adjustment accurately reflect costs incurred by a PACE-eligible population.

Response: CMS is continuing to study ways to predict the expenditures of high cost beneficiaries enrolled in MA and PACE plans. By statute, CMS must adjust payment to PACE organizations for frailty, and has historically made a separate adjustment to PACE rates under this authority. By law, CMS must pay all MA plans, including SNPs, using the same risk adjustment methodology.

Comment: One commenter asked if the reference to the 2008 HOS-M was a typographical error and if we instead meant the 2009 HOS-M.

Response: The commenter is correct; CMS will use the 2009 HOS-M as the source of ADL distribution for the 2010 frailty scores.

Section C. Normalization Factors for the Rx Hierarchical Condition Category (RxHCC) Model

Comment: Several commenters expressed concerns that normalizing the Part D risk scores based on Part D enrollees instead of Part D eligible beneficiaries would increase premiums and be disruptive to Part D beneficiaries. Two commenters variously estimated that the proposed 2010 Part D normalization factor of 1.146 would increase monthly beneficiary premiums by amounts ranging from $2 to $9. One commenter indicated that the proposed Part D normalization factor will result in a significant reduction to the 2010 Part D risk scores that will exceed the risk score trends compared to the 2008 base year. The commenter stated that this reduction in 2010 Part D risk scores will shift costs from the federal government to Medicare beneficiaries in a way that will cause Part D premiums to increase faster than prescription drug costs.

Response: We expect that the methodology change will increase beneficiary Part D premiums, but by a relatively modest amount ($1-$2). This change is necessary to help ensure that the beneficiary premium is equal to 25.5 percent of aggregate plan payments as specified in statute.

Comment: We received a couple of comments suggesting that CMS maintain the current methodology and develop the Part D normalization factor based on Part D eligible beneficiaries. The commenters expressed concerns that the proposed methodology would result in the decreased enrollment of healthy beneficiaries. One commenter indicated that normalizing the Part D risk scores based on Medicare Part D enrollees would increase the possibility of an upward spiral in premiums and a downward spiral in enrollment as healthy beneficiaries drop out or choose not to enroll in the Medicare Part D program in the first place.

Response: We disagree with the commenters. Using the risk scores of Part D enrollees to develop the Part D normalization factor will help to ensure that the beneficiary premium remains at the appropriate proportion of aggregate plan payment: approximately 25.5 percent from beneficiary plan premiums and 74.5 percent from the government as intended by Congress. We do not expect that the increase in Part D beneficiary premiums will be large enough to create a significant disincentive for the enrollment of healthy beneficiaries, nor that it will create an upward spiral in beneficiary premiums.

Comment: Several commenters recommended that CMS phase in the proposed change in methodology to create a smooth transition from the current methodology to the proposed methodology. Commenters recommended phasing-in this proposed change over 2, 3, or 4 years to provide Part D sponsors with sufficient time to adapt to this change and reduce disruption to Part D beneficiaries. One commenter stated that implementing a transition period for this change in methodology would be consistent with the phasing in of other significant changes such as the changes to the frailty factors and the low-income subsidy (LIS) benchmarks.

Response: We do not believe that an additional transition period is needed to phase-in the new methodology for determining the Part D normalization factor. The change in our methodology for computing the Part D normalization factor is intended to ensure that the beneficiary premium remains at the appropriate proportion of aggregate plan payment. We also note that to the extent that the Part D normalization factors for contract years 2008 and 2009 were developed based on the risk scores for Part D eligible beneficiaries the normalization factors were lower than they would have been if the normalization factor had been based upon Part D enrollees. As a result, these years were, in effect, a transition period before the implementation of a Part D normalization factor based upon Part D enrollees.

Comment: One commenter recommended that CMS synchronize the proposed change to the methodology for normalizing the Part D risk scores with the development of a new RxHCC model based on historical medical and prescription drug data. The commenter indicated that both changes would significantly affect beneficiaries and therefore, should be implemented during the same contract year to minimize disruption to beneficiaries.

Response: While we appreciate the concerns expressed by the commenter, we believe that the transition to normalizing based on Part D enrollees should not be delayed an additional year.

Comment: One commenter stated that the proposed methodology does not consider the risk scores of newly enrolled or newly eligible beneficiaries and recommended that CMS adjust the Part D normalization factor to account for these enrollees. Another commenter indicated that the composition of the Medicare Part D enrollee population could change under current financial conditions due to Medicare Part D eligible beneficiaries losing their employer group benefits. The commenter asserted that the proposed 2010 Part D normalization factor could be lower if there is an increase in the number of younger (and healthier) beneficiaries who seek to enroll in Medicare Part D due to loss of employer coverage.

Response: The risk scores for newly enrolled individuals were included when determining the 2010 Part D normalization factor. We believe that it would be inappropriate to make an adjustment to the 2010 Part D normalization factor based on current financial conditions since CMS cannot accurately determine how Part D enrollment will be affected. For example, while there may be an increase in the number of healthy beneficiaries who enroll due to the loss of employer benefits, there could just as likely be a significant increase in the number of LIS-eligible beneficiaries who enroll in Medicare Part D for the same reason.

Comment: We received a couple of comments suggesting that CMS include individuals receiving drug coverage under the Retiree Drug Subsidy program in the base of Part D enrollees used to normalize the Part D risk scores. The commenters asserted that these individuals are participants in the Medicare drug program under the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) and therefore, should be included as Part D enrollees. One commenter also recommended including Part D eligible individuals enrolled in employer plans when determining the Part D normalization factor.

Response: Part D beneficiaries enrolled in employer group/union-only waiver plans (EGWPs) were included when determining the Part D normalization factor. We disagree with the commenters' recommendation that CMS include individuals receiving drug coverage under the Retiree Drug Subsidy program when determining the Part D normalization factor. These individuals are not affected by Part D risk adjustment and are explicitly excluded from the Part D payment calculations including the national average monthly bid amount and the regional LIS benchmarks. Thus, we believe it would also be inappropriate to consider these individuals when determining the Part D normalization factor.

Section D. Budget Neutrality

The Deficit Reduction Act (DRA) of 2005 specifies the components that CMS must include in the estimate of budget neutral (BN) risk adjustment factor, and codifies the phase-out of the BN factor. As in prior years, the BN factor was estimated as the difference between aggregate payments to plans using 100 percent demographic payments and aggregate payments to plans using 100 percent risk adjustment payments, expressed as a percent of risk adjusted payments. For purposes of the calculation, CMS assumes that risk payments to plans will be at the local benchmarks, adjusted for each plan's risk score. CMS calculates a single BN factor for all MA plan enrollees.

The BN factor estimate for 2010 is 0.10%. This factor was calculated based on a full BN factor of 2.0%, multiplied by the BN phase-out percentage of 5 percent. 2010 is the fourth and final year of the phase-out required by the DRA, and 5 percent of the full BN factor is applied to the rates, as the same percentage for all counties.

Section E. Adjustment for MA Coding Pattern Differences

In the Advance Notice, we proposed a coding difference adjustment of 3.74%. This adjustment was based on adjusting for three years of differential coding between MA and FFS, i.e., from 2007 to 2010. This adjustment factor was calculated based on beneficiaries who were enrolled for seven months or more in any given year, using data for three cohorts (2004-2005, 2005-2006, and 2006-2007). In the Notice, we stated our intention to update the adjustment factor with data for an additional cohort (2007-2008) for the Rate Announcement.

Our analysis of the 2007-2008 cohort showed that coding pattern differences have accelerated and this finding has strengthened our conclusion that coding pattern differences between MA and FFS are having a notable impact on payment. Because this is the first year that CMS is implementing this MA coding adjustment under the provisions of the DRA, however, CMS is taking a conservative approach and implementing an adjustment factor using a coding difference factor based on the earliest three cohorts (2004-2005, 2005-2006, and 2006-2007). CMS will consider the 2007-2008 data and later cohort data for future MA coding pattern difference factors.

CMS received a number of comments suggesting that the stayer percentage and enrollment duration factor used to calculate the MA coding pattern difference adjustment factor should be based only on beneficiaries who are enrolled in MA for a full 12 months in any given year, rather than seven months or more. CMS concurs with these comments; in finalizing the 2010 MA coding pattern difference adjustment factor, CMS is basing the stayer percentage and enrollment duration factor on 12 months of continuous MA enrollment.

Based on these changes in methodology, the final 2010 MA coding intensity adjustment will be 3.41%. Table 1 summarizes the calculation of the adjustment.

Table 1: Calculation of Difference Factor

Calculation of difference factor for 2010 Cohorts between 2004 and 2007 EDF = 2.38 Stayer percentage = 81.8%	
Weighted average of Year 2 MA risk scores	0.9806
Weighted average differences in disease score growth	0.0171
Difference factor as a percent of risk score	1.75%
Apply EDF to obtain adjustment factor (2.38)	4.16%
Adjust for percent of stayers to allow application of adjustment factor to all enrollees' risk scores (81.8%)	3.41%

Comment: A number of commenters offered CMS strong support for our determination in the Advance Notice that we were required to apply a coding pattern difference adjustment in 2010. Several commenters cited several reasons why the adjustment was appropriate. They agreed with CMS that the adjustment will improve payment accuracy, reduce unnecessary Medicare expenditures, and better assure financial neutrality between FFS and MA. Some commenters opined that the adjustment was long overdue. Commenters noted that MA organizations had an incentive to identify and code diseases, whether the diseases were treated or not, and that as a result unadjusted risk scores show MA enrollees to be sicker than they actually are. Several commenters noted that the increased MA payments resulting from coding pattern differences are in addition to the 14% payment differential resulting from MA benchmarks being set above Medicare FFS levels. One commenter noted that because physicians in FFS do not have a financial incentive to code as intensely, MA plan risk scores can increase at a greater rate than FFS risk scores, making MA enrollees look less healthy and more costly without any change in their actual health status.

Response: We concur with these comments.

Comment: Several commenters argued that the coding pattern difference adjustment was being made on the assumption that coding observed in the FFS program is accurate, and argued that CMS should not penalize MA organizations for differing from FFS coding patterns if, in fact, these FFS patterns were somehow inaccurate or inadequate. One commenter expressed concern that the adjustment would penalize many organizations for doing what CMS and Congress intended when they implemented risk adjustment payments (invest resources to improve data collection and educate providers on proper documentation). One commenter contended that a significant differential should be expected between FFS and SNPs for SNPs that code accurately. Another commenter claimed that risk scores of beneficiaries in Original Medicare are depressed by the inadequate coding of chronic conditions on FFS claims. One commenter does not believe that it is in keeping with Congressional intent for CMS to make a negative adjustment to all plans regardless of whether improper or inaccurate coding has been identified; another commenter thought that an across-the-board adjustment conflicted with Congressional intent to adjust payments for "differences resulting from inaccurate coding."

Response: As we stated in the 2009 Advance Notice, we do not assume that the coding pattern differences that we found in our study are the result of improper coding. As documented in the 2009 Announcement, CMS believes that the statutory language in the DRA provision at issue provides for a payment adjustment if CMS establishes that there are "differences in coding patterns between Medicare Advantage plans and providers under part A and B."

Given the fact that the MA payment methodology is based on fee-for-service payments, and that the risk adjustment methodology is designed to compare the risk scores of MA plan enrollees to other plan enrollees and beneficiaries not enrolled in MA plans, for this comparison to be valid, MA plans must code the way Medicare Part A and B providers do in order for risk adjustments to be valid. This means that MA organizations are coding "accurately" when they are coding in a manner similar to fee-for-service coding used on the beneficiaries to whom MA plan enrollees are being compared. In this sense, "differences" in coding patterns, regardless of the source, would make the MA plan coding "inaccurate" for purposes of implementing risk adjustment.

This reading of the word "inaccurate" is supported by floor statements made by Senator Grassley, Congressman Barton, and Congressman Thomas. Senator Grassley made the following floor statement; the other two committee chairs made very similar statements:

> "Section 5301 and the joint statement which accompanied the conference report in the Senate requiring adjustments for differences in coding patterns is intended to include adjustments for coding that is inaccurate or incomplete for the purpose of establishing risk scores that are consistent across both fee-for-service and Medicare Advantage settings, even if such coding is accurate or complete for other purposes. This will ensure that the goal of risk adjustment—to pay plans accurately—is met."

Comment: One commenter argued that, since CMS did not make adjustments in 2008 and 2009, this necessarily must mean that data available to CMS as late as April 2008 did not demonstrate that the changes in risk scores were the result of differences in coding patterns, and that CMS accordingly should not apply an adjustment based on 2007 to 2008 data. Under this argument, CMS cannot now state that a change in risk score trends can be conclusively attributed to differences in coding patterns based on pre-April, 2008 dates. This commenter argued that CMS can adjust the capitation rates only to compensate for that one year of differential. In other words, the commenter argued that CMS implicitly had previously found that prior years of risk score trends can be explained based on factors other than coding patterns, and thus should not rely on the data to make an adjustment. Another commenter opined that the information in the 2010 Advance Notice fails to present substantive new evidence free of technical concerns.

Response: While, in previous years, CMS has delayed the application of a coding patterns difference adjustment in order to conduct further research, this did not mean that we had concluded that risk score trends were caused by factors other than coding pattern. Our most recent analysis – discussed below – has resulted in our decision to apply a coding pattern differences adjustment in 2010. We believe that, having concluded that the differences we have observed are in fact attributable to differences in coding patterns, it is appropriate to use data from the beginning of the program, as deemed necessary to better ensure appropriate and accurate payments.

Comment: Several commenters, noting that CMS had indicated in last year's Announcement that we would use the results from the risk adjustment data validation (RADV) audits to inform our assessment of whether risk score differences were driven by coding pattern differences, rather than by the health status of MA enrollees, inquired about our findings and how they supported the coding pattern difference adjustment. A number of commenters were concerned that CMS would be making an adjustment twice for the same coding effects if it applied both a coding pattern difference adjustment and made adjustments as a result of its RADV audits. Several commenters expressed concern that a prospective coding intensity adjustment in combination with future 2010 risk score audits could result in duplicate adjustments. A few commenters asked if CMS was adjusting the 2007 risk scores used in developing the MA coding pattern difference adjustment factor for adjustments made as a result of the RADV audits. Some commenters suggested that, instead of implementing a coding pattern difference adjustment, we rely on the RADV audits. They contended that the current risk score validation audit process was the appropriate system to determine coding accuracy and payments should only be adjusted for the subset of plans in which coding problems can be documented.

Response: CMS' strategy for determining the correct MA coding pattern difference for 2008 and 2009 was to ensure that we thoroughly understood the dynamics behind the coding pattern differences between MA and FFS. In this spirit, we agreed to assess whether the new annual medical record audits would be able to inform our study of MA coding pattern differences. Medical record audits serve the purpose of determining whether diagnosis codes submitted to CMS for risk adjustment payment purposes have a basis in the documented medical record, while our study of MA coding pattern differences has resulted in a better understanding of the differential growth in the number of diagnosis reported by MA plans and FFS providers. The results of the medical record audits supported our approach to calculating the MA coding pattern differences adjustment by failing to show a systematic correlation between coding pattern differences and errors in the reporting of documented coding.

Comment: Several commenters argued that CMS was not authorized to make a retroactive coding pattern difference adjustment. Another commenter asked if the adjustment would be used for 2010 alone, or would also be used to make retroactive adjustments. Several commenters opined that the DRA did not require a retroactive adjustment and that, since the MA payment methodology is fundamentally a prospective system, that absent an explicit statutory direction to impose a retroactive adjustment, CMS should not apply adjustments it now deems appropriate for 2008 and 2009 into 2010 payments. A couple commenters argued that the DRA established coding intensity to be a single annual adjustment made for each coverage year, if supported by the data, and felt that the MA coding pattern difference adjustment described in the Advance Notice was intended to retroactively apply an adjustment for 2008 and 2009. One commenter felt that this was not the intent of Congress and the other commenter felt that this adjustment would be made for years when CMS found that it did not have adequate information to justify an adjustment.

Response: CMS is not making a retroactive adjustment. We estimated the cumulative coding pattern difference in MA and FFS stayers' disease scores in 2010. We calculated this adjustment by applying a three-year enrollment duration factor (EDF) to the annual average difference in disease score growth, essentially calculating the adjustment to account for three years of coding pattern differences. As a result, the coding adjustment is an estimate of how much lower risk scores would be in 2010 if they rose at the same rate as FFS risk scores over the period 2007-2010. We note that some commenters supported using six years (2004-2010) in the calculation based, taking into account all measured differences since risk adjusted payments were begun.

Comment: One commenter believed that using a 2-year stayer cohort captures a large proportion of MA stayers that are new to MA with no coding history in year-one with potentially larger coding increases in the second year as the plan gains accurate diagnosis data. Another commenter opined that the calculation of the adjustment does not seem to acknowledge a trend observed by MA organizations in which a beneficiary's risk score increases more quickly during the second year that the beneficiary is enrolled in an MA plan and that, therefore, the enrollment effect that the agency attempts to isolate may be larger than assumed in the notice. One commenter suggested studying 3−and 4-year stayer cohorts; they also recommend that CMS study the cohort of individuals that would not qualify as stayers due to being in MA or FFS for only a single year over the examined time period.

Response: The method by which CMS constructs its two-year stayer cohorts ensures that the experience of beneficiaries newly enrolled in MA are not included in the difference measurement. Requiring enrollees to have been enrolled for thirty months results in first-year disease scores that were coded exclusively by either MA plans or FFS providers and, thus, CMS is comparing year-after-year disease scores that were coded exclusively by a single sector. These cohorts will capture some enrollees' second and third years in MA, but it will also capture differential disease score changes for enrollees who have been enrolled in either sector for longer periods of time. Therefore, the difference factor is calculated over all beneficiaries who have been enrolled in a sector over varying periods of time, thereby obtaining an average difference across all continually-enrolled beneficiaries.

The use of cohorts over more than two years would result in smaller cohorts of non-representative beneficiaries in that they were alive much longer and they were enrolled in their respective sector for longer than beneficiaries in the two-year cohorts. For example, beneficiaries who are in MA for at least 3 or 4 years are not identical to those who are enrolled for at least two years. Two-year cohorts capture the information needed while keeping the largest number of enrollees in the cohorts.

Comment: One commenter stated that, since CMS acknowledges that a significant portion of Medicare beneficiaries who join MA plans are switching from FFS, and that the vast majority of beneficiaries joining FFS are newly eligible and have very low risk scores, basing an adjustment of risk scores on a comparison of FFS to MA enrollees will overstate the differences between the two groups.

Response: CMS constructs the cohorts in such a way that "joiners" and "leavers" – beneficiaries who switch from one sector to the other – are excluded from the population on whom we calculate the difference factor. The cohorts only include beneficiaries who have been in MA or FFS for several years – at least 30 months.

Comment: A couple commenters expressed interest in having CMS recognize that MA plans' effort to "catch up" with FFS in the coding pattern difference adjustment factor. One commenter felt that changes in coding due to "catch up" fell outside the purview of the DRA and strongly suggested that the agency consider changes to the calculation of the adjustment to exclude "catch up" to more directly address the statutory requirement. Another commenter felt that, after seeking to take "catch up" into account last year, CMS should recognize it in the 2010 adjustment factor. One commenter offered an example of a way to adjust for "catch up" that involved applying a ratio of the amount by which the average MA risk score was below the FFS 1.0 when risk adjusted payments started, relative to the amount by which the average MA risk score was greater than the FFS 1.0 in later years.

Response: While we are using cohorts starting with 2004-2005 to calculate the average difference factor, we are only taking into account three years of experience in the enrollment duration factor (EDF). Any catch up occurring in the first three years (2004-2007) of risk adjusted payments is not factored into the duration factor and, therefore, not included in the coding pattern difference adjustment. In other words, by adjusting the annual average difference by the average enrollment over the past three years, CMS is only adjusting 2010 risk scores by

the cumulative effect of coding pattern differences over three years, and not over all six years since the start of risk adjusted payments.

Comment: One commenter stated that the enrollment duration factor (EDF) seems intended to reflect the number of beneficiaries to whom a coding intensity adjustment would have been appropriately applied in 2008 and 2009 (if the agency had made a determination to apply such an adjustment in time to affect payments in those years) and prospectively in 2010. Another commenter questioned why CMS was using an enrollment duration factor and felt that an adjustment based on the disease scores would take differences into account. This commenter argued that CMS had not established that there was a link between length of MA enrollment and higher risk scores or explained how the EDF meets with the intent of the DRA.

Response: The enrollment duration factor (EDF) is used to adjust the annual difference factor in order to approximate the experience of stayers in 2010. In other words, the EDF creates a single year, prospective estimate of cumulative difference between MA and FFS disease scores (not just the marginal growth in the difference from the previous year). A less nuanced way to calculate the cumulative difference would simply be to multiply the average annual difference (the difference factor) times the number of years being taken into account. The EDF allows CMS to adjust the annual average difference by the estimated enrollment experience of the beneficiaries in MA during the payment year.

Comment: Several commenters recommended that the adjustment incorporate an analysis of coding pattern differences in four cohorts available at the time the Announcement is published: 2004-2005, 2005-2006, 2006-2007, and 2007-2008. They felt that doing so would permit the agency to more precisely determine the appropriate magnitude of the adjustment while considering data from the 2004-2005 data collection year, when risk adjustment was first a significant component of MA plan payments. One commenter felt that, since the coding difference experience seems to be volatile and unpredictable, using four cohorts would add some stability to the calculation. They cited OACT's use of 5-year moving averages of the ratio of the county FFS per capita costs to national per capita costs when estimating the FFS costs in each county.

Response: Because 2010 is the first year that CMS is applying the MA coding pattern difference factor under the provisions of the DRA, we have decided to take a conservative approach and calculate the difference factor using only the first three cohorts, as described in the Advance Notice. After applying the new enrollment duration factor (EDF) (see below), the MA coding pattern difference factor for 2010 is 3.41.

Comment: Several commenters disagreed with the use of seven months enrollment in the prior year to determine whether someone is a stayer for purposes of the enrollment duration factor (EDF) and felt that twelve months would be a more appropriate measure. Commenters contended that an MA organization needed at least one full year of enrollment experience with a beneficiary to credibly calculate a member's risk score and that 12 months was in alignment with the idea that the adjuster should be applied to "stayers." One commenter understood that the EDF makes the assumption that the adjustment factor would be the same for members with between 7 and 30 months of plan membership, and believed that this was highly unlikely, and that the effect of relative coding intensity are likely to increase over time. One commenter asked

how CMS had validated that a 7 month time period is sufficient to capture the HCC diagnoses for a member.

Response: The objective of the enrollment duration factor (EDF) is to capture the average number of years a population of enrollees has had their diagnoses submitted by the MA sector; for this factor, we are not trying to capture change in disease score, but exposure to MA coding patterns. In response to industry concerns regarding the adequacy of seven months of enrollment in capturing and reporting enough diagnoses codes to establish a pattern, CMS will use twelve months in previous years as a criteria for calculating the EDF. Using twelve months, applied to the same time period as in the Advance Notice – 2007-2010 – the EDF that CMS will use in calculating the adjustment factor will be 2.38.

Comment: One commenter noted that plans with more turnover will have lower EDFs. Other commenters asked if an analysis had been done to see how much variance there is in enrollment duration from plan to plan.

Response: CMS recognizes that enrollment duration may differ among plans. Because we have determined that it is most appropriate to apply an industry-wide adjustment, the EDF used in the calculation will, by its construct, be an industry average.

Comment: One commenter wanted CMS to use the same definition of "stayer" when determining the stayer percentage as we do when developing the cohorts used for measuring the coding pattern difference (30 months of continuous enrollment).

Response: Because CMS will apply the adjustment to all enrollees' risk scores, not just stayers, we need to reduce the adjustment proportionately so that the aggregate effect is the same, whether we applied the adjustment to stayers only or to all enrollees. To calculate the actual adjustment to use in payment, we reduce it by the proportion of stayers in MA for the most current period available. In applying the twelve month enrollment criteria in calculating previous-year enrollment for the EDF, we also changed the calculation of the stayer percentage that we will use to reduce the adjustment factor for application in payment. The stayer percentage we will use is 81.8%.

Comment: Commenters suggested a number of additional factors that they thought CMS should adjust for in calculating the coding pattern difference adjustment factor. The additional factors suggested are: age, gender, originally disabled, Medicaid eligibility, institutional status, hospice status, beneficiaries with multiple chronic conditions, duration in managed care, health status, type of plan, plan size, socio-economic status, racial/ethnic differences, and enrollment in the Veterans Affairs or Department of Defense health programs. A number of commenters requested that CMS adjust for regional differences in FFS coding differences. One commenter felt that plans with a high proportion of recent FFS members or in regions where MA coding changes are not greater than FFS are disadvantaged. One commenter suggested that possible anti-selective effects in MA were resulting in an overestimate of MA's rising risk scores. One commenter asked how CMS knew that measured differences in coding changes between MA and FFS were really coding pattern changes and not changes in health status.

Response: CMS did take into account factors that we believed would have an important influence on the rate of change in disease score growth between MA and FFS. For example, we adjusted the difference factor (the annual average difference in disease score growth between MA and FFS) for age and survivor status variations between MA and FFS. Because a greater proportion of disabled beneficiaries are enrolled in FFS than in MA, and because disabled beneficiaries risk scores tend to grow more slowly than aged beneficiaries' risk scores, adjusting for age reduced the differences in disease score growth between the two sectors. In addition, the enrollment duration factor (EDF) takes into account the average duration of enrollment in the MA sector of those who are present in the year prior to the payment year. We believe that age and survivor status are correlated to the differential change in disease scores between MA and FFS, and that duration of enrollment in the MA sector directly affects how long a beneficiary's disease score has been exposed to this differential. It is not clear that other factors would affect differential changes in disease score.

Comment: One commenter inquired about which version of the CMS-HCC model we used to calculate the coding pattern differences.

Response: CMS used the version of the CMS-HCC model that was used in payment from 2004 through 2006 to calculate the difference factor. We ran all cohorts through the same version of the model, so that measurements of differences would not be affected by model changes.

Comment: One commenter wanted CMS to establish an appeals mechanism that would allow plans to demonstrate that their coding patterns are correct.

Response: As discussed above, the MA coding pattern difference adjustment is not adjusting for coding that is incorrect, but for coding that differs from FFS and is therefore inaccurate for payment. Further, the industry-wide adjustment factor will not be modified for individual plans.

Comment: In the 2010 Advance Notice, CMS invited comments on the decision to adjust for differences in disease growth for the three-year period prior to 2010, as well as on alternative approaches involving a greater or smaller number of years. A number of commenters wanted CMS to adjust for one year instead of three. One commenter states that using the annual rate going back to 2004 would the most reasonable approach. One commenter stated that CMS should make an adjustment on a prospective basis only, which they took to mean a single year adjustment. Several commenters argued that the DRA requires CMS to adjust for all differences in coding patterns, and suggested that CMS should adjust for all measured and projected differences, including those attributable to the excluded period for 2004-2007. Another commenter noted that, while one alternative was to make an adjustment for all years during which comprehensive risk adjustment has been in place – that is, 2004 to 2010 -- on balance they were inclined to think that the methodology described in the Advance Notice was appropriate.

Response: The difference factor, which takes into account coding pattern differences from 2004 to 2007, is an average annual difference in the growth of disease scores between MA and FFS. Based on the data that we have, it is clear that coding pattern differences have continuously grown since 2004 and that 2010 risk scores will incorporate repeated years of coding pattern differences. We have decided to maintain for 2010 the use of three cohorts as proposed in the Advance Notice.

Comment: One commenter expressed concern that the MA coding difference adjustment would reduce the disease score, causing a greater portion of the risk score to be based on demographic factors, which would introduce limitations and problems of the old AAPCC approach.

Response: CMS is calculating the MA coding pattern differences adjustment factor based on disease scores because that is the portion of the risk score that plans have control over. However, the adjustment is being applied simply as an overall proportional reduction to the risk scores, leaving the proportion of the risk score that is determined by diseases intact.

Comment: One commenter suggested that FFS normalization and MA coding pattern difference adjustment should be subtractive, not additive, or plans will be penalized twice for coding practices observed in the FFS program.

Response: The two adjustments address two different measures of coding changes: the FFS normalization factor adjusts risk scores for underlying changes in FFS coding and the MA coding pattern difference adjustment factor adjusts for coding patterns above and beyond the FFS changes.

Comment: One commenter asked if the three-year adjustment discussed in the Advance Notice would lead to a restatement of the historical budget neutrality adjustments for those years.

Response: As discussed above, the 2010 MA coding pattern differences adjustment is not a retroactive adjustment, but an estimate of the cumulative difference between MA and FFS stayers' disease score in 2010. CMS will take the projected reduction in 2010 risk scores into account when calculating the 2010 budget neutrality factor.

Comment: One commenter expressed concern that the extent of the adjustment may cause health plans to consider withdrawing from the market given the short time to prepare the 2010 bids. A couple commenters expressed concern that the proposed across-the-board 3.74% reduction would have a major negative effect and is a departure from last year's proposal to gather plan-specific coding changes through targeted audits.

Response: While we appreciate that the application of the MA coding pattern difference adjustment will need to be taken into account in MA plan bids, we believe that the final 3.41 percent adjustment is an appropriate correction that will result in more accurate payments. In addition, the adjustment is consistent with the statutory requirement that we study whether there are different diagnoses coding patterns between MA and FFS and, if we find differences, that we adjust MA risk scores accordingly.

Comment: A number of commenters did not support an industry-wide coding pattern difference adjustment and either wanted CMS to implement a more targeted adjustment or delay or phase in the adjustment. Some commenters wanted CMS to apply the coding pattern difference adjustment to a defined subset of plans that fail the risk validation audit or plans with larger differences in risk score growth. Commenters felt that an industry-wide adjustment would be unfair to plans that have under-coded and create an incentive of promoting coding intensity by those plan that have previously under-coded. Commenters suggested that CMS use a plan-specific EDF, or apply an adjustment in tiers to take into account different levels of turnover. A few commenters felt that SNPs would be at a disadvantage because there was an increased

volume of encounters for their members and because the percent of stayers was likely to be less than the average MA plan rate. A number of commenters supported an industry-wide adjustment; one commenter cited the following advantages: (1) industry-wide adjustments were the practice in other sectors of Medicare, (2) all MA plans should be paying close attention to coding and documentation and it was reasonable to expect coding changes to be widespread, (3) coding behavior of a particular provider does not necessarily affect just one plan, (4) beneficiaries move from one plan to another and retain the diagnosis codes assigned; and (5) when using MA data, a system-wide adjustment will ensure that baseline information is accurate.

Response: In addition to the reasons given by commenters, CMS was also persuaded by comments on the 2009 proposal – which proposed an adjustment on a subset of contracts – that an industry-wide adjustment provides an even playing field when plans compete: newer plans may be able to code just as intensely as older plans, but would not have been in existence long enough for CMS to calculate an adjustment factor for them. Further, applying an adjustment factor to a subset, or tiered adjustment factors across contracts, results in cut offs that can potentially appear unfair, especially if one contract falls just above and another just below a cutoff. To avoid these problems, as well as for the reasons cited by the more recent comments, we have decided that an industry-wide adjustment is the most efficient and effective approach to making an adjustment for MA coding pattern differences.

Comment: One commenter suggested that CMS should review and compare samples of MA plan member medical records with a FFS control group and that the difference in risk scores derived from the medical records could support an across-the-board coding pattern adjustment in a subsequent year.

Response: While a comparison of diagnostic coding captured on medical records in MA and FFS would indicate differences in documentation of diagnoses coding in the medical record, there are two key shortcomings of this approach in calculating an MA coding pattern difference adjustment factor. The key comparison in studying the impact on payment of differences in coding patterns between MA and FFS is the codes that are submitted and codes that are reflected in the model. In addition, CMS is taking into account changes in disease scores over time and taking a sample of medical records will not provide that information.

Comment: One commenter did not agree that CMS should calculate coding pattern differences for each individual and, instead, recommended that the difference be calculated by dividing the MA growth in risk scores by the FFS growth in risk scores for each age and survivor status grouping in each cohort.

Response: CMS did not calculate individual differences in disease score growth; we calculated the difference between the average growth in disease scores among MA stayers and the average growth in disease scores among FFS stayers for each cohort. This difference calculation was adjusted for each age and survivor grouping in each cohort. It is not clear how CMS would use the ratio of MA growth to FFS growth in applying an adjustment.

Comment: A number of commenters requested that CMS release all relevant information and calculations concerning the MA coding pattern difference adjustment factor in order to make sure that the adjustment is fully explained and transparent to the public to the same extent that

they are for the FFS program through regulation. A couple commenters believed that CMS has not provided enough transparency in the methodology used to calculate the coding pattern differences for the public to properly evaluate the calculation CMS has completed.

Response: We would be happy to provide addition information about the steps and results of our MA coding pattern differences analysis to interested stakeholders.

Section F. Encounter Data Reporting

Comment: One commenter encouraged CMS to continue its efforts to collect additional data from MA plans, including data relating to all medical encounters between beneficiaries and providers, to improve the accuracy of the risk adjustment system, and to measure the effectiveness and integrity of MA plan benefits.

Response: CMS will release guidance in 2009 regarding the collection and use of MA encounter data. As we discussed in the final IPPS rule in August 2008, CMS will provide opportunity for stakeholders to provide feedback on our plans for implementation.

Comment: One commenter expressed concern about the burden of collecting and reporting encounter data and asked that plans be given a long lead time to implement this new requirement; the commenter suggested that CMS phase in the changes.

Response: CMS is sympathetic to plans' desire for adequate lead time to implement encounter data requirements. We will explore options for the start up of reporting and will provide opportunity for feedback on our approach.

Section G. IME Phase Out

Comment: Related to CMS 4138-IFC −42 CFR 422.306(c) and the phase-out in MIPPA of the IME portion of the MA capitation rate, one commenter asked how a plan calculates the phase-out of the IME in a county and the role of 0.6% in determining the phase-out.

Response: To help plans identify the impact, CMS has separately identified the amount of IME for each county rate in the 2010 rate book. We intend to publish the rates with and without the IME reduction in future years as well. The role of 0.6% is that it is the maximum reduction possible to the FFS per capita costs in a county in 2010.

Section H. Location of Network Areas for PFFS Plans in Plan Year 2011

Comment: A commenter questioned CMS's interpretation of the statutory definition of "having" a network-based plan to mean offering a plan "that is generally open to enrollment," and asked CMS to clarify whether such plans are "open to enrollment" as of January 2009.

Response: First, CMS believes Congress intended to eliminate non-network PFFS plans only in those areas where at least two coordinated care plan options are available. Limited enrollment

plans are not generally available to current PFFS plan enrollees, and we believe should not be counted under the two plan test. We therefore excluded plans that are not generally open to enrollment from our analysis, such as employer group health plans and special needs plans. As required by MIPPA, for purposes of identifying the location of the network areas for plan year 2011, we determined whether at least two generally available network-based plans with enrollment as of January 1, 2009 exist in each county (or partial county in some cases). Therefore, for a network-based plan to be counted in our analysis, the plan was required to have at least 1 beneficiary enrolled in the plan as of January 1, 2009.

Comment: Three commenters recommended that CMS interpret the definition of "network area" to mean an area with at least two network-based plans that are offered by different MAOs in order to ensure meaningful choice for Medicare beneficiaries. Two of the commenters were concerned about the creation of regional monopolies if CMS interprets the definition of network area as an area with at least two network-based plans, where the plans can be offered by the same MAO.

Response: MIPPA defines "network area," for a given plan year, as the area that the Secretary identifies (in the announcement of the risk and other factors to be used in adjusting MA capitation rates for each MA payment area for the previous plan year) as "having at least 2 network-based plans with enrollment as of the first day of the year in which the announcement is made." "Network-based plan" is defined in MIPPA as (1) an MA plan that is a coordinated care plan as described in section 1851(a)(2)(A)(i) of the Act, excluding non-network regional PPOs; (2) a network-based MSA plan; or (3) a section 1876 cost plan. We interpret "having at least 2 network-based plans" to mean that there are at least 2 plans, which meet the definition of a network-based plan, that are offered by the same MAO as well as plans offered by different MAOs. We believe this interpretation is consistent with the statutory requirements for identifying network areas.

Comment: A commenter understood that the network-based plans with enrollment as of January 1, 2009 are used to determine the location of network areas for PFFS plans in CY 2011 as required by MIPPA, but wanted CMS to address what would happen if plans in this data group leave the market. The commenter asks whether this would result in a new list being issued?

Response: The methodology for identifying the location of network areas is specified in the statutory definition of a "network area." MIPPA defines "network area," for a given plan year, as the area that the Secretary identifies (in the announcement of the risk and other factors to be used in adjusting MA capitation rates for each MA payment area for the previous plan year) as "having at least 2 network-based plans with enrollment as of the first day of the year in which the announcement is made." We accordingly have used enrollment data as of January 1, 2009 to identify the network areas for plan year 2011. The methodology we used to identify the list of network areas for plan year 2011 in this notice is consistent with statutory requirements. However, should the circumstances reflected in this year's payment notice change such that an area no longer meets the standard of "having at least 2 network-based plans" in the area, CMS will determine at that time how this would affect PFFS plans in that area if bids have not yet been submitted for the subsequent year (e.g., if there are fewer than 2 network plans in the area on January 1, 2010).

Comment: Two commenters recommended that CMS evaluate the provider contracting data for regional PPOs in areas where a regional PPO's network structure is the deciding factor in determining whether the area is a network area. One of the commenters noted that CMS is relying on data from regional PPOs on how they meet access requirements in their service areas, without any validation of the regional PPOs' responses. The commenter is concerned that regional PPOs will face no negative consequences for over-reporting their network breadth and get a competitive advantage by excluding competing PFFS plans.

Response: Regional PPOs meet the definition of a network-based plan only in those areas where the plan is meeting access requirements through written contracts with providers. MIPPA requires us to identify the location of network areas for plan year 2011 in the *Announcement of Calendar Year (CY) 2010 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies.* Due to the limited amount of time we had available prior to the release of the list of network areas for plan year 2011, we used data in our analysis that was obtained directly from the regional PPOs on how these plans are meeting CMS' network adequacy requirements in each of the counties in their service area. The data reported to us by the regional PPOs is the best available data we have for identifying the location of the network areas for plan year 2011. We believe that using this data is appropriate for identifying the location of plan year 2011 network areas. CMS will conduct network adequacy reviews of the regional PPO access data on an annual basis in future years.

Comment: A commenter stated that network-based plans with enrollments of 10 or fewer members should not meet the requirement of a network-based plan as these plans do not appear to offer a compelling choice for seniors.

Response: MIPPA defines "network area," for a given plan year, as the area that the Secretary identifies (in the announcement of the risk and other factors to be used in adjusting MA capitation rates for each MA payment area for the previous plan year) as "having at least 2 network-based plans with enrollment as of the first day of the year in which the announcement is made." We interpret the phrase "with enrollment" to mean that a network-based plan is required to have at least 1 beneficiary enrolled in the plan in order to be counted for purposes of identifying the location of the network areas. We believe that interpreting "with enrollment" any differently would result in an artificial threshold and would not be consistent with the statute.

Section I. Adjustment to FFS Per Capita Costs for VA-DOD Costs

Comment: One commenter noted that 54 counties have a rate increase of greater than $12.50 per person per month. The commenter believes that $12.50 is not a negligible amount. The commenter would like CMS to provide more information as to why the 54 counties should not receive a rate adjustment. Specifically, the commenter wanted details on whether in these 54 counties, differences observed between the two populations appear to be normal, random variations and not indicative of true underlying differences of the FFS costs between the total and non-vets.

Response: We agree that a $12.50 adjustment is not a negligible amount. As discussed in the Notice, however, the observed variations are not attributable to a true underlying difference

between the veteran and non-veteran populations, but due to normal, random fluctuations. For example, the 54 counties identified with large differences have less than one-sixth of the average level of enrollment. Not surprisingly, the effect of a random fluctuation is more significant when smaller sample sizes are considered.

Comment: One commenter argued that the DOD data should help determine whether the effects are random rather than systematic. The commenter believes that if counties have substantial, nonrandom difference when the VA and DoD data are analyzed, adjustments should be made to county rates.

Response: We agree that the effects of DoD eligible enrollees need to be evaluated. We continue to work with the Department of Defense to obtain the necessary data to support this analysis. Recently the DoD published a Privacy Act notice which will allow us access to their data. Please refer to paragraph 8(d), "Notice to alter a system of records." 74 FR 400-4006 (January 22, 2009).

Comment: One commenter requested that CMS include the cost of care received at VA/DoD healthcare facilities in the calculation of MA benchmarks as required by law. By excluding the cost of care received at VA and DoD facilities, the commenter believes CMS is underestimating FFS spending which inappropriately reduces MA benchmarks. The commenter argued that geographic areas with higher numbers and concentrations of VA/DoD facilities will be impacted the hardest by excluding these costs. Congress required CMS to incorporate these costs for years beginning in 2004 and CMS has yet to implement this factor. In the Advance Notice to CY 2009 rates, the commenter states, CMS proposed an option to include VA/DoD costs in the calculation of MA benchmarks. Although the proposed methodology presented some problems, the commenter encourages CMS to continue to explore alternative ways to collect the necessary data to incorporate this required adjustment.

Response: As outlined in the CY 2010 Advance Notice, we evaluated VA data using the methodology included in the CY 2009 Advance Notice and concluded that there is insufficient evidence to incorporate a VA adjustment into the rate making process for 2010. This conclusion was based on the view that the differences observed between the veteran and non-veteran populations appear to be normal, random variations and not indicative of true underlying differences of the FFS costs between the two populations. CMS will continue to study this issue. We are working to obtain data from the DoD that will support a study similar to the VA analysis.

Section J. Calculation and Source Data of MSP Factor

Comment: Commenters requested that plans have a mechanism to request correction to the CMS data where inaccurate or inconsistent information is identified in the COB file.

Response: Plans will have access to the Electronic Correspondence Referral System (ECRS). When a discrepancy is noted, there will be a mechanism to initiate corrections to the CMS data. ECRS is an electronic interface between plans and the COB Contractor. ECRS will allow MSP representatives at plans, FFS contractors, and authorized CMS RO to complete various online forms and electronically transmit requests for changes to existing CWF MSP information, inquire concerning possible MSP coverage, and document transactions to the COB contractor.

ECRS will allow plans to submit post enrollment transactions that change or add to information posted by those plans.

Comment: Commenters requested details on how payments will be adjusted as a result of plan submitted corrections.

Response: Starting January 2010 we will adjust payments to account for beneficiaries with working aged and disabled Medicare Secondary Payer (WA/WD MSP) status.

Comment: Several commenters felt that COB data was not accurate because a lot of new data are being entered due to the implementation of Section 111 of MMSEA this year and plans will not have a chance to populate the database in time for a 2010 payment calculation and that the data are not sufficiently reliable. Commenters asked that CMS study the accuracy of the COB data before going forward with this policy.

Response: CMS believes the COB data submitted by other insurers and payers is the most accurate source of other coverage information and CMS is working with the COB contractor to establish additional procedures to validate and update COB data. We also expect plans to initiate changes to MSP status in the event they become aware of them. Please see the 2010 Call Letter for ongoing Part D plan sponsor beneficiary notification and data correction requirements. We will send the COB file to plans on a daily basis whenever changes to data are processed by CMS systems. We also plan edits to the MARx system and will undertake additional operational initiatives to further eliminate problems with the reliability of the data.

Comment: One commenter asked that CMS estimate the impacts of changing the MSP approach before moving forward with the elimination of the current method for collecting MSP data.

Response: CMS will post to HPMS estimated MSP impacts for each plan as part of the risk score information for the 2010 bidding cycle.

Comment: Several commenters stated it was too late in the process to stop the MSP survey for 2009 reporting.

Response: The COB contractor will maintain the COB data for MSP beneficiaries. Plans will no longer be responsible for the MSP survey for MA beneficiaries for Part C beginning in 2009 for payment year 2010. (Please see the 2010 Call Letter for ongoing Part D plan sponsor requirements for beneficiary notification and data corrections related to COB data in CMS systems.) Each year in the middle of February CMS announces changes to payment policy in the Advance Notice. Plans make their own business decisions as to when to begin administering the MSP survey and when to initiate implementation of other aspects of the MA program. Plans should keep in mind that although the survey is not required in 2009 for 2010 payment, data derived from completed surveys may be helpful to plans in initiating updates of MSP information in ECRS.

Comment: One commenter felt that CMS should revert to the MSP process in place prior to the Spring 2009 software release for submission of MSP data in 2009, as it is not necessary for plans to expend significant resources to update their IT coding systems in 2009 if they will be obsolete in under a year.

Response: The requirements laid out in the Spring 2009 software release regarding MSP will no longer be necessary, as MA plans will no longer be required to submit the survey for Part C in the summer/fall of 2009.

Comment: A few commenters requested details about the process used to separate WA/WD beneficiaries for MA payment from other COB data.

Response: We will adjust MA payments for Working Aged/Working Disabled MSP status. These beneficiaries have a special flag in the COB data that we will use to adjust payments. Plans should report all MSP statuses, such as workers' compensation and auto-liability, to ECRS so that other plans and original Medicare know of primary payers.

Comment: One commenter requested that CMS increase the USPCC for MA plans as if Medicare paid primary with respect to the working aged/disabled since MA plans have benefit payments reduced when they have working aged members.

Response: The coefficients in the CMS risk models do not account for the impact of individuals with MSP. The standard rate is raised by the risk model as if Medicare was paying primary for all MA beneficiaries. The MSP adjustment is then used to reduce the rate when an individual is WA/WD. In this way the adjustment is applied to the appropriate individuals and plans rather than to all individuals and plans.

Comment: One commenter asserted that many SNPs have a small number of working aged or working disabled beneficiaries or none at all. The commenter was concerned that an industry-level MSP factor based on averages from a common file would not inaccurately reflect the proportion of working aged and working disabled in SNP plans and would inaccurately reduce payments.

Response: We agree with the commenter that an industry level factor would not result in the most accurate MA payments since some plans may have more WA/WD beneficiaries than others. As stated in the Advance Notice, we plan to do an MSP adjustment that reflects the MSP status of the beneficiaries in each plan. We believe this will result in the most accurate MSP adjustment for all plans and enrollees.

Section K. Medicare Part D Benefit Parameters: Annual Adjustments for Defined Standard Benefit in 2010

Comment: We received a comment requesting clarification regarding whether the deductible for Part D non-full benefit dual eligible beneficiaries receiving the full subsidy with resources between $6,600 and $11,010 (individuals) or between $9,910 and $22,010 (couples) is $62.00 or $60.00.

Response: The deductible for Part D non-full benefit dual eligible beneficiaries receiving the full subsidy with resources between $6,600 and $11,010 (individuals) or between $9,910 and $22,010 (couples) is $63.00. We thank the commenter for identifying this error in Table III-1, Updated Part D Benefit Parameters for Defined Standard Benefit, Low-Income Subsidy, and Retiree Drug Subsidy. Please see Attachment IV for the revised Part D benefit parameters.

Comment: Two commenters requested that CMS describe and explain the methodology for calculating the 1.70% correction to the 2009 annual percentage increase in the Consumer Price Index (CPI) for prior year revisions. One commenter indicated that based on the calculation methodology described in the 2009 Advance Notice (1.0494/1.026 – 1), it appears that the correction to the 2009 annual percentage increase in the CPI should be 2.28% instead of 1.70%. The commenter asked that CMS provide an explanation if the methodology is different from the methodology provided in the 2009 Advance Notice.

Response: The methodology for calculating the revisions to the estimates of prior years' annual percentage increases in average expenditures for Part D drugs per eligible beneficiary and CPI are unchanged from 2009. An error was identified in a component of the calculation of the revisions. The updated prior year revisions percentage and annual percentage increase for 2009 are −1.07% and 4.66%, respectively, for the average expenditures for Part D drugs per eligible beneficiary. The updated prior year revisions percentage and annual percentage increase for 2009 are 2.28% and 2.65%, respectively, for CPI. Please see Attachment IV for the revised table.

Comment: Commenters requested clarification regarding whether the annual percentage trend for September 2009 in Table IV-2, Cumulative Annual Percentage Increase in CPI, should be expressed as a factor rather than a percentage.

Response: The value for the annual percent trend for September 2009 in this table should be 0.36%. We thank the commenters for identifying this error in Table IV-2 in the 2010 Advance Notice. Please see Attachment IV for the revised table.

Section L. Reporting Drug Costs When Contracting with a Pharmacy Benefit Manager (PBM)

Comment: One commenter indicated that requiring Part D sponsors to use the amount paid to the pharmacy or other provider to report drug costs and determine beneficiary cost sharing lowers Part D program costs by increasing beneficiary premiums. The commenter requested clarification regarding the expected impact of these increases in beneficiary premiums on the regional LIS benchmarks.

Response: Under this regulatory change, Part D sponsors must exclude the PBM spread and any other administration costs from the negotiated prices used to determine the Part D drug costs reported to CMS. As a result, CMS expects the drug costs reported by Part D sponsors to decrease, reducing the reinsurance and low-income cost sharing subsidy payments made by the federal government. These lower negotiated prices are also expected to decrease beneficiary cost sharing such that the total amount paid by beneficiaries for their prescription drug coverage (premiums plus cost sharing) would be lower. However, the expected reductions in beneficiary cost sharing and federal reinsurance and low-income cost sharing subsidy payments may increase plan liability. This increase in plan liability may result in higher Part D bids and higher beneficiary premiums for plans that utilize the lock-in pricing approach. Similarly, the regional LIS benchmarks may increase if beneficiary premiums increase for Part D plans which previously utilized the lock-in pricing approach. Thus, while this policy is expected to reduce federal reinsurance and low-income cost sharing payments to Part D sponsors, it is expected to

increase federal Part D payments overall due to increased federal direct subsidy payments resulting from higher Part D bids.

In addition to lowering the drug costs reported to CMS, this policy is expected to provide Part D sponsors with increased transparency regarding their drug costs and administration fees. This increase in transparency may allow Part D sponsors to negotiate their drug prices and administrative fees paid to PBMs more effectively, which could have a downward impact on Part D bids and beneficiary premiums. Thus, the reduction in beneficiary cost sharing and federal reinsurance and low-income cost sharing subsidies may increase Part D bids while the increase in transparency may decrease Part D bids. As a result, it is unclear whether this regulatory change will have the net impact of increasing Part D bids and beneficiary premiums.

Comment: One commenter requested clarification regarding the expected impact of beneficiary premium increases on supplemental benefits as Part D sponsors use A/B rebates to buy down the Part D premium. In addition, the commenter asked for clarification regarding whether special needs plans (SNPs) were more likely than other plans to use the lock-in pricing approach in 2009.

Response: Higher Part D beneficiary premiums may require some MA-PD plans to utilize a larger share of their A/B rebates to reduce their Part D premiums to $0, such that they have fewer A/B rebates available for providing supplemental benefits. However, as we stated previously, it is unclear whether Part D premiums will increase as a result of this regulatory change.

Based on the information provided by Part D sponsors regarding their pricing approach in 2008 and 2009, the percentage of SNPs utilizing the lock-in pricing approach is about the same as the percentage of Part D plans utilizing the lock-in pricing approach (approximately 20% in 2008 and 16% in 2009).

Attachment IV 2010 Part D Benefit Parameters

Updated Part D Benefit Parameters for Defined Standard Benefit, Low-Income Subsidy, and Retiree Drug Subsidy

Annual Percentage Increases

	Annual percentage trend for 2009	Prior year revisions	Annual percentage increase for 2009
Applied to all parameters but (1)	5.79%	−1.07%	4.66%
CPI (all items, U.S. city average): Applied to (1)	0.36%	2.28%	2.65%

Part D Benefit Parameters

	2009	2010
Standard Benefit Design Parameters		
Deductible	$295	$310
Initial Coverage Limit	$2,700	$2,830
Out-of-Pocket Threshold	$4,350	$4,550
Total Covered Part D Drug Spend at OOP Threshold (2)	$6,153.75	$6,440.00
Minimum Cost-sharing in Catastrophic Coverage Portion of Benefit		
Generic/Preferred Multi-Source Drug	$2.40	$2.50
Other	$6.00	$6.30
Part D Full Benefit Dual Eligible Parameters		
Copayments for Institutionalized Beneficiaries	$0.00	$0.00
Maximum Copayments for Non-Institutionalized Beneficiaries		
Up to or at 100% FPL		
Up to Out-of-Pocket Threshold (1)		
Generic/Preferred Multi-Source Drug (3)	$1.10	$1.10
Other (3)	$3.20	$3.30
Above Out-of-Pocket Threshold	$0.00	$0.00
Over 100% FPL		
Up to Out-of-Pocket Threshold		
Generic/Preferred Multi-Source Drug	$2.40	$2.50
Other	$6.00	$6.30
Above Out-of Pocket Threshold	$0.00	$0.00
Part D Non-Full Benefit Dual Eligible Full Subsidy Parameters		
Resources ≤ $6,600 (individuals) or ≤ $9,910 (couples) (4)		
Maximum Copayments up to Out-of-Pocket Threshold		
Generic/Preferred Multi-Source Drug	$2.40	$2.50
Other	$6.00	$6.30
Maximum Copayments above Out-of-Pocket Threshold	$0.00	$0.00
Resources bet $6,600-$11,010 (ind) or $9,910-$22,010 (couples) (4)		
Deductible (3)	$60.00	$63.00
Coinsurance up to Out-of-Pocket Threshold	15%	15%
Maximum Copayments above Out-of-Pocket Threshold		
Generic/Preferred Multi-Source Drug	$2.40	$2.50
Other	$6.00	$6.30
Part D Non-Full Benefit Dual Eligible Partial Subsidy Parameters		
Deductible (3)	$60.00	$63.00
Coinsurance up to Out-of-Pocket Threshold	15%	15%
Maximum Copayments above Out-of-Pocket Threshold		
Generic/Preferred Multi-Source Drug	$2.40	$2.50
Other	$6.00	$6.30
Retiree Drug Subsidy Amounts		
Cost Threshold	$295	$310
Cost Limit	$6,000	$6,300

(1) CPI adjustment applies to copayments for non-institutionalized beneficiaries up to or at 100% FPL.
(2) Amount of total drug spending required to attain out-of-pocket threshold in the defined standard benefit if beneficiary does not have prescription drug coverage through a group health plan, insurance, government-funded health program or similar third party arrangement.
(3) The increases to the LIS deductible, generic/preferred multi-source drugs and other drugs copayments are applied to the unrounded 2009 values of $60.13, $1.08, and $3.23 respectively.
(4) The actual amount of resources allowable will be updated for contract year 2010.

Medicare Part D Benefit Parameters for the Defined Standard Benefit: Annual Adjustments for 2010

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) directs CMS to update the statutory parameters for the defined standard Part D drug benefit each year. These parameters include the standard deductible, initial coverage limit, and catastrophic coverage threshold, and minimum copayments for costs above the annual out-of-pocket threshold. In addition, CMS is statutorily required to update the parameters for the low income subsidy benefit and the cost threshold and cost limit for qualified retiree prescription drug plans eligible for the Retiree Drug Subsidy. Included in this notice are (i) the methodologies for updating these parameters, (ii) the updated parameter amounts for the Part D defined standard benefit and low-income subsidy benefit for 2010, and (iii) the updated cost threshold and cost limit for qualified retiree prescription drug plans.

As required by statute, the parameters for the defined standard benefit formula are indexed to the percentage increase in average per capita total Part D drug expenses for Medicare beneficiaries. Accordingly, the actuarial value of the drug benefit increases along with any increase in drug expenses, and the defined standard Part D benefit continues to cover a constant share of drug expenses from year to year.

All of the Part D benefit parameters are updated using one of two indexing methods specified by statute: (i) the annual percentage increase in average expenditures for Part D drugs per eligible beneficiary, and (ii) the annual percentage increase in the Consumer Price Index (CPI) (all items, U.S. city average).

I. Annual Percentage Increase in Average Expenditures for Part D Drugs Per Eligible Beneficiary

Section 1860D-2(b)(6) of the Social Security Act defines the "annual percentage increase" as "the annual percentage increase in average per capita aggregate expenditures for covered Part D drugs in the United States for Part D eligible individuals, as determined by the Secretary for the 12-month period ending in July of the previous year using such methods as the Secretary shall specify." The following parameters are updated using the "annual percentage increase":

Deductible: From $295 in 2009 and rounded to the nearest multiple of $5.

Initial Coverage Limit: From $2,700 in 2009 and rounded to the nearest multiple of $10.

Out-of-Pocket Threshold: From $4,350 in 2009 and rounded to the nearest multiple of $50.

Minimum Cost-Sharing in the Catastrophic Coverage Portion of the Benefit: From $2.40 per generic or preferred drug that is a multi-source drug, and $6.00 for all other drugs in 2009, and rounded to the nearest multiple of $0.05.

Maximum Copayments below the Out-of-Pocket Threshold for certain Low Income Full Subsidy Eligible Enrollees: From $2.40 per generic or preferred drug that is a multi-source drug, and $6.00 for all other drugs in 2009, and rounded to the nearest multiple of $0.05.

Deductible for Low Income (Partial) Subsidy Eligible Enrollees: From $60[1] in 2009 and rounded to the nearest $1.

Maximum Copayments above the Out-of-Pocket Threshold for Low Income (Partial) Subsidy Eligible Enrollees: From $2.40 per generic or preferred drug that is a multi-source drug, and $6.00 for all other drugs in 2009, and rounded to the nearest multiple of $0.05.

II. Annual Percentage Increase in Consumer Price Index, All Urban Consumers (all items, U.S. city average)

Section 1860D-14(a)(4) of the Social Security Act specifies that the annual percentage increase in the CPI, All Urban Consumers (all items, U.S. city average) as of September of the previous year is used to update the maximum copayments below the out-of-pocket threshold for full benefit dual eligible enrollees with incomes that do not exceed 100% of the Federal poverty line. These copayments are increased from $1.10 per generic or preferred drug that is a multi-source drug, and $3.20 for all other drugs in 2009[2], and rounded to the nearest multiple of $0.05 and $0.10, respectively.

III. Calculation Methodology

Annual Percentage Increase

For the 2007 and 2008 contract years, the annual percentage increases, as defined in section 1860D-2(b)(6) of the Social Security Act, were based on the National Health Expenditure (NHE) prescription drug per capita estimates because sufficient Part D program data was not available. Beginning with the 2009 contract year, the annual percentage increases are based on Part D program data. For the 2010 contract year benefit parameters, Part D program data is used to calculate the annual percentage trend as follows:

$$\frac{\text{August 2008 – July 2009}}{\text{August 2007 – July 2008}} = \frac{\$2{,}829.52}{\$2{,}674.62} = 1.0579$$

In the formula, the average per capita cost for August 2007 – July 2008 ($2,674.62) is calculated from actual Part D prescription drug event (PDE) data and the average per capita cost for August 2008 – July 2009 ($2,829.52) is calculated based on actual Part D PDE data incurred from August – December, 2008 and projected through July, 2009.

The 2010 benefit parameters reflect the 2009 annual percentage trend as well as a revision to the prior estimates for prior years' annual percentage increases. Based on updated NHE prescription drug per capita costs and PDE data, the 2007, 2008 and 2009 increases are now estimated to be 6.42%, 5.33% and 6.12%. Accordingly, the 2010 benefit parameters reflect a multiplicative update of −1.07% for prior year revisions. In summary, the 2009 parameters outlined in section I are updated by 4.66% for 2010 as summarized by Table III-1.

[1] Consistent with the statutory requirements of 1860D-14(a)(4)(B) of the Social Security Act, the update for the deductible for low income (partial) subsidy eligible enrollees is applied to the unrounded 2009 value of $60.13.
[2] Consistent with the statutory requirements of 1860D-14(a)(4)(A) of the Social Security Act, the copayments are increased from the unrounded 2009 values of $1.08 per generic or preferred drug that is a multi-source drug, and $3.23 for all other drugs.

Table III-1. Annual Percentage Increase

Annual percentage trend for July 2009	5.79%
Prior year revisions	(1.07%)
Annual percentage increase for 2009	4.66%

Note: Percentages are multiplicative, not additive. Values are carried to additional decimal places and may not agree to the rounded values presented above.

Annual Percentage Increase in Consumer Price Index, All Urban Consumers (all items, U.S. city average)

The annual percentage increase in the CPI as of September of the previous year referenced in section 1860D-14(a)(4)(A)(ii) is interpreted to mean that, for contract year 2010, the September 2009 CPI should be used in the calculation of the index. To ensure that plan sponsors and CMS have sufficient time to incorporate the cost-sharing requirements into benefit, marketing material and systems development, the methodology to calculate this update includes an estimate of the September 2009 CPI based on the projected amount included in the President's FY2010 Budget. The September 2008 value is from the Bureau of Labor Statistics. The annual percentage trend in CPI for contract year 2010 is calculated as follows:

$$\frac{\text{Projected September 2009 CPI}}{\text{Actual September 2008 CPI}} \text{ or } \frac{219.6}{218.8} = 1.004$$

(Source: President's FY2010 Budget and Bureau of Labor Statistics, Department of Labor)

The 2010 benefit parameters reflect the 2009 annual percentage trend in the CPI, as well as a revision to the prior estimate for the 2008 annual percentage increase. The 2009 parameter update reflected an annual percentage trend in CPI of 2.60%. Based on the actual reported CPI for September 2008, the September 2008 CPI increase is now estimated to be 4.94%. Thus, the 2010 update reflects a multiplicative 2.28% correction for prior year revisions. In summary, the cost sharing items outlined in section II are updated by 2.65% for 2010 as summarized by Table III-2.

Table III-2. Cumulative Annual Percentage Increase in CPI

Annual percentage trend for September 2009	0.36%
Prior year revisions	2.28%
Annual percentage increase for 2009	2.65%

Note: Percentages are multiplicative, not additive. Values are carried to additional decimal places and may not agree to the rounded values presented above.

IV. Part D Reinsurance Payment Demonstration Adjustment

The fixed capitated option of the Part D Reinsurance Payment Demonstration includes a catastrophic benefit that begins at the total drug expense corresponding to the out-of-pocket threshold in the Defined Standard Benefit. For 2010, this amount is increased from $6,153.75 in 2009 to $6,440. Specifically, this is the minimum amount of total covered Part D drug expenditures that will have occurred when the beneficiary reaches the out-of-pocket threshold of $4,550 in 2010 in the defined standard benefit. This expense level is determined arithmetically as a function of the 2010 out-of-pocket threshold (as opposed to being indexed directly).

V. Retiree Drug Subsidy Amounts

As outlined in §423.886(b)(3) of the regulations implementing the Part D benefit, the cost threshold and cost limit for qualified retiree prescription drug plans that end in years after 2006 are adjusted in the same manner as the annual Part D deductible and out-of-pocket threshold are adjusted under §423.104(d)(1)(ii) and (d)(5)(iii)(B), respectively. Specifically, they are adjusted by the "annual percentage increase" as defined previously in this document and the cost threshold is rounded the nearest multiple of $5 and the cost limit is rounded to the nearest multiple of $50. The cost threshold and cost limit are defined as $275 and $5,600, respectively, for plans that end in 2008, and, as $295 and $6,000, respectively, for plans that end in 2009. For 2010, the cost threshold is increased to $310, and the cost limit is increased to $6,300.

April 5, 2010

NOTE TO: All Medicare Advantage Organizations, Prescription Drug Plan Sponsors, and Other Interested Parties

SUBJECT: Announcement of Calendar Year (CY) 2011 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter

In accordance with section 1853(b)(1) of the Social Security Act (the Act), we are notifying you of the annual Medicare Advantage (MA) capitation rate for each MA payment area for CY 2011, and the risk and other factors to be used in adjusting such rates. The capitation rate tables for 2011 are posted on the Centers for Medicare & Medicaid Services (CMS) web site at http://www.cms.gov/MedicareAdvtgSpecRateStats/ under Ratebooks and Supporting Data. The statutory component of the regional benchmarks is also posted at this website.

As required by Section 1102 of the Health Care and Education Affordability Reconciliation Act of 2010, the capitation rates for 2011 are the same as the capitation rates for 2010. In previous years' Rate Announcements, CMS included final estimates of the National Per Capita Growth Percentages (MA Growth Percentages) as well as tables summarizing the key assumptions that were used to develop the MA Growth Percentages. The final estimates of the MA Growth Percentages were used to trend the previous years' capitation rates to the payment year. Given that the capitation rates for 2011 are the same as the capitation rates for 2010, the MA Growth Percentages have no relevance for the 2011 capitation rates. Therefore, this Rate Announcement does not include final estimates of the MA growth percentages or the associated key assumptions tables.

Section 1853(b)(4) of the Act requires CMS to release county-specific per capita fee-for-service (FFS) expenditure information on an annual basis, beginning with March 1, 2001. In accordance with this requirement, FFS data for CY 2008 are being posted on the above website.

Information on deductibles for MSA standard and demonstration plans, and on the maximum out-of-pocket amount for MSA demonstrations plans, is below.

Attachment I presents responses to comments on the Advance Notice of Methodological Changes for CY 2011 MA Capitation Rates and Parts C and Part D Payment Policies (Advance Notice). Attachment IV presents the final Call Letter. We received 78 submissions in response to CMS' request for comments on the Advance Notice/Call Letter, published on February 19, 2010. Eight of the comments were from advocacy groups, 27 were from associations, 1 was from a Congressional agency, 2 were from members of the public, and 40 were from health plans.

Attachment II contains tables with the Part D benefit parameters; Attachment III contains tables with the 2011 Rx-HCC risk adjustment factors.

Key Changes from the Advance Notice/Call Letter:

CMS stated in the 2011 Advance Notice that, if new legislation were enacted after the Advance Notice was released, but before the Rate Announcement was published, we would incorporate changes into the Announcement. The Patient Protection and Affordable Care Act of 2010 (PPACA), as amended by the Health Care and Education Affordability Reconciliation Act of 2010 (Reconciliation Act), makes changes to title XVIII of the Act for 2011 that are reflected in this Announcement. The following items have been changed from the Advance Notice to the Announcement, some in response to this new legislation, as noted.

County Rates. Section 1853(j)(1)A) of the Act, as amended by Section 1102 of the Reconciliation Act, requires that CMS maintain the 2011 county rates, which are used for payment for aged and disabled beneficiaries, at the 2010 levels. Therefore, the 2011 capitation rates will not be rebased with updated FFS costs. In addition, because the growth percentage does not affect the 2011 county rates, we have not included the final estimate of the increase in the National Per Capita Growth Percentage for 2011 in the Rate Announcement.

ESRD Payment. In holding the capitation rates constant for 2011, CMS interprets Congress' intent that we minimize changes in the Part C payment methodology for 2011, in order to promote stability and predictability. Therefore, CMS will maintain the 2011 State rates, which are used for payment for End Stage Renal Disease beneficiaries, at the 2010 amounts.

Adjustment to FFS Per Capita Costs for VA-DOD Costs. In the Advance Notice, we concluded that there is sufficient evidence to warrant an adjustment to the FFS rates based on DoD data when the capitation rates are rebased using FFS rates. Given that the capitation rates will not be rebased in 2011 in accordance with Section 1102 of the Reconciliation Act, however, this adjustment will not occur in 2011. CMS will make this adjustment when the capitation rates are FFS rebased in 2012, as required under current law.

Part C Risk Adjustment Model. Based on our interpretation of Congressional intent regarding changes in Part C payment methodology, CMS will not implement the new CMS-HCC and CMS-HCC ESRD dialysis risk adjustment models or the recalibrated frailty factors in 2011. CMS will implement these new models in 2012. To reference the factors in the CMS-HCC risk adjustment model that will be used in 2011, see the 2009 Rate Announcement (published in April 2008). To reference the factors in the CMS-HCC ESRD risk adjustment model that will be used in 2011, see the 2008 Rate Announcement (published in April 2007).

Normalization Factors. Given the continued use of the current CMS-HCC and CMS-HCC ESRD risk adjustment models, the normalization factors for 2011 are calculated using these existing models and are as follows:

CMS-HCC aged-disabled model is 1.058.

CMS-HCC ESRD Functioning graft status is 1.088.

CMS-HCC ESRD dialysis model is 1.060.

MSP Factors. In maintaining current payment methodology, the 2011 MSP factors for aged/disabled or ESRD beneficiaries remain as follows:

Aged/disabled/postgraft: 0.174

ESRD dialysis/transplant: 0.215

Medical Savings Account (MSA) Plans. The maximum deductible for current law MSA plans for 2011 is $10,600. For MSA demonstration plans, the 2011 minimum deductible amount is $2,200, the maximum out-of-pocket amount is $10,600, and the minimum difference between the deductible and deposit is $1,000.

Manufacturer Discount Program. Per Section 3301 of the PPACA, as amended by Section 1101 of the Reconciliation Act, starting contract year 2011 pharmaceutical manufacturers will be required to provide certain beneficiaries access to discount prices for certain brand drugs purchased under Medicare Part D. The manufacturer discount prices will be equal to 50% of the plan's negotiated price defined at §423.100 minus any applicable dispensing fees. These discount prices must be applied prior to any prescription drug coverage or financial assistance provided under other health benefit plans or programs and after any supplemental benefits provided under the Part D plan.

Part D sponsors must make these discount prices available to their Part D enrollees at the point-of-sale. These manufacturer discount prices will be made available to Part D enrollees who have reached or exceeded the initial coverage limit and have incurred costs below the annual out-of-pocket threshold. Medicare beneficiaries will not be eligible to receive these discount prices if they are enrolled in a qualified retiree prescription drug plan or are eligible for the low-income subsidy. The costs paid by manufacturers towards the negotiated prices of drugs covered under this manufacturer discount program shall be considered incurred costs for eligible beneficiaries and applied towards their out-of-pocket threshold.

While this manufacturer discount program will not directly affect the Part D benefit, it may affect drug expenditures in the catastrophic phase of the Part D benefit. Therefore, Part D sponsors may take this into account when estimating plan liability in the catastrophic phase and in developing the reinsurance subsidy estimates for their Part D bids. Additional guidance will be provided at a later date regarding this manufacturer discount program and how Part D sponsors will be reimbursed for the manufacturer discounts made available to their enrollees at the point-of-sale.

Change to Part D Benefit: Reduced Cost sharing for Generic Drugs in the Coverage Gap. Per Section 1101 of the Health Care and Education Reconciliation Act of 2010, the coinsurance under basic prescription drug coverage for certain beneficiaries will be reduced for generic covered Part D drugs purchased during the coverage gap phase of the Part D benefit. The

coinsurance charged to eligible beneficiaries will be equal to 93% or actuarially equivalent to an average expected payment of 93%. To be eligible for this reduced cost sharing, a Part D enrollee must have gross covered drug costs above the initial coverage limit and true out-of-pocket costs (TrOOP) below the out-of-pocket threshold. Medicare beneficiaries will not be eligible for this reduced cost sharing if they are enrolled in a qualified retiree prescription drug plan or are eligible for the low-income subsidy. Part D sponsors must account for this reduced cost sharing when developing their Part D bids for contract year 2011.

LIS Benchmarks. In the Advance Notice, we described how low income beneficiaries in some Part D regions would have a very limited choice of zero-premium prescription drug plans under the statutory methodology for calculating the maximum government premium subsidy. We noted that we would continue to look into solutions to this issue for 2011. In this Rate Announcement, we note that we will calculate the LIS benchmarks using basic part D premiums before the application of Part C rebates, in accordance with Section 3302 of the PPACA and Section 1102 of the Reconciliation Act. Also in accordance with the PPACA, under Section 3303, Part D plans will be allowed to charge subsidy-eligible beneficiaries a monthly beneficiary premium equal to the applicable low-income premium subsidy amount, if the plan's adjusted basic beneficiary premium exceeds the low-income premium subsidy amount by a de minimis amount or less. CMS will issue subsequent guidance specifying the de minimis amount.

New Enrollee Risk Scores for Chronic Condition SNPs. For 2011, CMS developed a methodology that will allow us to adjust new enrollee risk scores for beneficiaries enrolled in chronic condition SNPs to take into account the condition(s) that enrollees in these particular SNPs must have as a condition of enrollment. Although this is a new payment methodology, Congress has required that CMS implement these new risk scores in 2011, per Section 3205 of PPACA . In this Rate Announcement, CMS describes the methodology that we will use to adjust the 'default' risk scores for new enrollees to reflect the predicted costs of full risk enrollees in chronic care SNPs.

Clinical Trials Cost Sharing. In the Advance Notice we stated that, starting in 2011, MA plans will be required to reimburse enrollees for the difference between fee-for-service cost sharing incurred for clinical trial items and services and the MA plan's in-network cost sharing for the same category of service. In addition, starting in 2011, the portion of clinical trial cost sharing that is not otherwise reimbursed by the MA plan must also be included in the out-of-pocket maximum calculation. In their comments, the industry raised concerns about operational challenges associated with identifying which beneficiaries participate in clinical trials and the amount of cost sharing they have incurred. In this Rate Announcement, we note that to receive reimbursement, beneficiaries (or providers acting on their behalf) must notify their plan that they have received clinical trial services and provide documentation of the cost sharing incurred, such as a Medicare Summary Notice (MSN). CMS will explore ways that we can provide this information to plans in the future to alleviate the potential burden on beneficiaries.

Reassignment. Each fall we conduct reassignment of certain low income subsidy (LIS) beneficiaries who were originally assigned to a Prescription Drug Plan (PDP) whose premium is below the LIS benchmark, but will go above the LIS benchmark in the following year. In the past, we have reassigned only individuals who have never chosen a plan on their own and, thus, remain in a plan into which they were auto-enrolled by CMS. For the fall of 2010, we solicited comment on expanding reassignment to these "choosers" based on their 2011 premium liability. We also solicited comment on the feasibility of considering past medication use as part of the reassignment process. In the Call Letter, we state that we will not reassign choosers at this time, but are considering several methods to make beneficiaries more aware of their options. CMS will also continue to evaluate the merits of reassigning beneficiaries based on beneficiary drug utilization.

Calendar. The Call Letter contains a combined calendar listing side-by-side key dates and timelines applicable to MA, MA-PD, Part D and cost-based plans. The calendar contains important operational dates for plans, such as the date that CMS will begin accepting bids, dates for non-renewing plans, and dates for beneficiary mailings. The calendar has changed slightly from the version included in the draft Call Letter based on comments we received. In addition, changes to some calendar items were made to comply with Sections 3203 and 3205 of the PPACA.

Encouragement of Sponsor Practices to Curb Waste of Unused Drugs Dispensed in the Retail Setting. As part of CMS's effort to contain health care costs and reduce waste associated with the Medicare prescription drug benefit, we requested that Part D sponsors consider allowing beneficiaries in the community (versus institutional) setting the option to request a trial supply of no more than 7 to 14 days of a Part D covered medication when first prescribed. We received several comments regarding this proposal, and address some of the concerns raised by the commenters in this final Call Letter.

Release of Payment Data. In the draft Call Letter, we announced that CMS is considering the public release of Part C and Part D payment data. We solicited comment on whether the release of such data would negatively affect the competitive nature of the bidding process. In the Rate Announcement, we announce that we intend to issue a regulation proposing to authorize the release of Part C and Part D payment data.

Proposals Adopted as Issued in the Advance Notice or Draft Call Letter:

As in past years, policies proposed in the Advance Notice that are not modified or retracted in the Rate Announcement become effective in the upcoming payment year, as set forth in the Advance Notice. Clarifications in the Rate Announcement supersede materials in the Advance Notice.

Rate Announcement

Recalibration and Clinical Update of the Rx HCC Risk Adjustment Model. In 2011, CMS will implement an updated version of the RxHCC risk adjustment model, including the coefficients for the community, institutional, and new enrollee segments of the model. The 2011 model will encompass both updates to the data years used to recalibrate the model and a clinical revision of the diagnoses included in each hierarchical condition category (RxHCC). Attachment V contains the updated risk adjustment factors.

Normalization Factors. The normalization factor for 2011 for the RxHCC risk adjustment model is the same as in the Advance Notice and is 1.029.

Frailty Adjustment Transition for PACE organizations. Frailty adjustment will be applied to payment to PACE organizations using the transition schedule for 2011 published in the 2008 Announcement (published April 2, 2007). In 2011 (year 4), we will use 25% of the pre-2008 frailty factors and 75% of the most recent frailty factors (published for payment year 2009).

Frailty Adjustment Transition for Certain Demonstrations. Frailty adjustment will no longer be applied to payment to the following MA plan types, per the phase-out schedule published in the 2008 Announcement (published April 2, 2007): Social Health Maintenance Organizations (S/HMOs), Minnesota Senior Health Options (MSHO)/ Minnesota Disability Health Options (MnDHO), Wisconsin Partnership Program (WPP) and Massachusetts Senior Care Options (SCO) plans.

Section 3205 of the *PPACA* provides the Secretary the authority to apply frailty payments to certain Special Needs Plans (SNPs), starting in 2011. To be eligible for these frailty adjusted payments, plans must meet the following three criteria:

- Dual SNP,
- Fully integrated with capitated contracts with States for Medicaid benefits, including long term care, and
- Have similar average levels of frailty as the PACE program.

CMS will not implement this provision in 2011, primarily due to the lack of data from the Health Outcome Survey (HOS) to allow us to determine accurately the frailty levels of dual eligible SNPs that have fully integrated contracts with States. CMS expects that larger sample sizes for dual SNPs in the 2011 HOS will allow the calculation and determination of frailty levels for CY 2012.

Adjustment for MA Coding Pattern Differences. For 2011, CMS will apply a 3.41% reduction to each Part C beneficiary's risk score.

EHR Incentives. Incentive payments to qualifying MA organizations may be available as early as calendar year 2011, payable in 2012. CMS has issued a proposed rule that would implement these provisions, CMS-0033-P, which was published on January 13, 2010.

Physician Quality Reporting Initiative (PQRI) and E-Prescribing. MAOs and cost-contracting HMOs are required to pay PQRI bonuses to non-contracted providers, and in the case of PFFS plans meeting access standards through payment of the FFS rate, "deemed contracting" providers.

Location of Network Areas for PFFS Plans in Plan Year 2012. The list of network areas for plan year 2012 can be downloaded from the following website: http://www.cms.gov/PrivateFeeforServicePlans/

Reinsurance Payment Demonstration Plans. In the Advance Notice, we reminded Part D sponsors that no Reinsurance Payment Demonstration plans will be offered in 2011.

Payment Reconciliation. The 2011 risk percentages and payment adjustments for Part D risk sharing are unchanged from contract year 2010.

Medicare Part D Benefit Parameters: Annual Adjustments for Defined Standard Benefit in 2011. See Attachment IV for the 2011 Part D benefit parameters for the defined standard benefit, low-income subsidy, and retiree drug subsidy.

Call Letter

Special Needs Plans (SNP), State Resource Center. The Resource Center provides States with helpful information as they engage in contract negotiations with MAOs seeking to offer new or expanded dual eligible special needs plans (SNP).

CAHPS and HOS Reporting for Special Needs Plans. For plan year 2011, the Consumer Assessment of Health Plans Survey (CAHPS) and the Medicare Health Outcomes Survey (HOS) will continue to sample, collect, and report data at the contract level. However, oversampling of SNP plan benefit packages will occur within each eligible contract to allow for a more focused analysis of SNP results.

HOS Survey Administration. The current year Healthcare Effectiveness Data Information Set (HEDIS) reporting category that reports the HOS results applies to the following managed care organization types with a minimum of 500 members that had a Medicare contract in effect on or before January 1, 2010: (1) all coordinated care contractors, including health maintenance organizations (HMOs), local preferred provider organizations (PPOs) and regional PPOs; (2) private fee-for-service (PFFS) contracts; (3) medical savings account (MSA) contracts; and (4) continuing 1876 cost contracts with open enrollment. Organizations eligible to report also include MA contracts with exclusively special needs plan benefit packages, regardless of institutional, chronically ill, or dual-eligible enrollment.

All Programs of All Inclusive Care for the Elderly (PACE) with contracts in effect on or before January 1, 2010 should administer the HOS-Modified (HOS-M) survey for current year reporting. Note that, effective 2010, the Minnesota Senior Health Options, Minnesota Disability

Health Options, Wisconsin Partnership Programs, and Massachusetts MassHealth Senior Care Options MA contracts are required to report HOS and no longer participate in HOS-M.

Potential New B versus D Coverage Determination for Beneficiaries with End Stage Renal Disease. CMS will include erythropoiesis stimulating agents, and other drugs and biologicals and their oral equivalents, furnished to individuals for the treatment of ESRD in the new bundled payment as "renal dialysis services." Any such drugs or biologicals that are included as "renal dialysis services" under the new ESRD PPS will not be eligible for coverage under Part D when furnished to individuals for the treatment of ESRD.

Recommended Deadlines for Cost-Based Plan Non-Renewals. Beginning with the application cycle for 2011 contracts, CMS is strongly encouraging all cost-based plans to follow the schedule established for MA plans and MA-PD plans for both submitting service area expansion applications as well as requesting non-renewal/service area reductions.

Coordination of Benefits (COB) User Fees. CMS is authorized to impose user fees on Part D sponsors for the transmittal of information necessary for benefit coordination between sponsors and other entities providing prescription drug coverage. The user fee for 2011 is $1.17 per enrollee per year.

Specialty Tier Threshold. In the Call Letter, we state that we will maintain the $600 threshold for drugs on the specialty tier. Thus, only Part D drugs with negotiated prices that exceed $600 per month may be placed in the specialty tier, and the specialty tiers will be evaluated and approved in accordance with section 30.2.4 of Chapter 6 of the Medicare Prescription Drug Benefit Manual.

Medicare Enrollment Assistance Demonstration. CMS is reevaluating its intended approach to the enrollment demonstration project based on the comments we received in the past, and we do not anticipate implementing the project for plan year 2011.

Risk Adjustment Data Validation (RADV). This notification is to remind contracting MA organizations of their obligations under 42 CFR 422.504(e)(2).

Questions can be directed to:

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Attachments

2011 ANNOUNCEMENT
TABLE OF CONTENTS

Attachment I. Responses to Public Comments

Section A. Estimate of the National Per Capita MA Growth Percentage for Calendar Year 2011

Comment: Many commenters requested more detail and documentation regarding how the growth percentage was calculated for the 2011 Advance Notice, including the basis for CMS' estimate.

Response: Section 1853(j)(1)A) of the Act, as amended by Section 1102 of the Reconciliation Act, requires CMS to maintain 2011 rates at 2010 levels. We will consider these commenters' requests when we develop and announce future growth percentages.

Section B. New Enrollee risk scores for C-SNPs

For 2011, CMS will implement new enrollee risk scores for new enrollees in chronic SNPs. New enrollee risk scores are used for those beneficiaries who do not have 12 months of Part B and, therefore, for whom CMS cannot calculate a full risk score. Because chronic SNP enrollees must, as a condition of enrollment, have specific conditions, the average new enrollee risk score of new enrollees in chronic SNPs is likely to understate these beneficiaries' risk.

New enrollee risk score factors for 2011 for Chronic SNP (C-SNP) enrollees are included in Attachment III, Table 7. The new enrollee factors were developed by first calculating an average risk score for continuing enrollees in chronic SNPs. We then adjusted the current new enrollee risk scores to take into account the incremental risk of continuing enrollees in chronic SNPs. As with the standard new enrollee model, the C-SNP new enrollee factors will include factors that differ depending on age, sex, Medicaid, and original entitlement. The C-SNP new enrollee factors comprise the standard new enrollee factors, plus an incremental amount. The increment to the new enrollee risk scores for C-SNPs is a result of chronic disease; CMS research found that the increment was the same for each category (non-Medicaid, Medicaid, originally disabled) across all age/sex groups, indicating that there no further increments are needed for the costs predicted by Medicaid and original entitlement status.

Comment: A number of commenters offered support for the proposal to implement new enrollee risk score for new enrollees in C-SNPs. One commenter requested that CMS implement these risk scores in such a manner that does not reduce the risk scores of other MA plans. Several commenters requested a comment period prior to Announcement, even if short. Several commenters wanted CMS to also apply separate new enrollee risk scores to dual SNPs -- they stated that dual SNPs enroll beneficiaries with a high level of severity, have high risk scores, and should not be penalized for the targeting of specialized care for high-risk populations. Some commenters wanted CMS to also apply similar new enrollee risk scores to PACE participants -- they argued that PACE new enrollee risk scores are not consistent with the number and

complexity of their medical conditions which contribute to their qualifying for nursing home level of care.

Response: We appreciate the support for developing a set of new enrollee risk scores for new enrollees in C-SNPs. CMS is not considering applying similar new enrollee risk scores to dual SNP and PACE enrollees. We believe that dual SNPs' new enrollee risk scores are adequate to address aggregate risk faced by these plans. The current new enrollee risk score model captures the additional costs due to Medicaid status. As discussed above, in creating the C-SNP model, we found that the new enrollee age/sex factors had a similar increment regardless of Medicaid status. This finding indicates that the predicted costs of Medicaid enrollees are fully accounted for in the current new enrollee model.

Section C. Normalization factors

Comment: Several comments requested that CMS release the underlying data and risk scores so organizations can better understand resulting trend and other factors. One commenter requested the CMS provide (1) historical risk scores for the population for each year (please note if the historical risk scores are normalized and provide the historical normalization factors) and (2) the predicted risk scores for all years included in the calculation of the normalization factor for both the Part C and Part D models. One commenter asked about the changes in the Part C and Part D normalization factors. They noted that the annual normalization factor for Part C has increased since last year, while the factor for Part D has decreased. All else equal, one would expect these trends to generally be in the same direction (since using the same diagnosis data). While the change in HCC models may contribute to this phenomenon, the commenters requested that CMS provide any additional insights as to why the trends are moving in opposite directions. Another commenter stated that Part D normalization factors have been unstable -- 1.085, 1.146, 1.029 – and asked whether it would be feasible to use any smoothing technique to reduce instability of this factor.

Response: The formula for calculating normalization factors used to adjust risk scores takes into account the following factors:

(1) The annual trend, calculated over a rolling set of annual risk scores years and updated each year. Risk scores are calculated without adjustment for trend or for MSP and are rebased to the last year in the trend (i.e., the last year in the trend is set to 1.00 and the previous years' risk scores are divided by the last year's risk score.)
(2) The number of years between the denominator year and the payment year.

In the case of Part D, although the annual trend has not varied much, the normalization factor has varied for two reasons: For 2010, as discussed in the Advance Notice and Rate Announcement for 2010, CMS changed the policy used to calculate the adjustment, from using the risk scores of beneficiaries eligible for Part D to using beneficiaries enrolled in a Part D plan when calculating

the annual trend. This change increased the normalization factor. For 2011, the Part D normalization factor decreases because it is adjusting risk scores trends from 2008 through 2011 (three years), rather than from the denominator of the original model (2004) through each successive payment year.

In the case of both the Part C and Part D, each year's normalization factor may change marginally due to updating the annual trend and, to a larger degree, as a result of any change in the gap between the denominator year and the payment year. The change in the normalization factor to account for coding trends between the denominator year and the payment year should not affect a plan's risk score, as long as the plan's coding trend is consistent with the average trend.

Part C 2011 normalization factor

The final CMS-HCC Part C normalization factor is 1.058.

- The Part C normalization factor is used to normalize the following risk scores: Aged/disabled community, aged/disabled institutional, aged/disabled new enrollee, ESRD postgraft community, ESRD postgraft institutional, and ESRD postgraft new enrollee.
- From 2008-2011, the postgraft factor has been different from the aged/disabled factor. This is because the model denominator years are different. The postgraft model normalization factor is calculated using the trend from the version of the CMS-HCC model with the same denominator as the ESRD postgraft model, which is 2005. The CMS-HCC model with a 2005 denominator was used for payment years 2007 and 2008.
- Population used to calculate annual trend: FFS beneficiaries.

CMS estimates an annual trend using a linear function applied to the following years' risk scores:

2005: 0.972
2006: 0.984
2007: 1.000
2008: 1.009
2009: 1.031

The linear annual trend over these five years (2005-2009) is 0.0141. This annual trend is applied for the years between the denominator year (2007) and the payment year (2011) by taking it to the fourth power. The normalization factor is obtained as follows: $1.0141^4 = 1.058$.

Part D 2011 normalization factor

The final CMS RxHCC Part D normalization factor is 1.029.

- The Part D normalization factor is used to normalize all Part D risk scores.
- Population used to calculate annual trend: PDP and MA enrollees

CMS estimates an annual trend using a linear function using the following years' risk scores:

2006: 0.981
2007: 0.990
2008: 1.000
2009: 1.009 (projected)
2010: 1.019 (projected)
2011: 1.029 (projected)

The linear annual trend is 0.009. This annual trend is applied for the years between the denominator year – 2009 – and the payment year – 2011 by taking it to the third power. The normalization factor is obtained as follows: $1.00949^3 = 1.029$.

Section E. Aged/Disabled MSP Factor

Comment: Several commenters noted that CMS had recently initiated a process to evaluate MA MSP data, and had recently provided updated data files to MA organizations to review and refine the data, and suggested that because this process was ongoing (and MA analysis and action to correct MSP status based upon the latest files had only recently begun), CMS should consider deferring recalculation of the MA MSP factor until 2012, when the reconciliation process will be more stable.

Response: MA plans are refreshing data for beneficiaries in MA plans. We have recently started paying MA plans based on this data. We calibrate the MSP factor based on FFS MSP data, which CMS has used for payment for a number of years. Therefore, the recalibrated MSP factor should be unaffected by the refresh. However, CMS is holding the MSP factor for the age/disabled model the same as in 2010, in keeping with the principle of minimizing changes to the Part C payment methodology.

Section F. Frailty Adjustment Factors

Comment: A few commenters wanted CMS to apply a frailty adjustment to SNPs that enroll a disproportionate number of frail elderly beneficiaries and/or adults with disabilities. One commenter believed that not paying SNPs for frailty was inconsistent with federal law that requires CMS to pay in relation to known costs for comparable populations in FFS and inconsistent with SNP statutory authority that requires targeting of high risk specials needs individuals. Commenters asked why CMS does not apply frailty-adjusted payments to SNPs that seek to specialize in the care of frail beneficiaries and to plans transitioning from demonstration status where they have maintained the same targeted, specialty care approach they used under demonstration status, when CMS assumed a frailty adjustment was necessary and appropriate.

Response: By law, CMS must use the same payment methodology for all MA plans, including Special Needs Plans (SNPs), except as explicitly provided for in statute. For example, Section

3205 of the PPACA permits CMS to make frailty-adjusted payments to certain dual SNPs – those with fully integrated, capitated contracts with States for Medicaid benefits, including long term care, and which have similar average levels of frailty as the PACE program. Thus, CMS cannot make frailty payments to any SNP that does not meet the PPACA criteria without implementing frailty payments program-wide.

Comment: One commenter requested clarification of the relationship between the changes in the HCC model and the reduction in unexplained costs related to frailty, e.g., did CMS assume that the frailty factor accounted for costs related to dementia – a condition excluded from the original HCC model? It would be very helpful to better understand which components of the new HCC model improved payment for frailty- related costs. Another commenter stated that nothing in the current risk adjustment model accounts for limitations in ADLs for those MA enrollees who live in the community, but who qualify for institutional level of care, and that the risk adjustment system must catch up with other efforts to rebalance spending from the nursing home to the community. Another commenter stated that the model still does not explain all costs for functionally impaired.

Response: To calibrate the frailty factors, CMS estimates the unexplained costs (the difference between predicted costs and actual costs) using the newly revised and recalibrated CMS-HCC risk adjustment model (including all the new HCCs in the model). Regression analysis is used to estimate the contribution of ADL factors to these unexplained costs.

Although the commenter who stated that the CMS-HCC model does not explain all costs for frail beneficiaries is correct, we disagree that it does not explain *any* of these costs. The explanatory power of the model can be illustrated by examining the frailty factors for Medicaid eligible beneficiaries. The CMS-HCC model predicts costs for this group particularly well, resulting in a very small residual frailty factors.

Because CMS is not implementing the recalibrated and revised CMS-HCC risk adjustment model, we are also not implementing the recalibrated frailty factors for 2011.

Section G. Coding Pattern Adjustment

Comment: A number of commenters questioned CMS' legal authority to make an adjustment based on differences in coding patterns in 2011, arguing that authority to do so was limited to years specified in the Deficit Reduction Act (DRA) that mandated such an adjustment for the years in question. These commenters cited language added by the DRA to section 1853(a) -- "analyses are incorporated into the risk scores only for 2008, 2009, and 2010" (emphasis added) -- and section 1853(k) – providing for the application of the required coding intensity adjustment to the same benefit years for which payment is affected by the budget neutrality phase out addressed in these provisions. Noting that proposed legislative changes would require the

Secretary to implement coding intensity in 2011 and subsequent years, the commenters argued that CMS does not currently have the authority to apply an MA coding adjustment.

Response: The DRA amendments to Section 1853(a)(1)(C) expressly mandated that CMS make an adjustment to the risk scores in 2008, 2009, and 2010, if a difference in MA and FFS coding patterns was found. Although the DRA used the phrase "only for 2008, 2009 and 2010," this limitation applies only to that mandate for an adjustment. Independent of this DRA language, CMS has broad authority under Section 1853(a)(3) to develop and implement a methodology for risk adjusting MA capitation payments "that accounts for variations in per capita costs based on health status…." Moreover, Section 1102 of the Reconciliation Act requires CMS to make an adjustment to risk scores for years subsequent to 2010 if a difference in MA and FFS coding patterns is found.

As noted above, commenters also cited Section 1853(k)(2)(B)(iv)(III), which requires CMS to "adjust the risk scores for differences in coding patterns between Medicare Advantage plans and providers under the original Medicare fee-for-service program under Parts A and B to the extent that the Secretary had identified such differences, as required in subsection (a)(1)(C)," as a time limited provision. However, this provision applies to the calculation of the risk scores used in calculating budget neutrality and therefore, does not apply to risk scores used in payment.

Comment: A number of commenters urged that CMS keep the adjustment the same as in 2010, assuming we were making an adjustment in 2011. These commenters support maintaining the 2010 adjustment level to avoid including yet another change to the payment calculation in a year when other revisions to the risk adjustment model are being implemented. Some commenters expressed concerns about the impact of the MA coding adjustment on their revenues, others thought that it was too large, in combination with normalization, and others expressed concern about the impact on plan benefits and beneficiaries.

Response: We understand the concerns elicited by the many changes anticipated for 2011. In keeping with the principle of limiting Part C payment methodology for 2011, CMS is retaining the proposed MA coding adjustment factor of 3.41% for 2011.

Comment: A number of commenters supported the CMS proposal to apply an MA coding adjustment in 2011. They opined that MA coding patterns result in higher risk scores that do not reflect differences in the health status of the two groups of beneficiaries, but rather differences in coding behavior which artificially suggest that MA enrollees are sicker than they actually are, and undermine the ability of the Medicare risk adjustment system to appropriately lower payments for enrollees who are healthier, on average, than those in FFS Medicare These commenters supported CMS using disease score growth for the four years between 2007 and 2011, instead of limiting the adjustment to a three-year period, as proposed, and adding additional years of data. One commenter urged that CMS update the factor each year just as we update the risk adjustment model's normalization factors each year.

Response: We appreciate the support for continuing to make a coding pattern adjustment. For future years, CMS will consider updating the adjustment using later data and adjusting for coding differences that will have occurred since 2007.

Comment: Several commenters opposed the use of the national average when applying an MA coding adjustment. Some commenters felt that a national average penalizes MAOs operating in geographic areas where local FFS coding increases are greater than the national average or where MA coding trends are below the national average. Commenters also argued that a national average presumes that all MAOs are similar in their coding differences, which is unlikely to be true, particularly when comparing smaller, regional organizations with less sophisticated tools and resources to larger national organizations, and that an adjustment based on all Medicare Advantage enrollees was reflective of larger plans experience. These commenters recommended that CMS derive and apply MA coding adjustments in a more targeted manner.

Response: While the commenter is correct that MA coding trends do differ among MAOs and it is possible that FFS coding trend differ by geographic area, the MA coding adjustment is akin to the normalization factor: industry-wide and not plan-specific in nature, in order to ensure that risk scores in the aggregate are at the correct level, given the coding patterns inherent in the CMS-HCC risk adjustment model and the FFS coding trends reflected in the Part C normalization factor.

Comment: One commenter urged CMS to undertake an analysis of other factors that might influence differences in rates of disease score growth among specific subsets of the Medicare population, e.g., Medicaid eligibles, or subsets of high-cost beneficiaries including beneficiaries with multiple chronic conditions.

Response: CMS' research to date does not support the position that Medicaid eligibility or having high costs has an impact on differential coding between MA and FFS. If other factors are found that CMS believes may affect the coding differential between sectors, we will consider including it in the coding adjustment factor in future years.

Comment: A number of commenters thought that CMS should handle coding intensity as an audit issue for those payers showing the highest probability of coding activity; they felt that it was unfair to reduce payments to all MAOs, when a few might be driving the aggregate coding intensity rate for MAOs generally. Several commenters contended that the MA coding adjustment and RADV audits both were intended to address inaccurate coding and that the 2011 MA coding adjustment is duplicative of any RADV audit-related adjustments. Commenters thought that, to avoid double counting the impact of inaccurate coding, the difference factor should take into account the impact of RADV audits (reduce overall coding intensity adjustment by future expected value of RADV adjustments) or was not necessary. A couple of commenters asked CMS to discuss how the RADV results are removed from the MA coding adjustment, or at least how it will avoid both affecting payments simultaneously.

Response: As we have noted in previous Advance Notices and Rate Announcements, the MA coding adjustment factor is not intended to adjust for inaccurate coding, but for the impact on risk scores of coding patterns that differ from FFS coding, the basis of the CMS-HCC model and the Part C normalization factor. RADV audits have the purpose of validating that diagnosis codes submitted for risk adjustment are documented in the medical record and, therefore, are correctly reported for the beneficiary in question. Moreover, we have not yet conducted RADV audits for the years in which we have applied an MA coding adjustment.

Comment: One commenter complained about the lack of an appeal mechanism, and thought that the adjustment should be nullified if coding is correct.

Response: As structured, the MA coding adjustment is a methodological adjustment to risk scores to ensure payment accuracy given differential coding patterns in MA and FFS. Since the MA coding adjustment is not plan-specific, and is not intended to target plans for their individual coding patterns, an appeal mechanism is not appropriate.

Comment: A couple of commenters believed that the coding adjustment had a disproportionate impact on SNPs, with one noting that this was due to greater numerical adjustment in risk scores for a plan serving high risk special needs individuals. The commenters opined that the adjustment would likely adversely impact SNPs, given the differential between FFS and SNPs, due to the SNP mandate to serve a high risk population with complex medical needs. These commenters urged that CMS devise and implement a plan to enhance the coding practices and accuracy of fee-for-service providers to create a level playing field relative to MA and FFS incentive to code accurately.

Response: As discussed above, CMS is applying an industry-wide adjustment for coding that adjusts risk scores in the aggregate to address coding trends in MA that differ from those in FFS. However, it is important to note the MA coding adjustment reflects *differences* in the year-to-year changes in the disease score portion of the risk score, not the absolute levels of FFS and MA risk scores. Therefore, it is not clear why plans with a higher level of risk scores would experience more or less differential coding than any other plan. Although CMS currently relies on FFS data to calibrate the CMS-HCC model, we anticipate using encounter data to calibrate the model in the future. At that time, a single normalization factor will be adequate to address coding trends and a separate MA coding adjustment factor will not be needed.

Section H. IME Phase Out

Comment: One commenter asked whether, when calculating the Standardized IME cost percentage (expressed as a percentage of FFS costs), the resulting ratio is constant during the phase-out period (i.e., if the IME costs and the FFS costs trend at the same rate), or if the IME cost represents what is left for IME costs yet to be phased-out.

Response: We anticipate recalculating the IME percentage of FFS cost in rebasing years.

Section I. Physician Quality Reporting Initiative (PQRI) and E-Prescribing

Comment: One commenter urged that CMS compensate physicians working under MA contracts for quality performance and e-prescribing commensurate with FFS provisions. This could be done either through a direct payment to physicians or inclusion of such compensation in MA payment, with contractual understanding that the payment amount, in total, would be passed on to participating physicians.

Response: MA payment rates already include an amount attributable to FFS costs for both PQRI and e-prescribing. This is so because when CMS computes 100 percent of FFS costs for purposes of §1853(c)(1)(D) of the Act in rebasing years, or when CMS computes the national per capita MA growth percentage per §1853(c)(6)(A) of the Act, the FFS costs attributable to PQRI and e-prescribing are included in the FFS amount used to establish the MA benchmarks. In effect, MAOs are already being paid for the PQRI and e-prescribing their providers do for MA plan enrollees, in a similar proportion to their efforts for FFS enrollees.

Section J. Clinical Trial Policy

Comment: Advocacy groups, MA organizations, and research associations wrote in support of the proposed clinical trial policy. Commenters generally said they believed the policy would improve coverage for clinical trial costs, as well as improve access and recruitment to clinical trials of MA plan members.

Response: Currently, most MA plan enrollees are responsible for the entire FFS coinsurance for clinical trial items and services, which is 20% of the total allowed amount for Part B services. The cost sharing requirements for similar in-network services are often much lower than they are under FFS for clinical trial items and services. We believe this new policy of limiting an MA enrollee's cost sharing to the plan's in-network cost sharing will increase participating in and access to clinical trial services for MA plan enrollees.

Comment: A few of the commenters misunderstood our policy change. They believed that it was within MAO discretion to choose whether to cover cost sharing for clinical trials at in-network levels. One commenter recommended allowing MAOs to choose which clinical trials would be eligible for cost sharing reduction (to in-network levels) by MAOs.

Response: It was our intent to say that our new policy is that MAOs must reduce cost sharing for clinical trial services to in-network cost sharing levels for items and services of the same category. It is not the case that MAOs can choose the clinical trials or clinical trial items and services to which this new policy applies. Rather, since such items and services are covered by Medicare, MAOs must also cover them. There is no plan discretion.

Comment: Two commenters asked us why we do not "waive" clinical trial cost sharing for MA plan enrollees, similar to the way we "waive" Part A and B deductibles related to clinical trial services reimbursed by FFS for MA plan enrollees.

Response: CMS does not "waive" deductibles related to clinical trial services for MA plan enrollees. Rather, the actuarial value of cost sharing in MA plans, as well as the fact that most MA plans use rebate dollars to buy-down cost sharing (including the actuarially equivalent cost sharing related to Part A/B deductibles), continues to apply. When we say that MA plan enrollees do not need to meet FFS deductibles we are simply acknowledging that enrollment in an MAO and payment of MA plan cost sharing already satisfies these deductible requirements in FFS.

Comment: Many plans expressed concerns with the operational challenges and administrative burdens that are associated with the new policy. Commenters were especially concerned that they do not have a way to identify enrollees who are participating in clinical trials, the services provided, the amount of the provider payment under FFS Medicare, as well as the cost sharing paid to the provider by the enrollee for covered clinical trial services. Many of the commenters pointed out that CMS rules prohibit MAOs from requiring their MA plan members to ask for plan permission, or to give MA plans notice when the member chooses to participate in a Medicare-qualifying clinical trial. One commenter urged CMS to require MA plans to provide reimbursement based on claims data, without requiring beneficiaries to submit receipts showing cost sharing was actually paid. Plans recommended that CMS work with MAOs to establish a process or mechanism for providing this information to MAOs. Commenters suggested two potential models for such a mechanism. One would be the process utilized by CMS to share Part B claims information with Cost Plans under certain circumstances, and the other would be the Medigap crossover claims process. One commenter recommended allowing providers of clinical trials to bill MAOs directly for the cost sharing their MA plan members incur.

Response: We will permit MAOs to ask members to submit MSNs (Medicare Summary Notices) related to clinical trial claims reimbursed by FFS. MSNs contain not only the amount reimbursed by FFS for items and services related to clinical trials, but also the amount of cost sharing owed by the MA plan member. Using this data from the MSN, MAOs should be able to compute the difference between MA plan in-network cost sharing for the same category of service, and thus compute the amount owed by the MAO to the member. We will also permit MAOs to seek MA member FFS cost sharing information directly from clinical trial providers. While we understand MAOs' operational concerns and will work with the industry to obtain the clinical trial data they want in an electronic format, we believe that MA enrollee participation in and access to clinical trial services outweighs the plans' concern for heightened administrative burden. Otherwise, we do not believe the administrative burden in processing these claims will be much greater than the burden MAOs already experience in processing other out-of-network claims.

Comment: Some commenters said it would be difficult to track the amount actually paid in cost sharing by an MA plan enrollee.

Response: MAOs will owe the difference between what the MA enrollee incurred in FFS cost sharing for covered clinical trial items and services and the plan's in-network cost sharing. The member is not required to have actually paid any of the cost sharing. The MAO owes the difference even if the member has not yet paid the clinical trial provider.

Comment: Two commenters suggested allowing MAOs to treat clinical trial services as out-of-network services, and suggested allowing MA plans to impose cost sharing and OOP maximums related to those services, rather than in-network services.

Response: Our policy is that MAOs will need to pay the difference between the FFS cost sharing for covered clinical trial services and the plan's in-network cost sharing for services of the same type, and to require the member's cost sharing liabilities to count towards the in-network OOP limit. Clinical trial services are covered under FFS Medicare and MAOs must cover all Medicare services as in-network services – see section 1852(a)(1)(A) of the Social Security Act. The fact that clinical trial item and services continue to be reimbursed by FFS Medicare provides a more than sufficient rationale for requiring MAOs to cover these services in this manner.

Comment: One MAO commented that the MAO conducts a number of clinical trials itself. This commenter and others went on to say that there is currently no requirement for an OOP maximum. Another commenter recommended requiring MA organizations to automatically add the appropriate cost-sharing for clinical trials toward the calculation of the MA plan's out-of-pocket (OOP) limit.

Response: MA plan members are free to participate in any certified clinical trial that any other (FFS) Medicare beneficiary can participate in. If an MAO conducts its own clinical trial, the MAO can explain the benefits of participating in the MAO-sponsored clinical trial. But, an MAO may not require pre-authorization for a non-plan-sponsored clinical trial, nor may it create impediments to a plan member's use of a non-plan clinical trial, even if the MAO believes it is sponsoring a clinical trial of a similar nature. The final choice in which, if any, clinical trial to participate is the MA plan member's. An MA plan can request, but not require, members to pre-notify the plan when members are participating in clinical trials. In addition, note that in CMS-4069-P CMS proposed requiring that MAOs have OOP maximums for both in-network and out-of-network cost sharing. If the rule in finalized as proposed and released in time, MAOs would be required to provide for OOP maximums for 2011. Finally, since in-network cost sharing will apply to non-plan clinical trial services, the in-network OOP maximum would be the appropriate place to count remaining member cost sharing liabilities for clinical trial services.

Comment: One commenter believed that requiring MAOs to reimburse claims from non-network providers of clinical trial items and services at in-network cost sharing rates would

result in a disparity of benefit administration in MA PPO plans. The commenter said that only individuals participating in clinical trials would be entitled to in-network cost sharing when being treated by non-network providers, while all other MA PPO plan enrollees who are not participating in clinical trials would have out-of-network cost sharing when receiving routine services from non-network providers.

Response: CMS does not believe that the clinical trial cost-sharing policy described in this Announcement creates a disparity in benefit administration.

Comment: Some commenters asked that CMS address the updates that would be necessary for the model Explanation of Coverage (EOC) and Plan Benefits Package (PBP).

Response: No update is necessary to the PBP since the cost sharing an enrollee would pay for clinical trial services would be the amount the plan filed for existing in-network benefits of the same category. For example if the clinical trial included a Part B drug or radiation therapy, the in-network cost sharing that had been entered for Part B drugs and radiation services would be the cost sharing that applied to the clinical trial services. As far as updating the EOC and other marketing materials are concerned, we will require MAOs to mention the new coverage of cost sharing (at in-network levels, and counting towards the in-network cap on OOP expenses) in the 2011 ANOC (Annual Notice of Change) and EOC.

Comment: One commenter requested guidance as to where clinical trial costs should appear in the BPT. One commenter was concerned that this policy change could pave the way to mid-contract year decisions to include new services as required benefits even though coverage of the services had not been part of the bid. Another commenter stated that regardless of whether clinical trial participation is considered an in-network or out-of-network service, plans will need to incorporate in their CY 2011 bids assumptions about the costs related to members' participation. This commenter said that because many MA plans now bear no responsibility for clinical trial costs, plans do not have a basis for making actuarial assumptions about costs for reimbursing enrollee cost sharing or applying clinical trial costs to OOP maximums. The commenter requests that CMS provide plans with data on enrollee participation in clinical trials, affiliated providers, and associated costs for use in bid preparation.

Response: The BPT does not have a separate entry for clinical trials. Plans can include expected cost sharing reductions in their estimate of costs and cost sharing for related in-network services. Preliminary data show that in 2008 a total of $230 million was spent nationally by CMS on clinical trial services (inpatient and outpatient – both FFS and MA enrollees). If more detailed data becomes available, we will provide it.

Section K. Adjustment to FFS Per Capita Costs for VA-DOD Costs

Comment: Section 1853(c)(1)(D)(iii) of the Act directs the Secretary to make an appropriate adjustment to MA payment rates to reflect CMS' "estimate on a per capita basis, of the amount

of additional payments that would have been made in the area involved under this title if individuals entitled to benefits under this title had not received services from facilities of the Department of Defense (DOD) or the Department of Veterans Affairs." OACT has analyzed DoD data and determined that an adjustment is appropriate. One commenter wrote in support of the proposed adjustment. Two additional commenters noted that the statutory authority for the VA-DoD adjustment began with the 2004 rates, yet 2011 will be the first year in which the Office of the Actuary (OACT) has determined that available data support its application. The commenters believed that because the statute allowed implementation to begin with 2004 rates, the adjustment should be calculated by applying it to the 2004 rates and trending it forward to 2011 or extrapolating the counties' 2004 MA rates up to 2011 using the applicable update for each year since 2004, in order to accurately determine its magnitude and the counties to which it should apply. The commenters note that this approach is similar to that used in 2004 to transition from the PIP-DCG risk adjustment model to the HCC model when OACT recalculated the 1998 county rates to reflect the new HCC model then updated the rates for all years from 1998 – 2004 to reflect application of the HCC risk adjustment model.

Response: Section 1853(c)(1)(D)(iii) of the Act directs the Secretary to incorporate the impact of including the costs of VA or DOD Military Facilities in the calculation of Fee-for-Service (FFS) costs. CY 2011 is the first time that data has been available that indicates such an adjustment is warranted in those counties with at least 10 Medicare members in the Uniformed Services Family Health Plan. Although there is some history for retroactively calculating the impact of model change to historic rates, there is no history for incorporating additional data into a historic FFS calculation. In fact, FFS costs are only incorporated into a county rate on a prospective basis in a periodic rebasing year. We plan to incorporate these findings in the county rates the next time we rebase the FFS rates.

Section L. Location of Network Areas for PFFS Plans in Plan Year 2012

"Network area" is defined in section 1852(d)(5)(B) of the Act, for a given plan year, as the area that the Secretary identifies (in the Rate Announcement for the previous plan year) as "having at least 2 network-based plans (as defined in section 1852(d)(5)(C) of the Act) with enrollment as of the first day of the year in which the announcement is made." "Network-based plan" is defined by MIPPA as: (1) an MA plan that is a coordinated care plan as described in section 1851(a)(2)(A)(i) of the Act, excluding non-network regional PPOs; (2) a network-based MSA plan; or (3) a section 1876 cost plan.

As required by MIPPA, for purposes of identifying the location of the network areas for plan year 2012, we determined whether at least two network-based plans with enrollment as of January 1, 2010 exist in each of the counties in the United States, including its 5 territories and the District of Columbia. In some cases, network areas consist of partial counties and are identified by zip codes.

Regional PPOs (RPPOs) meet the definition of a network-based plan only in those areas where the plan is meeting access requirements through written contracts with providers. In a January 19, 2010 HPMS memorandum titled "Transition of Private Fee-for-Service Contractors to Network-Based Access Requirements and Update", we issued an updated list of network areas for plan year 2011. This revision was necessary given that, after reviewing the 2009 Health Service Delivery (HSD) tables for all RPPOs in 601 counties where the presence of a network RPPO was the deciding factor in the county being considered a network area in 2011, we found that none of the RPPOs offered in these counties had contracted providers for all Medicare Part A and Part B services.

In our analysis to identify the network areas for plan year 2012, we used the updated 2009 RPPO provider access data, including the RPPO data we validated. We then reviewed the 2010 Health Service Delivery (HSD) tables for all RPPOs in the counties where the presence of a network RPPO was the deciding factor in the county being considered a network area in 2012 in order to ensure that these RPPOs had contracted providers for all Medicare Part A and Part B services and could be considered network-based plans.

The list of network areas for plan year 2012 can be downloaded from the following website: http://www.cms.gov/PrivateFeeforServicePlans/.

An existing PFFS plan may have some counties (or partial counties) in its current service area that meet the definition of a network area and other counties (or partial counties) that do not. As we stated in the 2010 Advance Notice, CMS will not permit an MA organization offering a PFFS plan to operate a mixed model where some counties (or partial counties) in the plan's service area are considered network areas and other counties (or partial counties) that are non-network areas (where there are no network-based plan options or only one other network-based plan).

Instead, the MA organization must establish a unique plan with a service area consisting of the counties (or partial counties) that are network areas and another plan with a service area consisting of the counties (or partial counties) that are non-network areas. The MA organization must file separate plan benefit packages for the PFFS plan that will operate in network areas and the plan that will operate in non-network areas.

PFFS plans operating in network areas in 2012 must establish networks of contracted providers to furnish services in these areas in accordance with section 1852(d)(4)(B) of the Act in order to meet Medicare access to services requirements. PFFS plans may not use alternate methods to meet access requirements in network areas. If an existing PFFS plan is not able to establish a network of contracted providers that CMS determines to be adequate in a network area, then the plan must exit from that area in plan year 2012. If an MA organization is not able to establish a network of contracted providers that CMS determines to be adequate in a network area, then it may not offer a PFFS plan in that area.

Current PFFS plans whose service areas lie solely in non-network areas can continue to operate as non-network plans, where the plans meet access requirements by establishing payment rates that are not less than the rates that apply under Original Medicare (42 CFR §422.114(a)(2)(i)) and having providers deemed to be contracted as provided under 42 CFR §422.216(f). PFFS plans in non-network areas may choose to operate as full network plans (42 CFR §422.114(a)(2)(ii)) or partial network plans (42 CFR §422.114(a)(2)(iii)).

CMS will not accept Notices of Intent and applications for non-network PFFS products for those counties (or partial counties) determined to be network areas.

Regardless of whether a PFFS plan meets access requirements exclusively through deeming or is subject to the requirement that it establish a network of providers with signed contracts, providers who do not have a contract with the PFFS plan continue to have the option of accepting a PFFS plan's terms & conditions of payment and becoming a deemed provider as described in 42 CFR §422.216(f).

Comment: A commenter asked that CMS reconsider its position that two MA plans count as two network plans for the purposes of the definition of "network area" when the plans are both offered by the same MA organization. The commenter believed that this interpretation was not consistent with the commenter's understanding of the intent of MIPPA, which the commenter believed envisioned two successfully operating and competing organizations. The commenter suggested that CMS's interpretation lends itself to 'gaming,' as a single organization could choose to introduce a second PBP (and not market it) in the interest of pushing out non-network PFFS plans, and then having exclusive access to beneficiaries who were enrolled in those plans. The commenter requested that CMS reconsider its position on this issue for contract year 2012, or, at the very least, put in place a strict monitoring program to assure that organizations operating the only network plan in their service area are not gaming CMS rules to force out non-network PFFS plans in a county without two competing network plans.

Response: MIPPA defines "network area" for a given plan year, as the area that the Secretary identifies (in the announcement of the risk and other factors to be used in adjusting MA capitation rates for each MA payment area for the previous plan year) as "having at least 2 network-based plans with enrollment as of the first day of the year in which the announcement is made." "Network-based plan" is defined in MIPPA as: (1) an MA plan that is a coordinated care plan as described in section 1851(a)(2)(A)(i) of the Act, excluding non-network regional PPOs; (2) a network-based MSA plan; or (3) a section 1876 cost plan. We interpret "having at least 2 network-based plans" to mean that there are at least 2 plans, which meet the definition of a network-based plan, that are offered by the same MAO or by different MAOs. We believe this interpretation is consistent with the statutory requirements for identifying network areas. We do not believe we have the statutory authority to interpret the definition of a "network area" in a different manner.

We do not agree with the commenter's concern about a single MA organization "gaming" the market by introducing a second PBP and not marketing it in order to remove non-network PFFS competition. A network-based plan is required to have at least one beneficiary enrolled in the plan in order to be counted for purposes of identifying the location of network areas. Therefore, if a plan has no enrollees, it would not be counted as a network-based plan.

Section M. Calibration of RxHCC model

Comment: Commenters offered support for decision to include a new RxHCCs for morbid obesity.

Response: We appreciate the support.

Comment: One commenter was concerned that the revised Part D risk adjustment model will result in significant underpayments for ESRD members. Based on their own analysis of the revised Part D scores, they found that the combination of per member per month and reconciliation payments from CMS will not cover their costs. The commenter recommended that CMS consider adding a factor into the model for ESRD status. This factor would help to address this inequity and reduce the negative payment impacts of the revised Part D risk model.

Response: In the RxHCC risk adjustment model, ESRD status is captured by reported diagnosis, except for the new enrollee models, for which we have no diagnoses. In the risk models for continuing enrollees, for whom we have diagnoses, we recognize stages of kidney failure with the 585 ICD-9 codes and dialysis status with V codes reported with the diagnoses. As continuing (full risk) enrollees go through the stages of kidney failure, they will be coded for different RxHCCs. As coding for CKD improves, we expect the coefficients of these RxHCCs to become better differentiated.

Comment: Several commenters suggested that CMS consider including data for beneficiaries enrolled in MA-PD plans as part of the next RxHCC risk adjustment model calibration.

Response: We thank commenters for this suggestion. We will consider this suggestion when we next recalibrate the RxHCC risk adjustment model.

Comment: If new model is found to result in material impact to plans, one commenter urged CMS to phase in the model changes so that the financial impact may be easier to absorb.

Response: CMS analyses have shown that most Part D plans' risk scores change 1% or less, and the vast majority change by 2% or less as a result of the revised and recalibrated RxHCC risk adjustment model. Further, no plans have commented to CMS with concerns about the impact of the RxHCC model in their Part D risk scores.

Comment: A couple of commenters asked that CMS apply the interactions in the institution model to the community model. One commenter wanted CMS to add major depression and

other major chronic conditions such as diabetes, CHF, and COPD, to the coefficients for disease interactions.

Response: Interaction terms can help predict costs when there are higher costs associated with having more than one condition than are captured by the individual demographic and HCC factors. Interaction terms are determined for each model segment (e.g., community and institutional) by assessing the ability of each interaction term to improve that model segment's ability to predict costs. There exist a plethora of possible interaction terms to include in each model segment, and decisions regarding inclusion are identical to those made in deciding which HCCs to include in a model – ability to predict costs for Medicare Part D benefits, as determined by the size of the coefficient and the t-value of the coefficient. When inclusion of an interaction term is not warranted by cost data, CMS does not add the term to the model.

Comment: One commenter stated that, while they expected payments for beneficiaries in long term institutional (LTI) settings to increase (because prices for drugs used by institutionalized beneficiaries in Part D have grown more rapidly than have prices for other Part D enrollees) and while there are legitimate reasons for prescription costs to be higher in long term care settings, ideally prospective Part D payments will continue to give sponsors incentives to manage growth in the drug spending of all enrollees. Similarly, the commenter noted that LIS enrollees experience higher spending and lower use of generic drugs. Inherent in the Part D risk adjustment model, CMS is paying plans more for LIS enrollees based on their higher average costs to plans. The commenter recommended that CMS look for examples of Part D plans that are doing a better job of providing needed medications and still managing the drug spending of their LTI and LIS enrollees, so that we can encourage similar techniques among other plans.

Response: CMS appreciates the comment and will consider these suggestions when further refining the Part D model.

Comment: A few commenters noted that, in numbering the RxHCCs in the revised model, new RxHCCs were assigned to previously-assigned numbers, e.g., Opportunistic Infections was RxHCC2 and is now RxHCC5. They stated that this renumbering may cause confusion with various systems, reporting and provider training and recommended that it would be easier to implement the new model if the numbering system changed to a new set of IDs or if old numbers were not re-used to mean something else.

Response: In addition to adding (RxHCCs) and deleting (RxHCCs) from the current models, the clinical update also modified RxHCCs that were retained in model. Direct comparisons between old and revised RxHCCs need to be made carefully, regardless of the numbering scheme. Due to the full-scale revision of the model, CMS decided to renumber all RxHCCs at this time.

Comment: Some commenters requested that CMS make available the population used to create the relative factors; the actual distribution of members used to create the community and institutional relative factors; and the population shifts from prior years to current model in the

above categories. Several commenters requested the regional impacts of model changes, with some commenters specifically asking for the impact data by the eight categories of the model, along with risk score impact (percent change). Commenters felt that this information would allow plans to understand the impact of the changes for the entire region, and would allow PDPs can to gauge the impact of changes in low income enrollment, thus improving the competitiveness of the bidding process.

Response: To develop the CMS RxHCC model segments, CMS used 100% of the 2007 and 2008 Standard Analytic Files for Part D. Standard Analytic Files comprising PDE data for 5% of the Part D enrollee population are available to the public upon request from the Research Data Assistance Center (ResDAC). Others can use these SAFs to conduct analyses of the impact of the new model on the Part D risk scores of various subsets of the Part D enrollee population.

Comment: One commenter asked that CMS provide PDPs with diagnostic information so they can better predict risk scores.

Response: Recognizing that PDPs do not have the ICD-9 codes submitted and used in risk score creation, CMS sent to all PDPs a set of Part D risk scores under the current and revised models on March 2, 2010.

Section N. LIS Benchmarks

Comment: Many commenters offered support for CMS's efforts to stabilize reassignments through the Medicare Demonstration to Revise the Part D Low-Income Benchmark Calculation, which was approved in August 2009. Commenters also requested the reinstatement of the de minimis policy, where beneficiaries in plans whose premiums were just over the benchmark were not reassigned. One commenter suggested calculating the low income benchmark premiums using only PDP plans that are eligible for reassignment and weighting the basic premiums by LIS enrollment. Commenters requested that CMS make their final policy known well before the deadline for bids, preferably in the 2011 Announcement.

Response: For 2010, CMS implemented the Medicare Demonstration to Revise the Part D Low-Income Benchmark Calculation. This demonstration allowed CMS to calculate the LIS benchmarks using basic Part D premiums before the application of Part C rebates. CMS received broad support for this demonstration from commenters. The demonstration was effective at reducing reassignment and stabilizing benchmarks. The approach focuses directly on the issue of MA rebates, which are the main cause of benchmark destabilization, while upholding the spirit of the statute, which directs us to calculate the benchmarks using premiums from both PDPs and MA-PDs.

In 2011, we will again calculate the LIS benchmarks using basic part D premiums before the application of Part C rebates, as required by Section 1860D-14(b)(2)(B)(iii) of the Act, as amended by Section 3302 of the PPACA and Section 1102 of the Reconciliation Act. Also in

accordance with, Section 1860D-14(a) of the Act, as amended by Section 3303 of the PPACA, Part D plans may be allowed to charge subsidy eligible beneficiaries a monthly beneficiary premium equal to the applicable low-income premium subsidy amount, if the plan's adjusted basic beneficiary premium exceeds the low-income premium subsidy amount by a de minimis amount or less. This approach will eliminate the need to move low-income subsidy beneficiaries to new plans simply because their existing plan's premium exceeded the LIS premiums subsidy amount by a de minimis amount. We will issue subsequent guidance on the de minimis amount and autoassignment.

Section O. Reinsurance Payment Demonstration

Comment: One commenter indicated that the previously released 2011 PD BPT Instructions included language stating that Reinsurance Demonstration plans offered in 2010 may be extended for 2011.

Response: We thank the commenter for bringing this language to our attention. The previously released 2011 BPT instructions were draft and did not reflect proposed policy changes for CY 2011. This language will be updated in the final PD BPT instructions. As proposed in the Advance Notice, Part D sponsors with Reinsurance Demonstration plans will not be allowed to offer such plans in 2011.

Comment: Commenters recommended that we extend the Part D Reinsurance Payment Demonstration. They indicated that this demonstration was successful in encouraging Part D sponsors to offer enhanced alternative plans and provide coverage in the coverage gap. They expressed concern that discontinuing this demonstration would 1) reduce the number of Part D plans offering gap coverage and 2) increase the premiums and cost sharing for beneficiaries currently enrolled in Reinsurance Demonstration plans. One commenter indicated that an increase in premiums resulting from the discontinuation of this demonstration would lead to adverse selection into plans that continue to offer coverage in the coverage gap. A few commenters indicated that ending this demonstration would be inconsistent with current legislative reform efforts to fill the coverage gap because the Part D Reinsurance Payment Demonstration provides the best current option for offering gap coverage.

Response: We implemented the Part D Reinsurance Payment Demonstration in 2006 due to concerns that the reinsurance provisions of the Part D benefit would create a create disincentive for Part D sponsors to offer enhanced alternative plans. Since the start of the Part D program, several sponsors have offered enhanced alternative plans. However, the majority of enhanced alternative plans offered have not been Reinsurance Demonstration plans. In addition, the majority of enhanced alternative plans providing gap coverage are not Reinsurance Demonstration plans. Therefore, we do not believe that this payment demonstration is necessary to provide an incentive for Part D sponsors to offer enhanced alternative plans and provide gap

coverage. For this same reason, we do not believe that ending this demonstration would be inconsistent with current efforts to fill the coverage gap.

We agree that discontinuing this demonstration might increase the premiums and cost sharing for beneficiaries currently enrolled in Reinsurance Demonstration plans. However, these beneficiaries will have the option to enroll in other enhanced alternative plans that may have lower premiums and/or cost sharing. We believe that the number of enhanced alternative plans offering gap coverage should mitigate the possibility of adverse selection.

Comment: Two commenters recommended that CMS reinstate this demonstration for contract year 2012 if the number of plans offering enhanced alternative coverage or the number of plans offering coverage in the coverage gap significantly decreases.

Response: Given the provisions in the PPACA, as amended by Section 1101 of the Reconciliation Act, that close the coverage gap over time, we do not believe that reinstatement of this demonstration will be needed.

Section P. Payment Reconciliation:

Comment: One commenter asked that CMS continue expansion of the risk corridors beyond 2011 if material changes are made to the Part D benefit due to health care reform.

Response: We appreciate the comment and will take this suggestion into consideration.

Section Q. Medicare Part D Benefit Parameters: Annual Adjustments for Defined Standard Benefit in 2011

Comment: A couple of commenters noted that due to the prior year revisions, the annual increase in drug costs is significantly greater than the increases applied to the Part D benefit parameters. One commenter stated that the Part D beneficiaries would receive less value under Part D as a result of the application of prior year revisions in the calculation of the annual percentage increase. The commenter explained that Part D beneficiaries would reach the coverage gap more quickly because the increase in the initial coverage limit is significantly less than the increases in drug price expected for 2011. The commenter recommended that CMS modify the calculation of the annual percentage increase to account for formulary changes and other cost cutting measures employed by Part D sponsors.

One commenter expressed concern that large changes in the Part D benefit parameters followed by no change could affect the stability of the Part D program. The commenter requested information regarding why the Part D benefit parameters were overstated for previous years, resulting in significant prior year revisions. In addition, the commenter asked whether the methodology for calculating the annual percentage increase could be revised to better predict the trend in Part D drug costs.

Response: The annual percentage increase (API) used to determine the Part D benefit parameters is calculated based on the formula described in the statute. That is, the API is equal to the increase in average per capita aggregate expenditures for Part D covered drugs for the 12-month period ending in July of the previous year. As such, there is no provision to directly allow for modification to the update to reflect the cost cutting efforts of the plans. To the extent that these efforts reduced Part D expenditures, they would have an impact on the API and, in turn, the Part D benefit parameters.

Since the law requires the API to be calculated based on data that hasn't been fully submitted at the time of the Announcement, projected data is used to determine the API. In subsequent years, revisions of prior estimates are necessary to reflect the actual increase in average per capita aggregate expenditures. The table shown below provides details for the prior year revisions that were included in the API for 2011.

	Current Estimate	Previous Estimate	Impact
YE July 2006 Increase	6.48%	6.42%	0.06%
YE July 2007 Increase	5.12%	5.34%	-0.21%
YE July 2008 Increase	4.42%	6.12%	-1.60%
YE July 2009 Increase	3.22%	5.79%	-2.43%
Total Prior Year Revision			-4.13%

As shown above, the total prior year revision occurred primarily from the 2008 and 2009 estimated increases. Drug spending in 2008 was lower than expected due to a significant decrease in the lag time in which the claims data was received. For 2009, Part D spending is now projected to be lower than last year based on preliminary 2009 Part D experience.

Comment: One commenter indicated that while the parameters of the defined standard are important, the most significant variables for most beneficiaries are tiering structure, formulary, and utilization management rules. The commenter stated that it is difficult for beneficiaries to access and understand this information when choosing a Part D plan. The commenter asked that CMS simplify the plan options so that beneficiaries can better understand these variables and the impact on their out-of-pocket costs.

Response: We appreciate the concerns raised by the commenter. We are currently addressing the issue of simplifying the prescription drug benefit for consumers by emphasizing that Part D sponsors offer meaningfully different plan benefit packages under the Part D program. Our final regulation (CMS-4085) will provide additional information regarding this requirement.

Comment: A couple of commenters expressed support for our use of Part D program data and prior year revisions to calculate the annual percentage increase. They indicated that Medicare beneficiaries will not see substantial increases in their out-of-pocket costs and the Out-of-pocket threshold as a result of our calculation methodology.

Response: We agree with the commenters that our current methodology is effective in ensuring that the defined standard Part D benefit covers a constant share of Part D drug expenses each year.

Attachment II. Final Updated Part D Benefit Parameters for Defined Standard Benefit, Low-Income Subsidy, and Retiree Drug Subsidy

Annual Percentage Increases

	Annual percentage trend for 2010	Prior year revisions	Annual percentage increase for 2010
Applied to all parameters but (1)	4.63%	-4.13%	.31%
CPI (all items, U.S. city average): Applied to (1)	1.58%	-1.64%	-.08%

Part D Benefit Parameters

	2010	2011
Standard Benefit		
Deductible	$310	$310
Initial Coverage Limit	$2,830	$2,840
Out-of-Pocket Threshold	$4,550	$4,550
Total Covered Part D Spend at Out-of-Pocket Threshold (2)	$6,440.00	$6,447.50
Minimum Cost-Sharing in Catastrophic Coverage Portion of the Benefit		
Generic/Preferred Multi-Source Drug	$2.50	$2.50
Other	$6.30	$6.30
Full Subsidy-Full Benefit Dual Eligible (FBDE) Individuals		
Deductible	$0.00	$0.00
Copayments for Institutionalized Beneficiaries	$0.00	$0.00
Maximum Copayments for Non-Institutionalized Beneficiaries		
Up to or at 100% FPL		
Up to Out-of-Pocket Threshold (1)		
Generic/Preferred Multi-Source Drug (3)	$1.10	$1.10
Other (3)	$3.30	$3.30
Above Out-of-Pocket Threshold	$0.00	$0.00
Over 100% FPL		
Up to Out-of-Pocket Threshold		
Generic/Preferred Multi-Source Drug	$2.50	$2.50
Other	$6.30	$6.30
Above Out-of-Pocket Threshold	$0.00	$0.00
Full Subsidy-Non-FBDE Individuals		
Eligible for QMB/SLMB/QI, SSI or applied and income at or below 135% FPL and resources ≤ $6,600 (individuals) or ≤ $9,910 (couples) (4)		
Deductible	$0.00	$0.00
Maximum Copayments up to Out-of-Pocket Threshold		
Generic/Preferred Multi-Source Drug	$2.50	$2.50
Other	$6.30	$6.30
Maximum Copayments above Out-of-Pocket Threshold	$0.00	$0.00
Partial Subsidy		
Applied and income below 150% FPL and resources below $11,010 (individual) or $22,010 (couple)		
Deductible	$63.00	$63.00
Coinsurance up to Out-of-Pocket Threshold	15%	15%
Maximum Copayments above Out-of-Pocket Threshold		
Generic/Preferred Multi-Source Drug	$2.50	$2.50
Other	$6.30	$6.30
Retiree Drug Subsidy Amounts		
Cost Threshold	$310	$310
Cost Limit	$6,300	$6,300

(1) CPI adjustment applies to copayments for non-institutionalized beneficiaries up to or at 100% FPL.

(2) Amount of total drug spending required to attain out-of-pocket threshold in the defined standard benefit if beneficiary does not have prescription drug coverage through a group health plan, insurance, government-funded health program or similar third party arrangement. Due to the reduced generic cost sharing discussed in the cover letter, this amount may be higher if a beneficiary purchases generic drugs in the coverage gap

(3) The increases to the LIS deductible, generic/preferred multi-source drugs and other drugs copayments are applied to the unrounded 2010 values of $62.93, $1.10, and $3.31, respectively.

(4) The actual amount of resources allowable will be updated for contract year 2011.

Attachment III. Final Rx-HCC Risk Adjustment Factors

Tables

Table 1. CMS RxHCC Model Relative Factors for Continuing Enrollees

[Note: This table is identical to the table published in the February 19, 2010 Advance Notice.]

		Continuing Enrollee (CE) RxHCC Model Segments				
Variable	**Disease Group**	Community, Non-Low Income, Age>=65	Community, Non-Low Income, Age<65	Community, Low Income, Age>=65	Community, Low Income, Age<65	Institutional
Female						
0-34 Years		-	0.266	-	0.405	1.555
35-44 Years		-	0.472	-	0.599	1.576
45-54 Years		-	0.578	-	0.672	1.490
55-59 Years		-	0.571	-	0.643	1.411
60-64 Years		-	0.577	-	0.617	1.357
65 Years		0.418	-	0.449	-	1.447
66 Years		0.418	-	0.449	-	1.447
67 Years		0.418	-	0.449	-	1.447
68 Years		0.418	-	0.449	-	1.447
69 Years		0.418	-	0.449	-	1.447
70-74 Years		0.415	-	0.439	-	1.367
75-79 Years		0.421	-	0.436	-	1.309
80-84 Years		0.431	-	0.432	-	1.254
85-89 Years		0.440	-	0.422	-	1.199
90-94 Years		0.438	-	0.399	-	1.127
95 Years or Over		0.414	-	0.328	-	0.981
Male						
0-34 Years		-	0.244	-	0.435	1.582
35-44 Years		-	0.396	-	0.562	1.542
45-54 Years		-	0.521	-	0.604	1.471
55-59 Years		-	0.519	-	0.571	1.377
60-64 Years		-	0.536	-	0.541	1.325
65 Years		0.425	-	0.367	-	1.384
66 Years		0.425	-	0.367	-	1.384
67 Years		0.425	-	0.367	-	1.384
68 Years		0.425	-	0.367	-	1.384
69 Years		0.425	-	0.367	-	1.384
70-74 Years		0.416	-	0.359	-	1.339

		Continuing Enrollee (CE) RxHCC Model Segments				
Variable	**Disease Group**	Community, Non-Low Income, Age>=65	Community, Non-Low Income, Age<65	Community, Low Income, Age>=65	Community, Low Income, Age<65	Institutional
75-79 Years		0.407	-	0.354	-	1.295
80-84 Years		0.402	-	0.342	-	1.265
85-89 Years		0.404	-	0.343	-	1.242
90-94 Years		0.429	-	0.364	-	1.197
95 Years or Over		0.433	-	0.357	-	1.094
Originally Disabled Interactions with Sex						
Originally Disabled		-	-	-	-	0.031
Originally Disabled_Female		0.066	-	0.102	-	-
Originally Disabled_Female_Age 65		-	-	-	-	-
Originally Disabled_Female_Age 66-69		-	-	-	-	-
Originally Disabled_Female_Age 70-74		-	-	-	-	-
Originally Disabled_Female_Age 75+		-	-	-	-	-
Originally Disabled_Male		0.018	-	0.091	-	-
Originally Disabled_Male_Age 65		-	-	-	-	-
Originally Disabled_Male_Age 66-69		-	-	-	-	-
Originally Disabled_Male_Age 70-74		-	-	-	-	-
Originally Disabled_Male_Age 75+		-	-	-	-	-

		Continuing Enrollee (CE) RxHCC Model Segments				
Disease Coefficients	**Description Label**	Community, Non-Low Income, Age>=65	Community, Non-Low Income, Age<65	Community, Low Income, Age>=65	Community, Low Income, Age<65	Institutional
RXHCC1	HIV/AIDS	1.625	2.381	2.123	2.545	1.082
RXHCC5	Opportunistic Infections	0.111	0.124	0.083	0.180	0.083
RXHCC8	Chronic Myeloid Leukemia	1.684	2.124	2.099	2.374	1.056
RXHCC9	Multiple Myeloma and Other Neoplastic Disorders	1.116	1.304	1.017	1.215	0.557
RXHCC10	Breast, Lung, and Other Cancers and Tumors	0.207	0.206	0.237	0.254	0.102
RXHCC11	Prostate and Other Cancers and Tumors	0.040	0.051	0.116	0.063	0.081
RXHCC14	Diabetes with Complications	0.246	0.186	0.275	0.271	0.158

		Continuing Enrollee (CE) RxHCC Model Segments				
Disease Coefficients	**Description Label**	Community, Non-Low Income, Age>=65	Community, Non-Low Income, Age<65	Community, Low Income, Age>=65	Community, Low Income, Age<65	Institutional
RXHCC15	Diabetes without Complication	0.173	0.151	0.213	0.222	0.113
RXHCC18	Diabetes Insipidus and Other Endocrine and Metabolic Disorders	0.242	0.564	0.187	0.624	0.126
RXHCC19	Pituitary, Adrenal Gland, and Other Endocrine and Metabolic Disorders	0.043	0.060	0.030	0.060	0.060
RXHCC20	Thyroid Disorders	0.037	0.091	0.046	0.104	0.037
RXHCC21	Morbid Obesity	0.038	0.013	0.037	0.049	0.069
RXHCC23	Disorders of Lipoid Metabolism	0.120	0.134	0.142	0.182	0.062
RXHCC25	Chronic Viral Hepatitis	0.078	0.042	0.220	0.111	–
RXHCC30	Chronic Pancreatitis	0.085	0.154	0.046	0.075	0.021
RXHCC31	Pancreatic Disorders and Intestinal Malabsorption, Except Pancreatitis	0.032	0.066	0.034	0.075	0.021
RXHCC32	Inflammatory Bowel Disease	0.264	0.245	0.190	0.315	0.075
RXHCC33	Esophageal Reflux and Other Disorders of Esophagus	0.135	0.111	0.161	0.175	0.075
RXHCC38	Aseptic Necrosis of Bone	0.053	0.153	0.044	0.233	0.068
RXHCC40	Psoriatic Arthropathy	0.321	0.447	0.571	1.011	0.377
RXHCC41	Rheumatoid Arthritis and Other Inflammatory Polyarthropathy	0.169	0.258	0.197	0.390	0.095
RXHCC42	Systemic Lupus Erythematosus, Other Connective Tissue Disorders, and Inflammatory Spondylopathies	0.122	0.236	0.161	0.266	0.084
RXHCC45	Osteoporosis, Vertebral and Pathological Fractures	0.093	0.157	0.125	0.181	0.027
RXHCC47	Sickle Cell Anemia	0.144	0.093	0.133	0.433	0.036
RXHCC48	Myelodysplastic Syndromes, Except High-Grade	0.211	0.370	0.299	0.231	0.426
RXHCC49	Immune Disorders	0.149	0.244	0.130	0.276	0.141
RXHCC50	Aplastic Anemia and Other Significant Blood Disorders	0.044	0.087	0.059	0.073	0.036
RXHCC54	Alzheimer`s Disease	0.468	0.265	0.310	0.184	0.016
RXHCC55	Dementia, Except Alzheimer`s Disease	0.250	0.097	0.143	0.049	–
RXHCC58	Schizophrenia	0.422	0.569	0.645	0.959	0.343

		Continuing Enrollee (CE) RxHCC Model Segments				
Disease Coefficients	**Description Label**	Community, Non-Low Income, Age>=65	Community, Non-Low Income, Age<65	Community, Low Income, Age>=65	Community, Low Income, Age<65	Institutional
RXHCC59	Bipolar Disorders	0.353	0.435	0.427	0.677	0.293
RXHCC60	Major Depression	0.265	0.337	0.308	0.439	0.205
RXHCC61	Specified Anxiety, Personality, and Behavior Disorders	0.159	0.216	0.220	0.439	0.175
RXHCC62	Depression	0.134	0.169	0.146	0.230	0.116
RXHCC63	Anxiety Disorders	0.056	0.122	0.088	0.182	0.116
RXHCC65	Autism	0.171	0.326	0.495	0.661	0.175
RXHCC66	Profound or Severe Mental Retardation/Developmental Disability	0.027	0.326	0.495	0.400	–
RXHCC67	Moderate Mental Retardation/Developmental Disability	0.023	0.178	0.404	0.294	–
RXHCC68	Mild or Unspecified Mental Retardation/Developmental Disability	0.010	0.054	0.239	0.144	–
RXHCC71	Myasthenia Gravis, Amyotrophic Lateral Sclerosis and Other Motor Neuron Disease	0.181	0.303	0.159	0.314	0.057
RXHCC72	Spinal Cord Disorders	0.061	0.156	0.072	0.095	–
RXHCC74	Polyneuropathy	0.085	0.203	0.082	0.182	0.058
RXHCC75	Multiple Sclerosis	0.451	0.811	0.494	1.338	0.123
RXHCC76	Parkinson`s Disease	0.406	0.485	0.295	0.292	0.154
RXHCC78	Intractable Epilepsy	0.355	0.636	0.354	0.915	0.124
RXHCC79	Epilepsy and Other Seizure Disorders, Except Intractable Epilepsy	0.214	0.267	0.170	0.370	0.079
RXHCC80	Convulsions	0.106	0.125	0.099	0.230	0.041
RXHCC81	Migraine Headaches	0.113	0.216	0.111	0.201	0.146
RXHCC83	Trigeminal and Postherpetic Neuralgia	0.093	0.170	0.107	0.154	0.079
RXHCC86	Pulmonary Hypertension and Other Pulmonary Heart Disease	0.253	0.397	0.292	0.345	0.121
RXHCC87	Congestive Heart Failure	0.175	0.089	0.247	0.108	0.099

		Continuing Enrollee (CE) RxHCC Model Segments				
Disease Coefficients	**Description Label**	Community, Non-Low Income, Age>=65	Community, Non-Low Income, Age<65	Community, Low Income, Age>=65	Community, Low Income, Age<65	Institutional
RXHCC88	Hypertension	0.170	0.078	0.219	0.096	0.064
RXHCC89	Coronary Artery Disease	0.145	0.082	0.133	0.046	0.017
RXHCC93	Atrial Arrhythmias	0.060	0.045	0.023	–	0.011
RXHCC97	Cerebrovascular Disease, Except Hemorrhage or Aneurysm	0.065	–	0.050	–	–
RXHCC98	Spastic Hemiplegia	0.142	0.239	0.056	0.149	0.011
RXHCC100	Venous Thromboembolism	0.013	0.043	–	0.085	–
RXHCC101	Peripheral Vascular Disease	0.056	0.030	0.093	0.064	–
RXHCC103	Cystic Fibrosis	0.198	0.665	0.223	1.346	0.117
RXHCC104	Chronic Obstructive Pulmonary Disease and Asthma	0.198	0.123	0.221	0.204	0.117
RXHCC105	Pulmonary Fibrosis and Other Chronic Lung Disorders	0.113	0.123	0.098	0.202	0.037
RXHCC106	Gram-Negative/Staphylococcus Pneumonia and Other Lung Infections	–	0.070	–	0.042	0.028
RXHCC111	Diabetic Retinopathy	0.094	0.085	0.079	0.039	0.035
RXHCC113	Open-Angle Glaucoma	0.142	0.103	0.154	0.124	0.101
RXHCC120	Kidney Transplant Status	0.266	0.170	0.386	0.407	0.338
RXHCC121	Dialysis Status	0.216	0.303	0.283	0.536	0.217
RXHCC122	Chronic Kidney Disease Stage 5	0.114	0.136	0.130	0.167	0.111
RXHCC123	Chronic Kidney Disease Stage 4	0.114	0.136	0.130	0.167	0.111
RXHCC124	Chronic Kidney Disease Stage 3	0.097	0.136	0.115	0.167	0.081
RXHCC125	Chronic Kidney Disease Stage 1, 2, or Unspecified	0.038	0.056	0.035	0.071	0.042
RXHCC126	Nephritis	0.038	0.036	0.035	0.070	0.013
RXHCC142	Chronic Ulcer of Skin, Except Pressure	0.040	0.055	0.028	0.061	–
RXHCC145	Pemphigus	0.110	0.151	0.123	0.258	–
RXHCC147	Psoriasis, Except with Arthropathy	0.106	0.188	0.206	0.289	0.126
RXHCC156	Narcolepsy and Cataplexy	0.267	0.328	0.164	0.440	0.104
RXHCC166	Lung Transplant Status	0.919	0.905	0.968	1.114	0.688
RXHCC167	Major Organ Transplant Status, Except Lung, Kidney, and Pancreas	0.411	0.372	0.417	0.480	0.338

		Continuing Enrollee (CE) RxHCC Model Segments				
Disease Coefficients	**Description Label**	Community, Non-Low Income, Age>=65	Community, Non-Low Income, Age<65	Community, Low Income, Age>=65	Community, Low Income, Age<65	Institutional
RXHCC168	Pancreas Transplant Status	0.266	0.170	0.386	0.351	0.338
Non-Aged Disease Interactions						
NonAged_RXHCC1	HIV/AIDS	-	-	-	-	1.093
NonAged_RXHCC58	Schizophrenia	-	-	-	-	0.388
NonAged_RXHCC59	Bipolar Disorders	-	-	-	-	0.243
NonAged_RXHCC60	Major Depression	-	-	-	-	0.115
NonAged_RXHCC61	Specified Anxiety, Personality, and Behavior Disorders	-	-	-	-	0.115
NonAged_RXHCC62	Depression	-	-	-	-	0.058
NonAged_RXHCC63	Anxiety Disorders	-	-	-	-	0.032
NonAged_RXHCC65	Autism	-	-	-	-	0.115
NonAged_RXHCC75	Multiple Sclerosis	-	-	-	-	0.477
NonAged_RXHCC78	Intractable Epilepsy	-	-	-	-	0.204
NonAged_RXHCC79	Epilepsy and Other Seizure Disorders, Except Intractable Epilepsy	-	-	-	-	0.040
NonAged_RXHCC80	Convulsions	-	-	-	-	0.034

Notes:

1. The relative risk scores in this table were calculated by dividing the parameter estimates by the Part D national average predicted expenditures (CMS Part D Denominator). The Part D Denominator value used was $1,086.61. This Part D Denominator is based on the combined PDP and MA-PD populations.
2. Because Part D drugs post-transplant are less costly for younger Medicare beneficiaries, RxHCC120, which takes precedence over RxHCC121, has a lower coefficient than RxHCC121 for those under age 65.

Source: RTI Analysis of 100% 2008 PDE, 2007 NCH, 2008 HPMS, 2008 CME, and 2007-2008 Denominator.

Table 2. RxHCC Model Relative Factors for New Enrollees, Non-Low Income

[Note: This table is identical to the table published in the February 19, 2010 Advance Notice.]

Variable	Baseline – Not Concurrently ESRD, Not Originally Disabled	Concurrently ESRD, Not Originally Disabled	Originally Disabled, Not Concurrently ESRD	Originally Disabled, Concurrently ESRD
Female				
0-34 Years	0.473	0.908	-	-
35-44 Years	0.789	1.224	-	-
45-54 Years	1.056	1.491	-	-
55-59 Years	1.124	1.559	-	-
60-64 Years	1.173	1.608	-	-
65 Years	0.764	1.199	1.148	1.583
66 Years	0.760	1.195	0.899	1.334
67 Years	0.760	1.195	0.899	1.334
68 Years	0.760	1.195	0.899	1.334
69 Years	0.760	1.195	0.899	1.334
70-74 Years	0.744	1.179	0.744	1.179
75-79 Years	0.681	1.116	0.681	1.116
80-84 Years	0.652	1.087	0.652	1.087
85-89 Years	0.570	1.005	0.570	1.005
90-94 Years	0.570	1.005	0.570	1.005
95 Years or Over	0.570	1.005	0.570	1.005
Male				
0-34 Years	0.323	0.758	-	-
35-44 Years	0.607	1.042	-	-
45-54 Years	0.870	1.304	-	-
55-59 Years	0.927	1.361	-	-
60-64 Years	1.017	1.452	-	-
65 Years	0.781	1.216	1.022	1.457
66 Years	0.765	1.200	0.765	1.200
67 Years	0.765	1.200	0.765	1.200
68 Years	0.765	1.200	0.765	1.200
69 Years	0.765	1.200	0.765	1.200
70-74 Years	0.727	1.162	0.727	1.162
75-79 Years	0.645	1.079	0.645	1.079
80-84 Years	0.544	0.979	0.544	0.979
85-89 Years	0.465	0.900	0.465	0.900
90-94 Years	0.465	0.900	0.465	0.900
95 Years or Over	0.465	0.900	0.465	0.900

NOTES:

1. The Part D Denominator used to calculate relative factors is $1,086.61. This Part D Denominator is based on the combined PDP and MA-PD populations.
2. Originally Disabled is defined as originally entitled to Medicare by disability only.
3. Concurrently ESRD is defined as at least one month in 2008 of ESRD status—dialysis, transplant, or post-graft.

Source: RTI Analysis of 100% 2008 PDE SAF, 2007-2008 HPMS, 2008 CME, and 2007-2008 Denominator.

Table 3. RxHCC Model Relative Factors for New Enrollees, Low Income

[Note: This table is identical to the table published in the February 19, 2010 Advance Notice.]

Variable	Baseline – Not Concurrently ESRD and Not Originally Disabled	Concurrently ESRD, Not Originally Disabled	Originally Disabled, Not Concurrently ESRD	Originally Disabled, Concurrently ESRD
Female				
0-34 Years	0.892	1.441	-	-
35-44 Years	1.241	1.790	-	-
45-54 Years	1.278	1.827	-	-
55-59 Years	1.165	1.713	-	-
60-64 Years	1.137	1.686	-	-
65 Years	0.868	1.417	1.061	1.610
66 Years	0.599	1.148	0.756	1.305
67 Years	0.599	1.148	0.756	1.305
68 Years	0.599	1.148	0.756	1.305
69 Years	0.599	1.148	0.756	1.305
70-74 Years	0.610	1.159	0.767	1.316
75-79 Years	0.665	1.214	0.823	1.372
80-84 Years	0.697	1.246	0.855	1.404
85-89 Years	0.696	1.245	0.854	1.402
90-94 Years	0.696	1.245	0.854	1.402
95 Years or Over	0.696	1.245	0.854	1.402
Male				
0-34 Years	0.836	1.385	-	-
35-44 Years	1.115	1.664	-	-
45-54 Years	1.075	1.623	-	-
55-59 Years	0.931	1.480	-	-
60-64 Years	0.882	1.431	-	-
65 Years	0.687	1.236	0.787	1.336
66 Years	0.445	0.994	0.549	1.098
67 Years	0.445	0.994	0.549	1.098
68 Years	0.445	0.994	0.549	1.098
69 Years	0.445	0.994	0.549	1.098
70-74 Years	0.457	1.006	0.561	1.110
75-79 Years	0.487	1.036	0.487	1.036
80-84 Years	0.480	1.029	0.480	1.029
85-89 Years	0.517	1.065	0.517	1.065
90-94 Years	0.517	1.065	0.517	1.065
95 Years or Over	0.517	1.065	0.517	1.065

NOTES:

1. The Part D Denominator used to calculate relative factors is $1,086.61. This Part D Denominator is based on the combined PDP and MA-PD populations.
2. Originally Disabled is defined as originally entitled to Medicare by disability only.
3. Concurrently ESRD is defined as at least one month in 2008 of ESRD status—dialysis, transplant, or post-graft.

Source: RTI Analysis of 100% 2008 PDE SAF, 2007-2008 HPMS, 2008 CME, and 2007-2008 Denominator.

Table 4. RxHCC Model Relative Factors for New Enrollees, Institutional

[Note: This table is identical to the table published in the February 19, 2010 Advance Notice.]

Variable	Baseline – Not Concurrently ESRD	Concurrently ESRD
Female		
0-34 Years	2.136	2.371
35-44 Years	2.136	2.371
45-54 Years	2.050	2.285
55-59 Years	2.013	2.248
60-64 Years	1.952	2.187
65 Years	2.024	2.259
66 Years	1.816	2.051
67 Years	1.816	2.051
68 Years	1.816	2.051
69 Years	1.816	2.051
70-74 Years	1.646	1.881
75-79 Years	1.578	1.813
80-84 Years	1.403	1.638
85-89 Years	1.235	1.470
90-94 Years	1.235	1.470
95 Years or Over	1.235	1.470
Male		
0-34 Years	2.159	2.394
35-44 Years	2.159	2.394
45-54 Years	2.098	2.333
55-59 Years	1.975	2.210
60-64 Years	1.826	2.061
65 Years	1.823	2.058
66 Years	1.715	1.950
67 Years	1.715	1.950
68 Years	1.715	1.950
69 Years	1.715	1.950
70-74 Years	1.603	1.838
75-79 Years	1.567	1.802
80-84 Years	1.533	1.768
85-89 Years	1.317	1.552
90-94 Years	1.317	1.552
95 Years or Over	1.317	1.552

NOTES:

1. The Part D Denominator used to calculate relative factors is $1,086.61. This Part D Denominator is based on the combined PDP and MA-PD populations.
2. Concurrently ESRD is defined as at least one month in 2008 of ESRD status—dialysis, transplant, or post-graft.
3. The Part D New Enrollee Institutional sample does not have an Originally Disabled add-on (set to $0 because of regression results).

Source: RTI Analysis of 100% 2008 PDE SAF, 2007-2008 HPMS, 2008 CME, and 2007-2008 Denominator.

Table 5. List of Disease Hierarchies for the Revised RxHCC Model

[Note: This table is identical to the table published in the February 19, 2010 Advance Notice.]

DISEASE HIERARCHIES

Rx Hierarchical Condition Category (RxHCC)	If the Disease Group is Listed in this column…	…Then drop the RxHCC(s) listed in this column
	Rx Hierarchical Condition Category (RxHCC) LABEL	
8	Chronic Myeloid Leukemia	9,10,11,48,50
9	Multiple Myeloma and Other Neoplastic Disorders	10,11,48,50
10	Breast, Lung, and Other Cancers and Tumors	11
14	Diabetes with Complications	15
18	Diabetes Insipidus and Other Endocrine and Metabolic Disorders	19
30	Chronic Pancreatitis	31
40	Psoriatic Arthropathy	41,42,147
41	Rheumatoid Arthritis and Other Inflammatory Polyarthropathy	42
47	Sickle Cell Anemia	50
48	Myelodysplastic Syndromes, Except High-Grade	50
54	Alzheimer's Disease	55
58	Schizophrenia	59,60,61,62,63,65,66,67,68
59	Bipolar Disorders	60,61,62,63
60	Major Depression	61,62,63
61	Specified Anxiety, Personality, and Behavior Disorders	62,63
62	Depression	63
65	Autism	61,62,63,66,67,68
66	Profound or Severe Mental Retardation/Developmental Disability	67,68
67	Moderate Mental Retardation/Developmental Disability	68
78	Intractable Epilepsy	79,80
79	Epilepsy and Other Seizure Disorders, Except Intractable Epilepsy	80
86	Pulmonary Hypertension and Other Pulmonary Heart Disease	87,88
87	Congestive Heart Failure	88
103	Cystic Fibrosis	104,105
104	Chronic Obstructive Pulmonary Disease and Asthma	105
120	Kidney Transplant Status	121,122,123,124,125,126,168
121	Dialysis Status	122,123,124,125,126
122	Chronic Kidney Disease Stage 5	123,124,125,126
123	Chronic Kidney Disease Stage 4	124,125,126
124	Chronic Kidney Disease Stage 3	125,126
125	Chronic Kidney Disease Stage 1, 2, or Unspecified	126
166	Lung Transplant Status	167,168
167	Major Organ Transplant Status, Except Lung, Kidney, and Pancreas	168

SOURCE: RTI International.

Table 6. Comparison of Current and Revised RxHCC Risk Adjustment Model RxHCCs

[Note: This table is identical to the table published in the February 19, 2010 Advance Notice.]

Version 01 RxHCCs			Version 03 RxHCCs	
RxHCC	**Description**	**Category Short Name**	**RxHCC**	**Description**
RXHCC1	HIV/AIDS	Infection	RXHCC1	HIV/AIDS
RXHCC2	Opportunistic Infections		RXHCC5	Opportunistic Infections
RXHCC3	Infectious Diseases			
RXHCC8	Acute Myeloid Leukemia	Neoplasm	RXHCC8	Chronic Myeloid Leukemia
RXHCC9	Metastatic Cancer, Acute Leukemia, and Severe Cancers		RXHCC9	Multiple Myeloma and Other Neoplastic Disorders
RXHCC10	Lung, Upper Digestive Tract, and Other Severe Cancers		RXHCC10	Breast, Lung, and Other Cancers and Tumors
			RXHCC11	Prostate and Other Cancers and Tumors
RXHCC17	Diabetes with Complications	Diabetes	RXHCC14	Diabetes with Complications
RXHCC18	Diabetes without Complication		RXHCC15	Diabetes without Complication
RXHCC19	Disorders of Lipoid Metabolism	Metabolic	RXHCC18	Diabetes Insipidus and Other Endocrine and Metabolic Disorders
RXHCC20	Other Significant Endocrine and Metabolic Disorders		RXHCC19	Pituitary, Adrenal Gland, and Other Endocrine and Metabolic Disorders
RXHCC21	Other Specified Endocrine/Metabolic/Nutritional Disorders		RXHCC20	Thyroid Disorders
			RXHCC21	Morbid Obesity
			RXHCC23	Disorders of Lipoid Metabolism
RXHCC24	Chronic Viral Hepatitis	Liver	RXHCC25	Chronic Viral Hepatitis
RXHCC31	Chronic Pancreatic Disease	Gastrointestinal	RXHCC30	Chronic Pancreatitis
			RXHCC31	Pancreatic Disorders and Intestinal Malabsorption, Except Pancreatitis
RXHCC33	Inflammatory Bowel Disease		RXHCC32	Inflammatory Bowel Disease
RXHCC34	Peptic Ulcer and Gastrointestinal Hemorrhage		RXHCC33	Esophageal Reflux and Other Disorders of Esophagus
RXHCC37	Esophageal Disease			
RXHCC39	Bone/Joint/Muscle Infections/Necrosis	Musculoskeletal	RXHCC38	Aseptic Necrosis of Bone
RXHCC40	Behçet's Syndrome and Other Connective Tissue Disease		RXHCC40	Psoriatic Arthropathy
RXHCC41	Rheumatoid Arthritis and Other Inflammatory Polyarthropathy		RXHCC41	Rheumatoid Arthritis and Other Inflammatory Polyarthropathy

Version 01 RxHCCs			Version 03 RxHCCs	
RxHCC	**Description**	**Category Short Name**	**RxHCC**	**Description**
RXHCC42	Inflammatory Spondylopathies		RXHCC42	Systemic Lupus Erythematosus, Other Connective Tissue Disorders, and Inflammatory Spondylopathies
RXHCC43	Polymyalgia Rheumatica		RXHCC45	Osteoporosis, Vertebral and Pathological Fractures
RXHCC44	Psoriatic Arthropathy			
RXHCC45	Disorders of the Vertebrae and Spinal Discs			
RXHCC47	Osteoporosis and Vertebral Fractures			
RXHCC48	Other Musculoskeletal and Connective Tissue Disorders			
RXHCC51	Severe Hematological Disorders	Blood	RXHCC47	Sickle Cell Anemia
RXHCC52	Disorders of Immunity		RXHCC48	Myelodysplastic Syndromes, Except High-Grade
RXHCC54	Polycythemia Vera		RXHCC49	Immune Disorders
RXHCC55	Coagulation Defects and Other Specified Blood Diseases		RXHCC50	Aplastic Anemia and Other Significant Blood Disorders
RXHCC57	Delirium and Encephalopathy	Cognitive	RXHCC54	Alzheimer's Disease
RXHCC59	Dementia with Depression or Behavioral Disturbance		RXHCC55	Dementia, Except Alzheimer's Disease
RXHCC60	Dementia/Cerebral Degeneration			
RXHCC65	Schizophrenia	Psychiatric	RXHCC58	Schizophrenia
RXHCC66	Other Major Psychiatric Disorders		RXHCC59	Bipolar Disorders
RXHCC67	Other Psychiatric Symptoms/Syndromes		RXHCC60	Major Depression
RXHCC75	Attention Deficit Disorder		RXHCC61	Specified Anxiety, Personality, and Behavior Disorders
			RXHCC62	Depression
			RXHCC63	Anxiety Disorders

Version 01 RxHCCs			Version 03 RxHCCs	
RxHCC	**Description**	**Category Short Name**	**RxHCC**	**Description**
		Developmental Disability	RXHCC65	Autism
			RXHCC66	Profound or Severe Mental Retardation/Developmental Disability
			RXHCC67	Moderate Mental Retardation/Developmental Disability
			RXHCC68	Mild or Unspecified Mental Retardation/Developmental Disability
RXHCC76	Motor Neuron Disease and Spinal Muscular Atrophy	Neurological	RXHCC71	Myasthenia Gravis, Amyotrophic Lateral Sclerosis and Other Motor Neuron Disease
RXHCC77	Quadriplegia, Other Extensive Paralysis, and Spinal Cord Injuries		RXHCC72	Spinal Cord Disorders
RXHCC78	Muscular Dystrophy		RXHCC74	Polyneuropathy
RXHCC79	Polyneuropathy, except Diabetic		RXHCC75	Multiple Sclerosis
RXHCC80	Multiple Sclerosis		RXHCC76	Parkinson`s Disease
RXHCC81	Parkinson's Disease		RXHCC78	Intractable Epilepsy
RXHCC82	Huntington's Disease		RXHCC79	Epilepsy and Other Seizure Disorders, Except Intractable Epilepsy
RXHCC83	Seizure Disorders and Convulsions		RXHCC80	Convulsions
RXHCC85	Migraine Headaches		RXHCC81	Migraine Headaches
RXHCC86	Mononeuropathy, Other Abnormal Movement Disorders		RXHCC83	Trigeminal and Postherpetic Neuralgia
RXHCC87	Other Neurological Conditions/Injuries			
RXHCC91	Congestive Heart Failure	Heart	RXHCC86	Pulmonary Hypertension and Other Pulmonary Heart Disease
RXHCC92	Acute Myocardial Infarction and Unstable Angina		RXHCC87	Congestive Heart Failure
RXHCC98	Hypertensive Heart Disease or Hypertension		RXHCC88	Hypertension
RXHCC99	Specified Heart Arrhythmias		RXHCC89	Coronary Artery Disease
			RXHCC93	Atrial Arrhythmias

Version 01 RxHCCs			Version 03 RxHCCs	
RxHCC	**Description**	**Category Short Name**	**RxHCC**	**Description**
RXHCC102	Cerebral Hemorrhage and Effects of Stroke	Cerebrovascular Disease	RXHCC97	Cerebrovascular Disease, Except Hemorrhage or Aneurysm
			RXHCC98	Spastic Hemiplegia
RXHCC105	Pulmonary Embolism and Deep Vein Thrombosis	Vascular	RXHCC100	Venous Thromboembolism
RXHCC106	Vascular Disease		RXHCC101	Peripheral Vascular Disease
RXHCC108	Cystic Fibrosis	Lung	RXHCC103	Cystic Fibrosis
RXHCC109	Asthma and COPD		RXHCC104	Chronic Obstructive Pulmonary Disease and Asthma
RXHCC110	Fibrosis of Lung and Other Chronic Lung Disorders		RXHCC105	Pulmonary Fibrosis and Other Chronic Lung Disorders
RXHCC111	Aspiration and Specified Bacterial Pneumonias		RXHCC106	Gram-Negative/Staphylococcus Pneumonia and Other Lung Infections
RXHCC112	Empyema, Lung Abscess, and Fungal and Parasitic Lung Infections			
RXHCC113	Acute Bronchitis and Congenital Lung/Respiratory Anomaly			
RXHCC120	Vitreous/Retinal Hemorrhage and Vascular Retinopathy except Diabetic	Eye	RXHCC111	Diabetic Retinopathy
RXHCC121	Macular Degeneration and Retinal Disorders, Except Detachment and Vascular Retinopathies		RXHCC113	Open-Angle Glaucoma
RXHCC122	Open-angle Glaucoma			
RXHCC123	Glaucoma and Keratoconus			
RXHCC126	Larynx/Vocal Cord Diseases	Ear, Nose, Throat		
RXHCC129	Other Diseases of Upper Respiratory System			
RXHCC130	Salivary Gland Diseases			
RXHCC132	Kidney Transplant Status	Kidney	RXHCC120	Kidney Transplant Status
RXHCC134	Chronic Renal Failure		RXHCC121	Dialysis Status
			RXHCC122	Chronic Kidney Disease Stage 5
			RXHCC123	Chronic Kidney Disease Stage 4
			RXHCC124	Chronic Kidney Disease Stage 3
			RXHCC125	Chronic Kidney Disease Stage 1, 2, or Unspecified
RXHCC135	Nephritis		RXHCC126	Nephritis

Version 01 RxHCCs			Version 03 RxHCCs	
RxHCC	**Description**	**Category Short Name**	**RxHCC**	**Description**
RXHCC137	Urinary Obstruction and Retention	Urinary, Genital		
RXHCC138	Fecal Incontinence			
RXHCC139	Incontinence			
RXHCC140	Impaired Renal Function and Other Urinary Disorders			
RXHCC144	Vaginal and Cervical Diseases			
RXHCC145	Female Stress Incontinence			
RXHCC157	Chronic Ulcer of Skin, Except Decubitus	Skin	RXHCC142	Chronic Ulcer of Skin, Except Pressure
RXHCC158	Psoriasis		RXHCC145	Pemphigus
RXHCC159	Cellulitis and Local Skin Infection		RXHCC147	Psoriasis, Except with Arthropathy
RXHCC160	Bullous Dermatoses and Other Specified Erythematous Conditions			
RXHCC165	Vertebral Fractures without Spinal Cord Injury	Injury		*(See Note 2.)*
RXHCC166	Pelvic Fracture			
		Sleep	RXHCC156	Narcolepsy and Cataplexy
RXHCC186	Major Organ Transplant Status	Transplant	RXHCC166	Lung Transplant Status
RXHCC187	Other Organ Transplant/Replacement		RXHCC167	Major Organ Transplant Status, Except Lung, Kidney, and Pancreas
			RXHCC168	Pancreas Transplant Status
		Disabled-Disease Interactions		
DRXHCC65	Age < 65 and RXHCC65 (Schizophrenia)			
DRXHCC66	Age < 65 and RXHCC66 (Other Major Psychiatric Disorders)			
DRXHCC108	Age < 65 and RXHCC108 (Cystic Fibrosis)			
		Interactions That Are in the V03 Institutional RxHCC Model *Only*		
			NonAged_RXHCC1	NonAged * HIV/AIDS
			NonAged_RXHCC58	NonAged * Schizophrenia
			NonAged_RXHCC59	NonAged * Bipolar Disorders
			NonAged_RXHCC60	NonAged * Major Depression
			NonAged_RXHCC61	NonAged * Specified Anxiety, Personality, and Behavior Disorders

Version 01 RxHCCs			Version 03 RxHCCs	
RxHCC	Description	Category Short Name	RxHCC	Description
			NonAged_RXHCC62	NonAged * Depression
			NonAged_RXHCC63	NonAged * Anxiety Disorders
			NonAged_RXHCC65	NonAged * Autism
			NonAged_RXHCC75	NonAged * Multiple Sclerosis
			NonAged_RXHCC78	NonAged * Intractable Epilepsy
			NonAged_RXHCC79	NonAged * Epilepsy and Other Seizure Disorders, Except Intractable Epilepsy
			NonAged_RXHCC80	NonAged * Convulsions

NOTES:
1. NonAged is defined as age < 65 as of February 1 of the payment year.

SOURCE: RTI International.

Table 7. CMS-HCC Model for New Enrollees in Chronic Condition Special Needs Plans (C-SNPs)

	Non-Medicaid & Non-Originally Disabled	Medicaid & Non-Originally Disabled	Non-Medicaid & Originally Disabled	Medicaid & Originally Disabled
Female				
0-34 Years	0.811	1.126	—	—
35-44 Years	1.001	1.316	—	—
45-54 Years	1.180	1.495	—	—
55-59 Years	1.326	1.641	—	—
60-64 Years	1.389	1.704	—	—
65 Years	0.768	1.238	1.369	1.839
66 Years	0.803	1.273	1.404	1.874
67 Years	0.830	1.300	1.431	1.901
68 Years	0.873	1.343	1.474	1.944
69 Years	0.902	1.372	1.503	1.973
70-74 Years	1.020	1.457	1.632	2.069
75-79 Years	1.255	1.629	1.754	2.128
80-84 Years	1.393	1.767	1.892	2.266
85-89 Years	1.502	1.876	2.001	2.375
90-94 Years	1.639	2.013	2.138	2.512
95 Years or Over	1.593	1.967	2.092	2.466
Male				
0-34 Years	0.728	1.071	—	—
35-44 Years	1.008	1.351	—	—
45-54 Years	1.148	1.491	—	—
55-59 Years	1.308	1.651	—	—
60-64 Years	1.415	1.758	—	—
65 Years	0.856	1.330	1.392	1.866
66 Years	0.875	1.349	1.486	1.960
67 Years	0.978	1.452	1.589	2.063
68 Years	0.981	1.455	1.592	2.066
69 Years	0.998	1.472	1.609	2.083
70-74 Years	1.186	1.597	1.684	2.095
75-79 Years	1.422	1.859	1.782	2.219
80-84 Years	1.581	2.018	1.941	2.378
85-89 Years	1.776	2.213	2.136	2.573
90-94 Years	1.890	2.327	2.250	2.687
95 Years or Over	1.996	2.433	2.356	2.793

Notes:

1. For payment purposes, a new enrollee is a beneficiary who did not have 12 month of Part B eligibility in the data collection year. CMS-HCC new enrollee models are not based on diagnoses, but include factors for different age and gender combinations by Medicaid and the original reason for Medicare entitlement.
2. The relative factors in this table were calculated by estimating the incremental amount to the standard new enrollee risk model needed to predict the risk scores of continuing enrollees in C-SNPs.

SOURCE: RTI International analysis of 2008 C-SNP risk scores.

Attachment IV: 2011 Call Letter

How to Use This Call Letter

The 2011 Call Letter contains information on the Part C, cost-based (Quality and Performance Measures section only), and Part D programs. Also, we indicate when certain sections apply to cost-reimbursed HMOs, PACE programs, and employer and union-sponsored group health plans (EGWPs).

This year's letter is structured differently from prior year call letters. Section 1 provides new policy for MA plans, MA-PD plans, PDPs and cost-reimbursed HMOs. Section 2 provides updated information for Parts C and D organizations/sponsors, including the updated calendar for CY 2011.

Over the past year, CMS has committed its resources to improving the quality of plan choices for beneficiaries who elect to enroll in Medicare Advantage and prescription drug plans. As part of this effort, CMS:

- Published a proposed regulation (4085-P) on October 22, 2009 that would make revisions to the Parts C and D regulations to ensure meaningful differences among plan offerings, strengthen beneficiary protections, and improve data for CMS oversight and quality assessment.
- Released new or revised Medicare manual chapters.
- Non-renewed a number of plans for CY 2010 because they had little or no enrollment, thus reducing beneficiaries' confusion when choosing to enroll in a Medicare Advantage or prescription drug plan.
- Conducted listening sessions for industry and advocacy groups before the end of CY 2009, to give them the opportunity to communicate their concerns to CMS regarding any procedural or operational issues they would like CMS to address in the 45-day notice and call letter for CY 2011.

Since we anticipate that this year's final Call Letter will be released the same day as the issuance of the final rule (4085-F), the content is limited to clarification of current policy and operational guidance. We remind sponsoring organizations to continue to remain responsible for familiarizing themselves with new statutory requirements, regulations, and guidance governing the MA and Part D programs, including the Medicare Advantage and Prescription Drug Benefit Manuals. CMS will separately issue technical and procedural clarifications regarding bid and formulary submissions, benefits, HPMS data, CMS marketing models, and other operational issues of interest to sponsoring organizations.

We hope this information helps you implement and comply with CMS policies and procedures as you prepare either to offer a plan for the first time or continue offering plans under the MA and/or Part D programs.

If you have questions concerning this Call Letter, please contact:
Christopher McClintick at Christopher.McClintick@cms.hhs.gov for Part C Call Letter items
Christine Hinds at Christine.Hinds@cms.hhs.gov for Part D Call Letter items

Table of Contents

Section 1 - New Policy

Part C

I. Special Needs Plans (SNP)

State Resource Center

Section 164 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) directed CMS to provide technical assistance to States to promote Medicare-Medicaid benefit integration for dual eligible populations. The Resource Center was CMS' response to equip States with helpful information as they engage in contract negotiations with MAOs seeking to offer new or expanded dual eligible special needs plans (SNP).

The goal of the State Resource Center is to support State Medicaid agencies' efforts to increase coordination with MAOs offering specialized plans for dually eligible individuals (dual eligible SNPs). Additionally, the State Resource Center provides a forum for States to make inquires and share knowledge about the coordination of State and Federal policies pertaining to SNPs. To these ends, since its establishment the resource center has—

- Developed best practices with respect to model contracts with States
- Led training sessions
- Established a website to provide information on coordination issues (http://www.cms.gov/SpecialNeedsPlans/05_StateResourceCenter.asp)

II. Quality and Performance Measures

CAHPS and HOS Reporting for Special Needs Plans

For plan year 2011, the Consumer Assessment of Health Plans Survey (CAHPS) and the Medicare Health Outcomes Survey (HOS) will continue to sample, collect, and report data at the contract level. However, oversampling of SNP plan benefit packages will occur within each eligible contract to allow for a more focused analysis of SNP results. CMS will release information about the expected increase in sample size for applicable organizations in future guidance.

CMS is currently analyzing limited aggregate SNP data available from prior HOS and CAHPS data sets and will publicly share findings in a report that will be released later in 2010.

Note: Continuing 1876 cost contracts should continue to report the same quality and performance measures as they have in the past.

HOS Survey Administration

The current year Healthcare Effectiveness Data Information Set (HEDIS) reporting category that reports the HOS results applies to the following managed care organization types with a minimum of 500 members that had a Medicare contract in effect on or before January 1, 2010: (1) all coordinated care contractors, including health maintenance organizations (HMOs), local preferred provider organizations (PPOs) and regional PPOs; (2) private fee-for-service (PFFS) contracts; (3) medical savings account (MSA) contracts; and (4) continuing 1876 cost contracts with open enrollment. Organizations eligible to report also include MA contracts with exclusively special needs plan benefit packages, regardless of institutional, chronically ill, or dual-eligible enrollment.

All Programs of All Inclusive Care for the Elderly (PACE) with contracts in effect on or before January 1, 2010 should administer the HOS-Modified (HOS-M) survey for current year reporting. A minimum enrollment threshold does not apply to the HOS-M. Note that, effective 2010, the Minnesota Senior Health Options, Minnesota Disability Health Options, Wisconsin Partnership Programs, and Massachusetts MassHealth Senior Care Options MA contracts are required to report HOS and no longer participate in HOS-M.

Part D

I. Part D Benefits

Potential New B versus D Coverage Determination for beneficiaries with End Stage Renal Disease

CMS published a notice of proposed rulemaking (NPRM) in the Federal Register on September 29, 2009 that would implement a case-mix adjusted bundled prospective payment system (PPS) for Medicare outpatient end-stage renal disease (ESRD) dialysis facilities beginning January 1, 2011, in compliance with the statutory requirement of the Medicare Improvements for Patients and Providers Act (MIPPA) of 2008. (74 FR 49922) The proposed ESRD PPS would replace the current basic case-mix adjusted composite payment system and the methodologies for the reimbursement of separately billable outpatient ESRD services. In accordance with MIPPA, the rule proposes to include erythropoiesis stimulating agents, and other drugs and biologicals and their oral equivalents, furnished to individuals for the treatment of ESRD in the new bundled payment as “renal dialysis services”. Any such drugs or biologicals that would be defined as “renal dialysis services” under the new ESRD PPS would not be eligible for coverage under Part D when furnished to individuals for the treatment of ESRD. Rather, these drugs or biologicals and all other renal dialysis services would be covered under the Medicare Part B benefit. CMS will explore the possibility of providing an indicator on transaction reply reports to identify ESRD beneficiaries in the dialysis stage that could assist Part D sponsors with making associated

Medicare Part B vs. Part D determinations. CMS plans to publish the ESRD PPS final rule in 2010.

Encouragement of Sponsor Practices to Curb Waste of Unused Drugs Dispensed in the Retail Setting

As part of CMS's effort to contain health care costs and reduce waste associated with the Medicare prescription drug benefit, we requested in the draft call letter comments from beneficiary advocate groups and the industry regarding a trial supply program. Specifically, CMS encouraged that Part D sponsors consider allowing beneficiaries in the community (versus institutional) setting the option to request a trial supply of no more than 7 to 14 days of a Part D covered medication when first prescribed. As explained in the draft call letter, Part D sponsors would be expected to prorate cost-share amounts associated with that prescription. We received many comments regarding our request for plan sponsors to consider providing trial supplies of drugs for reduced (prorated) copayments.

While no requirements have been proposed, we want to emphasize that any trial program contemplated by CMS would be strictly voluntary for the beneficiary and, therefore, should not result in additional burden being placed on beneficiaries. In our view, neither the Part D plan sponsors nor the Federal government would determine whether a beneficiary should receive a trial size of a new medication. As envisioned, use of the trial program would be driven exclusively by the beneficiary and his/her prescriber. In practice, the program would begin at the prescriber's office, when the beneficiary received an initial prescription for a new medication and requested a trial supply. If the prescriber thought this appropriate and agreed, the prescriber might write either one prescription for a trial period, or two prescriptions (e.g. one for the initial trial supply and a second prescription for the remainder of a 30 day (or greater) fill which would be filled if the beneficiary and the clinician agreed the therapy should be continued.). Since the prescriber would determine whether the medication being prescribed could be dispensed in a trial or is a medication that should not, or could not be prescribed in trial doses (e.g. antibiotic or prescription ointment), no harm would be expected to come to the beneficiary. Furthermore, since the prescriptions could be written during one office visit, additional visits to the prescriber would not necessarily be required and should not be a burden to the beneficiary. If a beneficiary would have difficulty returning to the pharmacy, presumably he or she would not elect to make use of this option.

We received a number of comments asserting that savings realized by this program would be offset by additional dispensing fees, administrative (programming) costs, or costs of a fill that would otherwise be made available via a free prescription sample. We believe further outreach and discussion with prescribers, pharmacists, and Part D sponsors are warranted to explore these assertions. We would certainly expect plans and pharmacies to negotiate dispensing fees to appropriately reimburse for multiple dispensing events associated with trial fills. However, we also believe that the additional costs of both a trial supply and follow-up supply of some

medications might well be offset by savings associated with reduced dispensing of other medications that become discontinued due to adverse reactions or other reasons. And while it is true that samples received at the prescriber's office are generally available at no cost to the beneficiary or the plan, we believe the use of samples sometimes results in additional costs to the program in the long run and may even increase the risk of adverse medication events as long as plan sponsor drug utilization review (DUR) systems do not reflect the drug therapies initiated through sample use.

We also received a number of positive comments supporting our efforts to curb drug waste. For instance, one commenter indicated that patients should not be asked to shoulder the expense of a 30 or 90 day prescription when it is not clear that the therapy will be an effective course of treatment. However, many commenters qualified their support by indicating their wish to observe the trial program in practice, and suggested technical issues that may develop while implementing the trial program. We understand that the implementation of a voluntary trial program would result in plan programming changes and require clarification of other Part D benefit rules. We were informed that the current "partial fill" standard may not accommodate a voluntary trial fill; therefore, CMS will work with NCPDP to explore whether any changes to adjudication standards are needed to accommodate such transactions. In the meantime, certain practices such as the initial issuances of two prescriptions, mentioned above, might be accommodated without need for changes to the standard. CMS will also contemplate the need for additional guidance around how a trial fill would impact Part D benefit rules, specifically application of the Part D low-income subsidy cost share at the pharmacy and our current transition policy.

CMS would also like to further explore the additional studies, plan programs and drug waste disposal programs cited in the call letter comments. Of particular interest is further discussion with the industry regarding the SMARxT program. While environmental considerations warrant additional thought, we do not agree with one commenter's concerns that the benefits of a trial program may be offset by other additional waste (more plastic bottles and paper inserts, additional trips to pharmacies). We believe the harmful effects on the environment from unused drugs (biological implications) have a much greater impact on the environment than the recyclable surplus noted by the commenter. Furthermore, analysis of the environmental impact of additional trips to the pharmacy would likely find that many beneficiaries time their pharmacy visits during other scheduled outings. Therefore, we suspect the environmental impact of additional pharmacy visits on the environment would be negligible.

We appreciate the extensive comments submitted in response to our request, and we have been persuaded that extensive discussions with prescribers, pharmacies and Part D sponsors are warranted before we would contemplate any requirements in this area. We continue to believe that trial fills of new drug therapies for chronic diseases might be a welcome addition to the Part D program, particularly when the drugs involved have significant probabilities of being discontinued due to side effects or other outcomes as determined between the beneficiary and

his/her prescriber. We commit to exploring this idea further in the coming months. In the meantime, we continue to encourage our Part D sponsors to consider the implications of implementing such a program, as well as any other waste reduction strategies, with their network pharmacy contacts and with CMS.

II. Reassignment

In the draft call letter, we requested comments on two policy issues related to the annual reassignment of certain low-income subsidy (LIS) beneficiaries in stand-alone prescription drug plans (PDPs). Currently, reassignment is limited to LIS beneficiaries who remain in the PDPs to which they were initially assigned by CMS, or in PDPs to which they were subsequently reassigned. All reassignments are done on a random basis to PDPs in a region with premiums below the LIS benchmark in the following year.

First, we requested comments on whether CMS should reassign LIS beneficiaries who chose their PDP on their own if their premium liability would be $10.00 or more the following year ("choosers"). Slightly more than half of commenters supported the proposal to reassign some choosers in principle, although, there was no consensus on the $10.00 threshold. Many of the supporters suggested additional criteria to identify choosers for reassignment, such as whether the plan had a premium over the LIS benchmark when the individual originally selected it, whether one's payment ability or enrollment in a State Pharmaceutical Assistance Program (SPAP). Those who opposed reassigning choosers cited concerns about the need to respect beneficiary choice, the possibility of creating disruptions of drug regimens, and CMS' inability to discern which choosers wanted to stay in their current plan. They also noted that the policy would work against CMS' longstanding goal of minimizing the number of reassignments. There was consensus among both supporters and opponents that additional outreach and education would be helpful.

Given the mixed response to this proposal, the lack of any evidence that this population is failing to pay its premiums, and concerns over the possibility of unintended negative consequences for affected enrollees, we have decided not to expand our reassignment process for 2011 to include this population. However, will continue to explore the merits of this approach for future years and other ways to help beneficiaries enroll in the plans that best meet their needs. We agree that additional education and outreach are warranted, and are considering several methods to make beneficiaries more aware of their options.

CMS also solicited comments on whether reassignments should be based on beneficiary drug utilization (often called "strategic" or "beneficiary-centered" reassignment) rather than our current random methodology among benchmark PDPs. The majority of commenters supported modifying reassignment in this way; however, some commenters expressed concern about whether such reassignments could be conducted effectively. CMS will continue to evaluate the merits of this approach, but we will not pursue implementation for the 2011 contract year. We believe additional analysis is warranted and are committed to continuing to examine the costs

and benefits of strategic assignment both for individual beneficiaries and for the Part D program as a whole.

Section 2 - Updates to Parts C and D Policy/Calendar

2011 MA, MA-PD, Part D and Cost-Based Plan Calendar **(All dates, unless identified as statutory, are subject to change)**				
2010 ***Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D Sponsors also apply to MA and cost-based plans offering a Part D benefit.**		***Part C**	***Part D Sponsors**	**Cost**
March 5, 2010	Initial Submission deadline for risk adjustment data with dates of service January 1, 2009 through December 31, 2009.	✓		✓
March 29, 2010	Release Health Plan Management System (HPMS) formulary submissions module.	✓	✓	
Early April 2010	Release guidance regarding potentially duplicative and /or low enrollment plans for 2011 bid submission.	✓	✓	
TBD	Conference call with industry to discuss the 2011 Call Letter.	✓	✓	✓
Early April 2010	Information about renewal options for contract year 2011 (including HPMS crosswalk charts) will be provided to plans.	✓	✓	
Early April 2010	Release guidance regarding benefits review standards for 2011 bid submissions.	✓	✓	
April 5, 2010	2011 Final Call Letter released. Announce CY 2011 MA Capitation Rates and MA and Part D Payment Policies. *(applies to Part C and Part D Sponsors only)*	✓	✓	✓
April 9, 2010	2011 Plan Creation Module, Plan Benefit Package (PBP), and Bid Pricing Tool (BPT) available on HPMS.	✓	✓	
April 19, 2010	2011 Formulary Submissions due from all sponsors offering Part D (11:59 p.m. EDT). Transition Attestations due to CMS *(Part D sponsors only)*	✓	✓	
April 20-21	Medicare Advantage and Part D Spring Conference	✓	✓	✓

2011 MA, MA-PD, Part D and Cost-Based Plan Calendar **(All dates, unless identified as statutory, are subject to change)**				
2010 ***Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D Sponsors also apply to MA and cost-based plans offering a Part D benefit.**		***Part C**	***Part D Sponsors**	**Cost**
May 2010	Final ANOC/EOC, LIS rider, EOB, formularies, transition notice, provider directory, and pharmacy directory models for 2011 will be available for all organizations. (Models containing significant revisions will be released for public comment prior to this date).	✓	✓	
May 3, 2010	Voluntary Non-Renewal. CMS strongly encourages MA and MA-PD plans to notify us of an intention to non-renew a county or counties for individuals, but continue the county for "800 series" EGWP members, by May 3, 2010.	✓		✓
May 3, 2010	*Voluntary non-renewal*: CMS strongly encourages Part D Sponsors to notify us of any type of service area reduction, or conversion to offering employer-only contracts by May 3, 2010, so that we can make the required changes in HPMS to facilitate sponsors' ability to correctly upload their bids in June.		✓	
May 14, 2010	CMS begins accepting CY 2011 bids via HPMS. *(applies to Part C and Part D Sponsors only)*	✓	✓	✓
May 21, 2010	PBP/BPT upload available		✓	
Mid-May/June 2010	CMS sends contract eligibility determinations to applicants based on review of the 2011 applications for new contracts or service area expansions.	✓	✓	✓
Late Spring/Early Summer 2010	Update of MA/PDP Enrollment, Eligibility, and Disenrollment guidance; update of the Medicare Marketing Guidelines for CY 2011.	✓	✓	✓
Tentative date - June 4, 2010	CMS begins accepting CY 2011 marketing material for review.	✓	✓	✓

2011 MA, MA-PD, Part D and Cost-Based Plan Calendar **(All dates, unless identified as statutory, are subject to change)**				
2010 ***Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D Sponsors also apply to MA and cost-based plans offering a Part D benefit.**		***Part C**	***Part D Sponsors**	**Cost**
June 7, 2010	Deadline for submission of CY 2011 bids for all MA plans, MA-PD plans, PDP, cost-based plans offering a Part D benefit, "800 series" EGWP and direct contract EGWP applicants and renewing organizations; deadline for cost-based plans wishing to appear in the 2010 Medicare Options Compare to submit PBPs (11:59 p.m. PDT). Voluntary Non-Renewal. Deadline for MA plans, MA-PD plans, PDPs and Medicare cost-based contractors and cost-based sponsors to submit a contract non-renewal, service area reduction notice to CMS for CY 2011. Deadline also applies to an MAO that intends to terminate a current MA and/or MA-PD plan benefit package (i.e., Plan 01, Plan 02) for CY 2011.	✓	✓	✓
June 14, 2010	CMS begins accepting Supplemental Formulary files, Free First Fill file, Partial Gap file, Excluded Drug file, Over the Counter (OTC) drug file, and Home Infusion file through HPMS. CMS begins accepting CY 2011 Actuarial Certifications in HPMS.	✓	✓	
June 14, 2010	Requests for SB administrative changes may begin.	✓	✓	✓
June 30, 2010	Final date to submit CY 2010 marketing materials for assured CMS' review and approval. NOTE: This date does not apply to CY 2010 file and use materials since these may be filed with the appropriate CMS regional office five calendar days prior to their use.	✓	✓	✓
Late June 2010	Non-Renewal. CMS to issue an acknowledgement letter to all MA, MA-PD and Medicare cost-based plans that have notified CMS they are non-renewing or reducing their service area.	✓		✓

2011 MA, MA-PD, Part D and Cost-Based Plan Calendar **(All dates, unless identified as statutory, are subject to change)**				
2010 ***Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D Sponsors also apply to MA and cost-based plans offering a Part D benefit.**		***Part C**	***Part D Sponsors**	**Cost**
Late June or early July, 2010	Industry training on revised Medicare Marketing Guidelines and Annual Notice of Change (ANOC)/Evidence of Coverage (EOC) and other marketing models.	✓	✓	✓
Late June or early July, 2010	Submission deadline for agent/broker total compensation amounts due to CMS.	✓	✓	✓
August, 2010	Non-Renewal. CMS to release a special election period (SEP) letter to plans remaining in the service areas of plans that have non-renewed. Additionally, CMS to post the model final non-renewal notification letter, and State-specific final notification letter. Release of the 2011 Part D national average monthly bid amount, the Medicare Part D base beneficiary premium, the Part D regional low-income premium subsidy amounts, and the Medicare Advantage regional PPO benchmarks. Rebate reallocation period begins after release of the above amounts.	✓	✓	✓
Early August, 2010	CMS encourages cost-based plans to submit their summary of benefits (SBs) by this date so that materials can be reviewed and approved prior to the publishing of "Medicare Options Compare" and the *Medicare & You* handbook. SBs must be submitted by this date to be assured of being included.			✓
Early August, 2010	Requested for SB changes to benefits information may begin.	✓		✓
August 2, 2010	Deadline for CMS to inform currently contracted organizations of CMS' decision not to authorize a renewal of a contract for 2011.	✓	✓	
August 3, 2010	Plans are expected to submit non-model Low Income Subsidy (LIS) riders to the regional office for review.		✓	

2011 MA, MA-PD, Part D and Cost-Based Plan Calendar **(All dates, unless identified as statutory, are subject to change)**				
2010 ***Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D Sponsors also apply to MA and cost-based plans offering a Part D benefit.**		***Part C**	***Part D Sponsors**	**Cost**
August 13, 2010	Dual eligible SNPs that are fully integrated with the State are expected to submit the Annual Notice of Change and Summary of Benefits to the regional office for review.	✓		
Late August, 2010	Non-Renewal: Final date for CMS to approve final beneficiary notification letter of non-renewal.	✓	✓	
Late August/Early September, 2010	CMS completes review and approval of 2011 bid data. Submit attestations, contracts, and final actuarial certifications.	✓	✓	
September 1, 2010	Submission date for contracting MAOs (new and expanding) to provide CMS with a ratified contract with the State in order to operate a Medicaid dual eligible SNP for CY 2011.	✓		
September 1, 2010	Plans are expected to submit model Low Income Subsidy (LIS) riders to the regional office for review.		✓	
September 3, 2010	Initial Submission deadline for risk adjustment data with dates of service from July 1, 2009 through June 30, 2010.	✓		✓
September, 2010	If applicable, plans preview the 2011 *Medicare & You* plan data in HPMS prior to printing of the CMS publication (not applicable to EGWPs). CMS begins accepting plan correction requests upon contract approval.	✓	✓	✓

2011 MA, MA-PD, Part D and Cost-Based Plan Calendar **(All dates, unless identified as statutory, are subject to change)**				
2010 ***Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D Sponsors also apply to MA and cost-based plans offering a Part D benefit.**		***Part C**	***Part D Sponsors**	**Cost**
October 1, 2010	Plans may begin CY 2011 marketing activities. Once an organization begins marketing CY 2011 plans, the organization must cease marketing CY 2010 plans through mass media or direct mail marketing (except for age-in mailings). Organizations may still provide CY 2010 materials upon request, conduct one-on-one sales appointments and process enrollment applications. Plans are required to include information in CY 2010 marketing and enrollment materials to inform potential enrollees about the possibility of plan (benefit) changes beginning January 1, 2011. Last day for Part D sponsors to request plan benefit package (PBP) plan corrections via HPMS.	✓	✓	✓
October 1, 2010	Deadline for cost-based, MA, and MA-PD organizations to request a plan correction to the plan benefit package (PBP). Deadline for cost-based, MA and MA-PD organizations to request of a SB hard copy change. Dual eligible SNPs that are fully integrated with the State and plan to use a non-standardized, non-combined EOC are expected to submit these for regional office review.	✓		✓

2011 MA, MA-PD, Part D and Cost-Based Plan Calendar **(All dates, unless identified as statutory, are subject to change)**				
2010 ***Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D Sponsors also apply to MA and cost-based plans offering a Part D benefit.**		***Part C**	***Part D Sponsors**	**Cost**
October 2, 2010	Non-Renewal. The final beneficiary non-renewal notification letter must be a personalized letter and received by PDPs, MA plan , MA-PD plans, and cost-based plan enrollees by October 2, 2010. PDPs, MA plans, MA-PD plans, and Medicare cost-based organizations may not market to beneficiaries of non-renewing plans until after October 2, 2010.	✓	✓	✓
October 8, 2010	Tentative date for 2011 plan benefit data to be displayed on Medicare Options Compare and for 2011 plan drug benefit information to be displayed on the Medicare Prescription Drug Plan Finder on Medicare.gov (not applicable to EGWPs).	✓	✓	✓
Mid-October, 2010	Non-Renewal. CMS to issue an acknowledgement letter to all Medicare cost-based plans that are non-renewing or reducing their service areas.			✓
October 15-29, 2010	CMS mails the 2011 *Medicare & You* handbook to Medicare beneficiaries.	✓	✓	✓

2011 MA, MA-PD, Part D and Cost-Based Plan Calendar **(All dates, unless identified as statutory, are subject to change)**				
2010 ***Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D Sponsors also apply to MA and cost-based plans offering a Part D benefit.**		***Part C**	***Part D Sponsors**	**Cost**
October 31, 2010	CY 2011 standardized, combined Annual Notice of Change (ANOC)/Evidence of Coverage (EOC) is due to current members of all MA plans, MA-PD plans, PDPs, and cost-based plans offering Part D. MA and MA-PD plans must ensure current members receive the combined ANOC/EOC by October 31. Organizations are not required to mail the Summary of Benefits (SB) to existing members when using the combined, standardized ANOC/EOC; however the SB must be available upon request. Exception: Dual eligible SNPs that are fully integrated with the State are not required to use the standardized, combined ANOC/EOC. Dual eligible SNPs that are fully integrated with the State must mail an Annual Notice of Change and Summary of Benefits before this date to ensure receipt by members by October 31. All plans offering Part D must mail their LIS riders and abridged or comprehensive formularies before this date to ensure receipt by members by October 31.	✓	✓	

2011 MA, MA-PD, Part D and Cost-Based Plan Calendar **(All dates, unless identified as statutory, are subject to change)**				
2010 ***Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D Sponsors also apply to MA and cost-based plans offering a Part D benefit.**		***Part C**	***Part D Sponsors**	**Cost**
November 15, 2010	2011 Annual Coordinated Election Period begins. All organizations must hold open enrollment (for EGWPs, see Chapter 2 of the Medicare Managed Care Manual, Section 30.4.4). Medicare Marketing Guidelines require that all plans mail a CY 2010 EOC to each new member no later than when they notify the new member of acceptance of enrollment. Organizations offering Part D must mail their Low Income Subsidy Rider (LIS) and abridged or comprehensive formularies with the EOC for new members. New members with an effective date of January 1, 2011 or later do not need to (but may) receive the ANOC portion of the standardized/combined ANOC/EOC.	✓	✓	✓
Mid November 2010	Notices of Intent (NOI) for CY 2012 due for MA plans, MA-PD plans, PDPs, "800 series" EGWPs and Direct Contract EGWPs.	✓	✓	✓
Mid November 2010	CMS issues pending HPMS contract numbers for CY 2012 to MA plans, MA-PD plans, cost plans, PDPs, and EGWP NOIs.	✓	✓	✓
November – December, 2010	Non-Renewal. CMS to issue "close out" information and instructions to MA plans, MA-PD plans, PDPs, and cost-based plans that are non-renewing or reducing service areas.	✓	✓	✓
December 1, 2010	Medicare cost-based plans not offering Part D must send the combined ANOC/EOC for receipt by members by December 1, 2010.			✓
December 1, 2010	Non-Renewal. Cost-based plans must publish notice of non-renewal.			✓
December 31, 2010	2011 Annual Coordinated Election Period ends.	✓	✓	

2011 MA, MA-PD, Part D and Cost-Based Plan Calendar **(All dates, unless identified as statutory, are subject to change)**				
2010 ***Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D Sponsors also apply to MA and cost-based plans offering a Part D benefit.**		***Part C**	***Part D Sponsors**	**Cost**
December 31, 2010	Dual eligible SNPs that are fully integrated with the State must mail an Evidence of Coverage, LIS riders and abridged or comprehensive formularies before this date to ensure receipt by members by December 31. SNPs that were disproportionate percentage SNPs in 2009 must disenroll all non-special needs members who were enrolled prior to January 1, 2010. Chronic care SNPs must disenroll all members of chronic care SNPs who no longer qualify for the special needs requirement after the redesignation of chronic conditions for 2010 and were enrolled prior to 1/1/2010.	✓		
2011				
January 1, 2011	Plan Benefit Period Begins.	✓	✓	✓
January 1 – February 15, 2011	MA Annual 45 Day Disenrollment Period (ADP).	✓		
Early January, 2011	Automated CY 2012 applications released.	✓	✓	✓
Early January, 2011	Industry training on CY 2012 applications.	✓	✓	✓
January 31, 2011	Final Submission deadline for risk adjustment data with dates of service January 1, 2009 through December 31, 2009	✓		✓
Late February, 2011	Applications due for CY 2012.	✓	✓	✓
March 4, 2011	Initial Submission deadline for risk adjustment data with dates of service January 1, 2010 through December 31, 2010	✓		✓

2011 MA, MA-PD, Part D and Cost-Based Plan Calendar **(All dates, unless identified as statutory, are subject to change)**				
2010 ***Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D Sponsors also apply to MA and cost-based plans offering a Part D benefit.**		***Part C**	***Part D Sponsors**	**Cost**
September 2, 2011	Initial Submission deadline for risk adjustment data with dates of service from July 1, 2010 through June 30, 2011	✓		✓

I. Recommended Deadlines for Cost-Based Plan Non-Renewals

Beginning with the application cycle for 2011 contracts, CMS is strongly encouraging all cost-based plans to follow the schedule established for MA, MA-PD for both submitting service area expansion applications as well as requesting non-renewal/service area reductions. Use of concurrent time frames will allow for a more efficient allocation of CMS resources and consistency across managed care programs.

II. Coordination of Benefits (COB) User Fees

CMS is authorized to impose user fees on Part D sponsors for the transmittal of information necessary for benefit coordination between sponsors and other entities providing prescription drug coverage. CMS may review and update this user fee annually to reflect the costs associated with COB activities. For contract year 2010, the Part D COB user fee was decreased to $1.89 per enrollee per year. While we continue to work on the de-linking of the enrollment and payment modules in MARx as well as other projects to improve the quality reliability and timeliness of the COB-related data, a review of the incremental on-going costs of COB activities in 2011 indicates the Part D COB user fee can be decreased further to $1.17 per enrollee per year for contract year 2011. This COB user fee will be collected at a monthly rate of $0.13 for the first 9 months of the coverage year (for an annual rate of $0.10 per enrollee per month) for a total user fee of $1.17 per enrollee per year. Part D sponsors should account for this COB user fee when developing their 2011 bids.

III. Specialty Tier Threshold

For contract year 2011, we will maintain the $600 threshold for drugs on the specialty tier. Thus, only Part D drugs with negotiated prices that exceed $600 per month may be placed in the specialty tier, and the specialty tiers will be evaluated and approved in accordance with section 30.2.4 of Chapter 6 of the Medicare Prescription Drug Benefit Manual. In addition to cost calculations, CMS considers claims history in reviewing the placement of drugs on Part D sponsors' specialty tiers. Except for newly approved drugs for which Part D sponsors would have little or no claims data, CMS will approve specialty tiers that only include drugs on specialty tiers when their claims data demonstrates that the majority of fills exceed the specialty tier cost criteria. Part D sponsors should be prepared to provide CMS the applicable claims data during the formulary review process.

IV. Medicare Enrollment Assistance Demonstration

In late 2009, CMS announced that it was considering the implementation of a Medicare Enrollment Assistance Demonstration Project. Under the proposed demonstration, CMS envisioned hiring a contractor to reach out to a targeted group of Medicare beneficiaries with comprehensive information and assistance services to help them in understanding and choosing

among their Medicare coverage options. CMS sought stakeholder input on the development of the project and received input from a diverse group of stakeholders during an Open Door Forum and written comment period.

Stakeholders were generally supportive of enhancing the information available to inform coverage decision-making and exploring efforts to develop more effective outreach to specific beneficiary populations. However, stakeholders did not offer strong support of the Medicare Enrollment Assistance Demonstration Project as a method for developing and testing those strategies. Therefore, CMS is reevaluating its intended approach to the enrollment demonstration project based on the comments we received, and we do not anticipate implementing the project for plan year 2011.

V. Risk Adjustment Data Validation (RADV)

This is to remind contracting MA organizations of their obligations under 42 CFR 422.504(e)(2). MAOs are required to provide CMS access to facilities and records used in the determination of amounts payable under an MA contract. This obligates MAOs to provide CMS access to facilities and records (including medical records) that are to be used for risk-adjustment data validation (RADV) purposes, since such records are used for the determination of amounts payable under the MA contract. We would also like to stress the importance of including specific language in contracts with providers that reminds them of their obligation to cooperate in the provision of such records, in accordance with 42 CFR 422.310(e).

VI. Release of Part C and Part D Payment Data

In the draft Call Letter, we announced that CMS is considering the public release of Part C and Part D payment data after risk adjustment and Part D payment reconciliation has been complete. We solicited comment on whether the release of such data would negatively affect the competitive nature of the bidding process.

In their comments, numerous plans objected to the proposed release of payment data on the grounds that the data are confidential and commercially sensitive and, therefore, protected from public disclosure under FOIA. Commenters stated that CMS's release of the information may violate the Trade Secrets Act in the absence of specific regulatory authority authorizing release. In the near future, we intend to publish a proposed regulation which would propose to authorize the release of Part C and D data.

April 4, 2011

NOTE TO: All Medicare Advantage Organizations, Prescription Drug Plan Sponsors, and Other Interested Parties

SUBJECT: Announcement of Calendar Year (CY) 2012 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter

In accordance with section 1853(b)(1) of the Social Security Act (the Act), we are notifying you of the annual Medicare Advantage (MA) capitation rate for each MA payment area for CY 2012, and the risk and other factors to be used in adjusting such rates. The capitation rate tables for 2012 are posted on the Centers for Medicare & Medicaid Services (CMS) web site at http://www.cms.gov/MedicareAdvtgSpecRateStats/ under Ratebooks and Supporting Data. The statutory component of the regional benchmarks, transitional phase-in periods for the Affordable Care Act rates, qualifying counties, and each county's applicable percentage are also posted at this website.

Attachment I shows the final estimates of the increases in the National Per Capita MA Growth Percentages for 2012 and the national Medicare fee-for-service growth percentage. These growth rates will be used to update the 2012 rates. As discussed in Attachment I, the final estimate of the increase in the National Per Capita MA Growth Percentage for combined aged and disabled beneficiaries is -0.16 percent. Attachment II provides a set of tables that summarizes many of the key Medicare assumptions used in the calculation of the National Per Capita MA Growth Percentages.

Section 1853(b)(4) of the Act requires CMS to release county-specific per capita fee-for-service (FFS) expenditure information on an annual basis, beginning with March 1, 2001. In accordance with this requirement, FFS data for CY 2009 are being posted on the above website.

Information on deductibles for MSA plans is included below.

Attachment III presents responses to comments on the Advance Notice of Methodological Changes for CY 2011 MA Capitation Rates and Parts C and Part D Payment Policies (Advance Notice). Attachment VII presents the final Call Letter. We received 96 submissions in response to CMS' request for comments on the Advance Notice/Call Letter, published on February 18, 2011. Three of the comments were from advocacy groups, 23 were from associations, 3 were from members of the public, 2 were from states, and 65 were from health plans.

Attachment IV contains tables with the Part D benefit parameters; Attachment V contains details regarding the Part D benefit parameters; Attachment VI contains tables with the frailty, 2012 revised CMS-HCC, ESRD and Rx-HCC risk adjustment factors.

Key Changes from the Advance Notice:

National MA Growth Percentage. Attachment I provides the final estimates of the National MA Growth Percentages (growth trends) and information on deductibles for MSA.

Quality Bonus Payment Demonstration. Attachment III provides the revised Quality Bonus Payment Demonstration.

Under the demonstration the QBP percentage for each star rating will be as follows:

Stars Rating	QBP Percentage for 2012/2013	QBP Percentage for 2014
Less than 3 stars	0%	0%
3 stars	3%	3%
3.5 stars	3.5%	3.5%
4 stars	4%	5%
4.5 stars	4%	5%
5 stars	5%	5%

CMS will apply the QBP percentage to the applicable amount and the specified amount when calculating the blended benchmark and will not cap the blended rate at the level of the pre-Affordable Care Act rate for plans with 3 to 5 stars. A new MA contract offered by a parent organization that has not had any MA contract(s) with CMS in the previous three years is treated as a qualifying contract, per statute, and is assigned three stars for QBP purposes for 2012 and 2013, and 3.5 stars in 2014. These contracts are treated as new MA contracts during the demonstration until the contract has enough data to calculate a star rating. For a parent organization that has had MA contract(s) with CMS in the previous three years, any new MA contract under that parent organization will receive a weighted average of the star ratings earned by the parent organization's existing MA contracts. A low enrollment contract is a contract that could not undertake Healthcare Effectiveness Data and Information Set (HEDIS) and Health Outcome Survey (HOS) data collections because of a lack of a sufficient number of enrollees to reliably measure the performance of the health plan. For 2012, low enrollment contracts receive 3 stars for QBP purposes under the demonstration.

PACE Risk Adjustment Model. In light of the comments we received in response to our proposal to not implement a new CMS-HCC risk adjustment model, we have decided to implement the clinically updated model initially proposed in the 2011 Advance Notice for PACE organizations for 2012.

The updated model has 87 HCCs, compared to the 70 in the CMS-HCC risk adjustment model that will continue to be used for MA plan payment. The changes to the condition categories include additions, deletion, and revisions. As a result of these changes, there are additional

diagnosis codes that need to be submitted for 2012 risk scores. PACE organizations need to make certain that their systems are updated to report these additional diagnosis codes from dates of services in 2011, and should review the model software located on the CMS website at: http://www.cms.gov/MedicareAdvtgSpecRateStats/06_Risk_adjustment.asp#TopOfPage to become familiar with the new model.

Frailty Adjustment.

Attachment VI provides an update to the Frailty Adjustment factors.

In 2012, in order to determine which FIDE SNPs have levels of frailty similar to PACE and would therefore receive frailty adjusted payments in 2012 we will use the lowest score of the range of applicable PACE organization frailty scores.

Normalization. The Part D normalization factor is 1.031, rather than the 1.032 published in Advance Notice.

Update to Acceptable Physician Specialty Types for Risk Adjustment Data Submission. CMS has updated the Acceptable Physician Specialty Types for the purpose of submitting risk adjustment data. .

The updates include additions and one deletion, effective January 1, 2010. The additions are: Interventional Pain Management (IPM) (code 09), Speech Language Pathologist (code 15), Hospice and Palliative Care (code 17), and Geriatric Psychiatry (code 27). Note that Multispecialty Clinic or Group Practice (code 70) is not an Acceptable Physician Specialty Type for risk adjustment. The updated list will be posted to the CSSC Operations website to reflect these changes. www.csscoperations.com.

Part D Benefit Parameters. Attachment V provides the 2012 Part D benefit parameters for the defined standard benefit, low-income subsidy, and retiree drug subsidy. The chart has changed slightly from the version included in the Advance Notice based on a comment we received.

We are making a correction to the annual percentage increase for 2011 values in the Advance Notice. The correct value appears in Table III-1 on page 36 of the 2012 Advance Notice and is 0.98%. The value for the annual percentage increase in Table III-4 and the descriptive sentence immediately preceding the table should also be 0.98%, not 1.01%. See Attachment IV, which contains this correction.

Proposals Adopted as Issued in the Advance Notice:

As in past years, policies proposed in the Advance Notice that are not modified or retracted in the Rate Announcement become effective in the upcoming payment year, as set forth in the Advance Notice. Clarifications in the Rate Announcement supersede materials in the Advance Notice.

Rebasing County Rates
We will rebase the FFS capitation rates for 2012.

MA Benchmark, Quality Bonus Payments and Rebate
We are implementing a number of changes in the MA payment methodology for CY 2012 as a result of payment changes enacted in the Affordable Care Act, including the following: a new blended benchmark as the MA county rate, the new methodology used to derive the new ACA blended benchmark county rates, identify the qualifying bonus counties, how to determine transitional phase-in periods, and the applicability of the star system on the rebates.

Changes to the Medicare Advantage Ratebook
We will improve the calculation of the USPCC and the AGA methodology by excluding hospice claims and cost plan data, modifying the calculation of FFS costs to account for variations in small counties, and changing the tabulation of FFS payments in Puerto Rico based on beneficiaries enrolled in both Part A and Part B.

IME Phase Out. For 2012, CMS will continue phasing out indirect medical education amounts from MA capitation rates.

Adjustment to FFS Per Capita Costs for VA-DOD Costs. We have concluded that there is sufficient evidence to warrant an adjustment to the FFS rates based on DoD data and we will be making this change.

Clinical Trials. We are continuing the policy of paying on a fee-for-service basis for qualified clinical trial items and services provided to MA plan members that are covered under the National Coverage Determinations on clinical trials.

End Stage Renal Disease (ESRD) Payment. CMS concludes the phase-in of the revised State capitation rates used to determine payments for enrollees in dialysis and transplant status in 2012. CMS will update the ESRD State capitation rates. Also, we will pay Functioning Graft enrollees based on the blended MA benchmark for the county minus the amount of any rebate dollars (if any) allocated to reduce plan enrollees' Part B premium and/or Part D basic premium, where the blended benchmark depends on the quality bonus payment (QBP) for the contract within which the person is enrolled.

Location of Network Areas for PFFS Plans in Plan Year 2013. The list of network areas for plan year 2013 is available on the CMS website at http://www.cms.hhs.gov/PrivateFeeforServicePlans/.

End of Medicare Advantage Medical Savings Account (MSA) Plan Demonstration Program.
We are not seeking an extension of the MSA Demonstration program, nor will we accept new applications.

Employer Group Waiver Plan (EGWP) Bidding. In the Advance Notice we announced our concerns about the level of EGWP bids relative to individual market bids and invited comments on ways to address our concerns. We are considering the comments that we received, but will not make any changes to EGWP bidding at this time.

CMS-HCC Risk Adjustment Model. In the Advance Notice we announced that we were not proposing to implement the new model for Part C for 2012 in order to minimize change during 2012, the first year of the blended benchmarks under the Affordable Care Act. As proposed, For all plans, except PACE plans, we are not implementing an update to the CMS-HCC Risk Adjustment model in 2012.

Recalibration of the ESRD Risk Adjustment Model. We are implementing an update to the ESRD Risk Adjustment model. The 2012 ESRD model has 87 HCCs, compared to the 70 used in the CMS-HCC risk adjustment model used prior to 2012. The changes to the condition categories include additions, deletion, and revisions. As a result of these changes, there are additional diagnosis codes that need to be submitted for 2012. MA organizations serving ESRD beneficiaries need to make certain that their systems are updated to report these additional diagnosis codes from dates of services in 2011, and should review the model software located on the CMS website at: http://www.cms.gov/MedicareAdvtgSpecRateStats/06_Risk_adjustment.asp to become familiar with the new model.

Adjustment for MA Coding Pattern Differences. We will implement an MA coding pattern difference adjustment of 3.41% for payment year 2012.

Normalization Factors. The normalization factors for 2012 are:

CMS-HCC model used for MA plans is 1.079.
CMS-HCC model used for PACE organizations is 1.051
CMS-HCC ESRD Functioning graft status is 1.051.
CMS-HCC ESRD dialysis model is 1.012.

MSP Factors. The 2012 MSP factor for ESRD beneficiaries is as follows:

ESRD dialysis/transplant: 0.189
Post-graft: 0.174

Affordable Care Act-Mandated Risk Adjustment Evaluation. CMS has published the Affordable Care Act-Mandated Risk Adjustment Evaluation at:
http://www.cms.gov/MedicareAdvtgSpecRateStats/06_Risk_adjustment.asp

Encounter Data Collection. MA Organizations and Cost plans will be required to submit encounter data beginning in 2012.

Risk Adjustment Processing System (RAPS) File Changes. Effective on January 1, 2012, CMS is modifying the format of the RAPS file in risk adjustment data collection to accommodate the implementation of coding sets using ICD-10.

Risk Adjustment Data Validation (RADV). CMS will continue conducting RADV audits and is setting forth mandatory system standards as described in the Advance Notice.

Prospective Coverage Gap Discount Program (CGDP) Payments. CMS provides monthly prospective payments to Part D sponsors for the manufacturer discounts made available to their enrollees under the CGDP. CMS will determine the monthly prospective CGDP payments for each plan by multiplying the plan-specific prospective CGDP payment amount estimated in the Part D bid by the number of non-LIS beneficiaries enrolled in the Part D plan. Consistent with the methodology proposed in the Advance Notice, no adjustment will be made to the prospective CGDP payments to reflect that manufacturer discounts under the CGDP do not include fill fees.

Cost Sharing for Non-LIS Beneficiaries in the Coverage Gap. In 2012, the coinsurance charged to eligible beneficiaries under basic prescription drug coverage for non-applicable covered Part D drugs purchased during the coverage gap phase will be 86%.

Update of the Rx-HCC Model. We will implement an update to the Part D risk adjustment model to account for the impact of the new Part D cost sharing benefit structure on LIS vs. Non-LIS beneficiaries.

DeMinimis Premium Policy. Part D sponsors may not rely on the *de minimis* premium policy to waive any part of their Part D premiums for partial subsidy or non-LIS beneficiaries.

Payment Reconciliation. The 2012 risk percentages and payment adjustments for Part D risk sharing are unchanged from contract year 2011.

Questions can be directed to:

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Attachments

2012 ANNOUNCEMENT
TABLE OF CONTENTS

Attachment I. Final Estimate of the Increase in the National Per Capita MA Growth Percentages and the National Medicare Fee-for-Service Growth Percentage for 2012

The Table 1 below shows the National Per Capita MA Growth Percentages (NPCMAGP) for 2012. An adjustments of 0.59 percent for the combined aged and disabled is included in the NPCMAGP to account for corrections to prior years' estimates as required by section 1853(c)(6)(C). The combined aged and disabled increase is used in the development of the ratebook. Since a new ESRD model based on 2009 data is being used, the NPCMAGP shown for ESRD below is the current trend from 2009 to 2012.

Table 1 - Increase in the National Per Capita MA Growth Percentages for 2012

	Prior Increases	Current Increases			NPCMAGP for 2012 With §1853(c)(6)(C) adjustment[1]
	2003 to 2010	2003 to 2010	2010 to 2012	2003 to 2012	
Aged+Disabled	41.07%	41.91%	−0.75%	40.84%	−0.16%
ESRD[2]	N/A	2.83% [3]	3.29%	6.21% [4]	6.21% [4]

[1]Current increases for 2003 to 2012 divided by the prior increases for 2003 to 2010 (Aged+Disabled only).
[2]Increases for ESRD reflect an estimate of the increase for dialysis-only beneficiaries.
[3]Current increase for 2010 only.
[4]Reflects 3-year increase from 2009 to 2012.

The Affordable Care Act of 2010 requires the Medicare Advantage benchmark amounts be tied to a percentage of the county FFS amounts. There will be a transition to the percentage of FFS over a number of years. Table 2 below provides the increase in the FFS USPCC which will be used for the county FFS portion of the benchmark. The percentage increase in the FFS USPCC is shown as the current projected FFS USPCC for 2012 divided by projected FFS USPCC for 2010 as estimated in the 2010 Rate Announcement released on April 6, 2009.

Table 2 – Increase in the FFS USPCC Growth Percentage

Current projected 2012 FFS USPCC	$743.54
Prior projected 2010 FFS USPCC	$741.89
Percent increase	0.22%

Table 3 below shows the monthly actuarial value of the Medicare deductible and coinsurance for 2010 and 2012. In addition, for 2012, the actuarial value of deductibles and coinsurance is being shown for non-ESRD only, since the plan bids will not include ESRD benefits in 2012. These data were furnished by the Office of the Actuary.

Table 3 - Monthly Actuarial Value of Medicare Deductible and Coinsurance for 2010 and 2012

	2010	2012	Change	2012 non-ESRD
Part A Benefits	$40.31	$40.92	1.5%	$38.93
Part B Benefits[1]	$100.01	$100.20	0.2%	$92.90
Total Medicare	$140.32	$141.12	0.6%	$131.83

[1]Includes the amounts for outpatient psychiatric charges.

Medical Savings Account (MSA) Plans. The maximum deductible for current law MSA plans for 2012 is $10,600.

Attachment II. Key Assumptions and Financial Information

The USPCCs are the basis for the National Per Capita MA Growth Percentages. Attached is a table that compares the published United States Per Capita Costs (USPCC) with current estimates for 2003 to 2012. In addition, this table shows the current projections of the USPCCs through 2014. We are also providing an attached set of tables that summarizes many of the key Medicare assumptions used in the calculation of the USPCCs. Most of the tables include information for the years 2003 through 2014.

Previously, most of the tables in this attachment showed information for aged and disabled non-ESRD separately. Since the MA payment rates are now exclusively based on combined aged and disabled data, we are showing most information on a combined basis. The ESRD information presented is for the combined aged-ESRD, disabled-ESRD and ESRD only.

All of the information provided in this enclosure applies to the Medicare Part A and Part B programs. Caution should be employed in the use of this information. It is based upon nationwide averages, and local conditions can differ substantially from conditions nationwide.

None of the data presented here pertain to the Medicare prescription drug benefit.

Comparison of Current Estimates of the USPCC with Published Estimates – non-ESRD

Calendar Year	Part A			Part B			Part A & Part B		
	Current Estimate	Published Estimate	Ratio	Current Estimate	Published Estimate	Ratio	Current Estimate	Published Estimate	Ratio
2003	294.35	282.50	0.960	249.42	229.47	0.920	543.77	511.97	0.942
2004	312.39	318.43	1.019	274.13	261.89	0.955	586.52	580.32	0.989
2005	332.45	339.49	1.021	293.62	280.58	0.956	626.07	620.07	0.990
2006	343.81	342.67	0.997	314.53	312.09	0.992	658.34	654.76	0.995
2007	354.60	362.06	1.021	332.39	335.47	1.009	686.99	697.53	1..015
2008	371.61	379.02	1.020	353.03	352.75	0.999	724.64	731.77	1.010
2009	386.14	408.50	1.058	370.50	357.89	0.966	756.64	766.39	1.013
2010	393.94	407.38	1.034	377.71	360.25	0.954	771.65	767.63	0.995
2011	399.73	407.38	1.019	391.25	360.25	0.921	790.98	767.63	0.970
2012	402.32	402.32	1.000	363.54	363.54	1.000	765.86	765.86	1.000
2013	405.84	—	—	374.95	—	—	780.79	—	—
2014	410.94	—	—	392.22	—	—	803.16	—	—

Comparison of Current Estimates of the USPCC with Published Estimates - ESRD

PART A:

Calendar Year	All ESRD				Basis for Growth Percentage	
	Current Estimate	Published Estimate	Ratio	Current Cumulative Trend	Adjustment Factor for Dialysis-only	Adjusted Current Cumulative Trend
2009	2240.55	1885.71	0.842			
2010	2326.46	2133.76	0.917	1.0383	1.0018	1.0402
2011	2364.76	2133.76	0.902	1.0554	1.0036	1.0592
2012	2415.74	2415.74	1.000	1.0782	1.0054	1.0840
2013	2451.51	—	—	1.0942	1.0072	1.1021
2014	2489.49	—	—	1.1111	1.0090	1.1211

PART B:

Calendar Year	All ESRD				Basis for Growth Percentage	
	Current Estimate	Published Estimate	Ratio	Current Cumulative Trend	Adjustment Factor for Dialysis-only	Adjusted Current Cumulative Trend
2009	2679.76	2371.73	0.885			
2010	2668.11	2523.56	0.946	0.9957	1.0227	1.0183
2011	2677.69	2523.56	0.942	0.9992	1.0459	1.0451
2012	2614.84	2614.84	1.000	0.9758	1.0697	1.0437
2013	2698.10	—	—	1.0068	1.0939	1.1014
2014	2928.32	—	—	1.0928	1.1188	1.2225

PART A & PART B:

Calendar Year	All ESRD				Basis for Growth Percentage	
	Current Estimate	Published Estimate	Ratio	Current Cumulative Trend	Adjustment Factor for Dialysis-only	Adjusted Current Cumulative Trend
2009	4920.31	4257.44	0.865			
2010	4994.57	4657.32	0.932	1.0151	1.0130	1.0283
2011	5042.45	4657.32	0.924	1.0248	1.0261	1.0515
2012	5030.58	5030.58	1.000	1.0224	1.0388	1.0621
2013	5149.61	—	—	1.0466	1.0527	1.1017
2014	5417.81	—	—	1.1011	1.0683	1.1764

Summary of Key Projections under Present Law [1]

Part A

Year	Calendar Year CPI Percent Increase	Fiscal Year PPS Update Factor	FY Part A Total Reimbursement (Incurred)
2003	2.2	3.0	3.6
2004	2.6	3.4	8.6
2005	3.5	3.3	8.6
2006	3.2	3.7	6.2
2007	2.9	3.4	5.8
2008	4.1	3.3	7.6
2009	−0.7	2.7	7.3
2010	2.1	1.9	4.8
2011	1.2	−0.6	4.2
2012	1.7	1.9	4.9
2013	1.9	1.4	4.3
2014	2.0	2.3	5.0

Part B[2]

Calendar Year	Physician Fee Schedule		Part B Hospital	Total
	Fees	Residual[3]		
2003	1.4	4.5%	4.4%	6.8%
2004	1.8	5.9%	11.0%	9.8%
2005	1.5	3.2%	10.6%	7.0%
2006	0.2	4.6%	5.1%	6.1%
2007	0.0	3.5%	8.1%	4.3%
2008	0.5	3.3%	6.4%	4.8%
2009	1.1	2.1%	8.7%	3.8%
2010	1.3	1.0%	5.0%	2.0%
2011	0.9	4.4%	6.7%	3.6%
2012	−29.4	8.2%	5.8%	−7.6%
2013	−0.3	3.2%	6.5%	3.6%
2014	1.3	3.5%	6.5%	5.4%

[1]Percent change over prior year.
[2]Percent change in charges per Aged Part B enrollee.
[3]Residual factors are factors other than price, including volume of services, intensity of services, and age/sex changes.

Medicare Enrollment Projections under Present Law (In Millions)

Non-ESRD

	Part A		Part B	
Calendar Year	Aged	Disabled	Aged	Disabled
2003	34.426	5.929	33.027	5.187
2004	34.837	6.248	33.282	5.458
2005	35.243	6.574	33.608	5.746
2006	35.780	6.851	33.960	5.986
2007	36.430	7.128	34.449	6.212
2008	37.359	7.321	35.122	6.404
2009	38.236	7.496	35.793	6.620
2010	38.975	7.655	36.467	6.866
2011	39.847	8.175	37.316	7.281
2012	41.179	8.498	38.476	7.588
2013	42.628	8.810	39.781	7.853
2014	44.034	9.001	41.030	8.028

ESRD

Calendar Year	Total Part A	Total Part B
2003	0.382	0.370
2004	0.399	0.382
2005	0.416	0.398
2006	0.435	0.415
2007	0.452	0.432
2008	0.470	0.449
2009	0.487	0.466
2010	0.504	0.483
2011	0.527	0.505
2012	0.548	0.526
2013	0.568	0.545
2014	0.584	0.561

Part A Projections under Present Law for non-ESRD (Aged+Disabled) [1]

Calendar Year	Inpatient Hospital Aged + Disabled	SNF Aged + Disabled	Home Health Aged + Disabled	Managed Care Aged + Disabled	Hospice: Total Reimbursement (in Millions) Aged + Disabled
2003	2,571.52	371.33	124.41	458.36	5,733
2004	2,692.59	414.46	134.04	501.30	6,832
2005	2,787.71	451.64	141.04	603.00	8,016
2006	2,743.52	476.99	141.92	758.13	9,341
2007	2,693.59	505.57	144.35	907.53	10,477
2008	2,689.15	537.35	149.39	1,079.18	11,347
2009	2,670.91	553.97	152.50	1,252.42	12,210
2010	2,734.78	571.66	153.81	1,261.43	13,156
2011	2,733.29	590.69	148.80	1,318.30	14,164
2012	2,806.28	614.08	148.78	1,253.04	15,203
2013	2,899.72	640.38	154.67	1,169.76	16,128
2014	3,028.86	670.73	158.07	1,067.93	17,028

[1]Average reimbursement per enrollee on an incurred basis, except where noted.

Part B Projections under Present Law for non-ESRD (Aged+Disabled) [1]

Calendar Year	Physician Fee Schedule Aged + Disabled	Part B Hospital Aged + Disabled	Durable Medicare Equipment Aged + Disabled
2003	1240.44	378.70	197.68
2004	1367.31	433.70	198.34
2005	1404.38	493.22	196.40
2006	1403.32	513.10	197.88
2007	1381.45	542.45	195.83
2008	1380.96	571.66	201.29
2009	1401.39	617.17	181.21
2010	1439.78	644.68	179.47
2011	1481.74	686.25	184.30
2012	1096.02	738.80	196.29
2013	1147.89	810.03	195.09
2014	1245.06	894.09	211.29

Calendar Year	Carrier Lab Aged + Disabled	Other Carrier Aged + Disabled	Intermediary Lab Aged + Disabled
2003	74.78	333.74	61.72
2004	80.61	361.00	66.14
2005	82.56	363.88	69.24
2006	85.44	362.10	69.57
2007	91.42	367.23	69.55
2008	95.26	370.44	70.27
2009	103.68	377.38	74.94
2010	105.01	373.18	76.14
2011	109.17	380.27	77.17
2012	115.25	398.63	78.09
2013	123.10	424.41	82.13
2014	131.96	455.92	87.17

Calendar Year	Other Intermediary Aged + Disabled	Home Health Aged + Disabled	Managed Care Aged + Disabled
2003	114.10	136.89	421.83
2004	119.70	156.61	471.86
2005	139.93	179.63	560.92
2006	142.25	203.11	770.82
2007	151.19	232.85	932.61
2008	158.37	252.97	1,108.18
2009	176.69	279.29	1,210.17
2010	181.34	281.28	1,228.80
2011	193.06	272.79	1,286.60
2012	181.69	273.42	1,262.40
2013	199.29	284.65	1,210.13
2014	219.73	291.10	1,146.03

[1]Average reimbursement per enrollee on an incurred basis.

Claims Processing Costs as a Fraction of Benefits

Calendar Year	Part A	Part B
2003	0.001849	0.011194
2004	0.001676	0.010542
2005	0.001515	0.009540
2006	0.001245	0.007126
2007	0.000968	0.006067
2008	0.000944	0.006414
2009	0.000844	0.005455
2010	0.000773	0.005055
2011	0.000773	0.005055
2012	0.000773	0.005055
2013	0.000773	0.005055
2014	0.000773	0.005055

Approximate Calculation of the USPCC and the National MA Growth Percentage for Combined (Aged+Disabled) Beneficiaries

The following procedure will approximate the actual calculation of the USPCCs from the underlying assumptions for the contract year for both Part A and Part B.

Part A:

The Part A USPCC can be approximated by using the assumptions in the tables titled "Part A Projections Under Present Law for non-ESRD (Aged+Disabled)" and "Claims Processing Costs as a Fraction of Benefits." Information in the "Part A Projections" table is presented on a calendar year per capita basis. First, add the per capita amounts over all types of providers (excluding hospice). Next, multiply this amount by 1 plus the loading factor for administrative expenses from the "Claims Processing Costs" table. Then, divide by 12 to put this amount on a monthly basis.

Part B:

The Part B USPCC can be approximated by using the assumptions in the tables titled "Part B Projections under Present Law for non-ESRD (Aged+Disabled)" and "Claims Processing Costs as a Fraction of Benefits." Information in the "Part B Projections" table is presented on a calendar year per capita basis. First, add the per capita amounts over all types of providers. Next, multiply by 1 plus the loading factor for administrative expenses and divide by 12 to put this amount on a monthly basis.

The National Per Capita MA Growth Percentage:

The National Per Capita MA Growth Percentage for 2012 (before adjustment for prior years' over/under estimates) is calculated by adding the USPCCs for Part A and Part B for 2012 and then dividing by the sum of the current estimates of the USPCCs for Part A and Part B for 2010.

Attachment III. Responses to Public Comments

Section A. Estimate of the National Per Capita MA Growth Percentage for Calendar Year 2012

Comment: Commenters requested more detail and documentation regarding how the growth percentage was calculated for the Advance Notice, including the basis for CMS' estimate. Commenters asked that CMS include key assumptions underlying the estimate, information on revisions to prior year estimates as shown in Table I of the Advance Notice, and fee schedule and utilization trend assumptions by categories of service (as is typically shown in Attachment II of the Announcement). Commenters also requested that CMS place more documentation in the Advance Notices for future years to assist organizations in understanding the growth percentage.

Response: We will consider providing more detailed information in the Advance Notice to assist in understanding the preliminary estimate of the growth percentage. Regarding the year-by-year revisions to prior year estimates, we believe the final Announcement already has sufficient information to do such calculations. One can compare the USPCCs in Attachment II in the prior Announcement with the current Announcement to see how the year-by-year increases have changed.

The national Medicare fee-for-service growth percentage is used to calculate the FFS rates. CMS has not previously included an estimate of the fee-for-service growth percentage in the Advance Notice. We have, however, decided to do so for 2012 and future years because of the importance of the FFS rates in the calculation of the blended benchmarks.

Comment: One commenter asserted that CMS has consistently understated the MA growth percentage in its annual announcements, on average by approximately 1.5 percentage points. The commenter is concerned that this is not driven by the physician fee cut issue and that there may be a bias in CMS' estimation methodologies that needs to be addressed.

Response: Looking back at the original growth percentage estimates for each year from 2004 to 2010 compared to the current estimates for those years, the original estimates are on average 1% - 1.5 % lower. However, the original estimates included the physician update cuts before they were overridden by subsequent fixes by Congress. The current estimates reflect the actual payment rates. If the original estimates were adjusted to reflect the eventual overrides for those years, the comparison would be more favorable and would indicate no particular bias in CMS' estimation methodologies.

Comment: Two commenters stated that the estimates for the 2010-2012 growth rate (2.5-3%) are significantly lower than historical actual growth rates, which average about 6%. The commenters asked that CMS explain the drivers for the trend deceleration for 2010-2012.

Response: Current estimates for the growth rates for 2006 through 2009 average about 5%. Impacts of the Affordable Care Act (ACA) start in 2010 and 2011, which is holding down the increase in those years. In addition, for FY 2011, there is some recoupment of excess coding and documentation under the MS-DRG system for hospital services. For 2012, in addition to continued ACA cuts, the current estimate reflects the almost 30 percent cut in the physician update.

Comment: Commenters asked for a detailed explanation of the projected restatements of prior year estimates of the MA growth rate back to 2004 in order to better understand the current growth rate. The commenter requested that going forward, this information be included in the Advance Notice as well as the Announcement. Commenters asked for information about the impact of physician fee cuts, the medical inflationary trend, and the ACA.

Response: There is sufficient detail presented in each year's Announcement to describe the major reasons for change in prior year's estimates. As previously stated, we will consider presenting more detailed information in the Advance Notice as well.

The growth percentages can change for several years back. In the current restatement, we don't believe that the revised estimates are materially different for 2004 through 2007. In fact, in the preliminary estimate, two of those years had slightly negative adjustments and two were slightly positive. There generally isn't any particular bias in the adjustments for prior years.

For the more recent years, there can be significant changes to the prior years. The last Announcement that contained rate information was released in April of 2009. The data used in the baseline projections at that time was data reported through the middle of 2008. Hence, it is not surprising to experience significant changes to the 2008 and later growth rates. What we have seen in the data reported since the middle of 2008 is that Part A inpatient hospital admissions and real case mix were down for 2008 and 2009 compared to what was previously assumed. This explains most of the change for those two years.

In the 2010 Announcement, the previous growth factors assumed the approximate 20% cut in the physician update, whereas the current estimate for 2010 reflects the actual payment rates. Hence, there is a large positive adjustment. Included in the adjustment for 2010 as a partial offset are the initial impacts of the ACA implementation. There are some ACA provisions which increase spending, but they are outweighed by the provisions which reduce spending.

The prior year's adjustment for 2011 is the same as the current trend, since the effective update for 2011 MA payment rates was 0 percent due to the provision in the ACA which froze MA payment rates for the year. The current trend reflects a 0 percent update for physician payments as well as other currently scheduled updates for FFS providers. Included in this trend are further cuts in FFS provider payment rates provided for by the ACA, other ACA provisions, and some recoupment of excess coding and documentation in the MS-DRG system for inpatient hospital payments in FY 2011.

For 2012, the large negative trend reflects the assumed almost 29.5% cut in the physician update.

Comment: One commenter asked that CMS provide the assumptions underlying the estimates of the USPCC.

Response: Attachment II of this Notice provides the major underlying economic, demographic and health assumptions used in the development of the USPCC. In addition, per capita amounts by type of service are shown in the attachment.

Comment: One commenter noted that Table I-2 shows the national per capita MA growth percentage for ESRD back to 2010 and asked for data from prior years. The commenter also asked CMS to explain the low ESRD trend in 2012 of .94%.

Response: Since the ESRD ratebook has been updated to a 2009 base, the trends prior to 2009 are no longer relevant. The updated data for 2009 implicitly includes adjustments for prior years.

Since the bulk of ESRD expenditures is for dialysis services, and dialysis services are not heavily physician expenditures, the large negative physician update for 2012 does not play as big a role as it does for non-ESRD expenditures. Therefore, there is a small positive trend as opposed to the negative trend estimated for non-ESRD expenditures.

Comment: Several commenters contended that, given the fact that Congress since 2003 has made adjustments to avoid reductions in physician payments under the SGR formula, it can be expected that Congress will again act legislatively to eliminate the reduction in payment for 2012 provided for under current law. These commenters accordingly requested that CMS include the impact of the expected SGR "fix" when calculating the national per capita MA growth percentage and prior year revision. Commenters recommended that CMS disclose the legislative and/or regulatory basis that requires it to ignore the consistent repeal of the SGR-legislated fee schedule reductions. One commenter noted that the policy is especially problematic for PFFS plans.

Response: CMS's consistent interpretation and longstanding practice has been to base the projected growth percentage on the law as it exists on the date of the announcement of the payment rate update. The statute requires that the growth percentage reflect the Secretary's estimate of the projected per capita rate of growth in expenditures "under this title." We believe that the best reading of this statutory language is that the growth percentage should be based on the provisions of "this title" (Title XVIII) as of the date that the rates are announced. As a result, every ratebook to date has been based on a USPCC increase estimated under the then current law. Changes to the Medicare statute are a fairly common occurrence. There have been a number of years where Medicare expenditures were expected to be reduced by pending legislative action. In those years, if we had anticipated the legislative changes in the projections, payments to Medicare Advantage plans would have been reduced. By following current law as the basis for

the projection, any judgment regarding the likelihood or implications of unknown possible law changes is removed.

Comment: Commenters noted that the President's Budget Proposal proposes funding for a two year fix to the cut in physician rates and that it assumes that a permanent fix will be found. Commenters assert that the growth percentage and Part C rates should be based on identical assumptions.

Response: While the President's Budget Proposal may "reflect the Administration's best estimate of future Congressional action based on what the Congress has done in recent years for physician payments," it is still a proposal, not law. CMS's policy is still that the growth rate increases reflect current law. The Administration remains committed to a permanent, fiscally responsible, solution to the Medicare physician payment system. A permanent solution would improve payment rates for MA plans as well as physicians in the future. If such a solution – or even a temporary extension to prevent a payment cut in 2012 -- could be enacted early this year, it could affect MA rates for 2012.

Section B. MA Benchmark, Quality Bonus Payments and Rebate

Comment: One commenter requested clarification on how the rates will be calculated and applied to Regional Plans.

Response: We appreciate the opportunity to clarify this policy. The 2012 regional rates will continue to be a blend of a plan bid component and a regional benchmark. There will be regional benchmarks for each appropriate level of star rating (e.g., less than 3 stars, 3 stars, 3.5 stars, etc.), and these regional benchmarks will be blended with the plan bid component to determine the regional rate. These two components will then be weighted together by the percentage of Medicare beneficiaries enrolled in Fee-for-Service (FFS) vs. Medicare Advantage (MA) plans nationwide to determine the 2012 rate.

Comment: One commenter inquired as to whether the status of a qualifying county will be reflected in the ratebook or if plans will need to make an adjustment in their bids to account for the extra revenue.

Response: The ratebook contains multiple rates for each county so that the appropriate rate for each plan within a county will be applied to that plan based both on the plan's star rating and status as a qualifying county.

Comment: One commenter requested confirmation that the star ratings in effect for 2011 will be the basis for determining 2012 quality bonus percentages.

Response: The commenter's assumptions are correct. The star rating assigned in 2011 will be the star rating used to determine the 2012 quality bonus percentage.

Comment: A number of commenters commended CMS for providing MA organizations the relevant and important data for determining which qualifying counties would receive double quality bonus payments, applicable phase-down periods, and the county quartile percentages.

Response: We appreciate the support for having published this information.

Comment: Several commenters requested that CMS clarify the methodology under which the national average Fee-For-Service Amount will be determined, while one other commenter expressed difficulty in recreating the methodology used by CMS to divide counties into quartiles and requested that CMS publish additional details on these calculations.

Response: The quartiles were determined based on the published 2009 FFS county rates, where the territories were excluded from the determination of the quartile cutpoints. The details on the methodology and calculations used for determining county quartiles as well as the other figures used to determine the national fee for service average can be found in the risk2012.csv file in the rate calculation data files posted on the CMS website. Details regarding the National Medicare Fee-for-Service Growth Percentage are in Attachment I.

Comment: Several commenters requested that CMS provide a written confirmation that the new blended benchmarks being implemented in accordance with the Affordable Care Act will not be applied as the MA county rate applied to PACE organizations.

Response: We welcome the opportunity to clarify this issue. The blended benchmarks will not be used as the MA county rates applied to the payment to PACE organizations. The PACE rates will be published in a separate ratebook.

Comment: One commenter asked CMS to specify how the amount of rebate for new plans under existing parent organizations would be determined and recommended that the determination be made in the same manner that the quality bonus percentage is specified for such plans.

Response: CMS has described how the amount of rebate would be determined for plans, including new plans in the proposed regulation proposed in response to the ACA in November 2010. New contracts offered by existing parent organizations will receive a star rating based on the star rating of all plans offered by the parent organization. The rebate percentages, and quality bonus percentages, are based on this star rating.

Comment: Many commenters offered support for the Quality Bonus Payment Demonstration asserting that the demonstration is an appropriate transition to an incentive-based payment system that rewards MA plans for achieving meaningful quality-based goals. These commenters set forth their belief that it is important that plans be evaluated on their ability to meet benchmarks established well in advance of the payment year to which quality based payments are applied, and the three year demonstration gives them an opportunity to use the resources gained from the demonstration on quality improvement. A number of commenters also

expressed their support for expanding this demonstration to stand-alone prescription drug plans in the future.

We received a number of comments on possible revisions to the demonstration. Several commenters contended that rewards to high quality plans should be more significant. One commenter recommended that CMS consider modifying the demonstration to recognize the investment plans have made without financial incentives to improve their quality and customer satisfaction, suggesting that CMS reduce the payments to 3 and 3.5 star plans and to increase quality bonus payments to plans with a star rating of 4 or higher. Another commenter recommended enhancing the bonus amount between 4 and 4.5 star plans to provide increased incentive to achieve the higher rating if the 5 star appears too difficult, also suggesting that enhanced bonus dollars could be given to those plans consistently achieving a 5 star rating. A few commenters believe it is not necessary to extend the quality bonus payment percentages to the entire blended county rate for plans with fewer than 5 stars, and that the benchmarks for the 3 to 4.5 star plans should not exceed the caps established in the ACA. A few commenters also suggested that CMS consider also rewarding plans that demonstrate significant incremental improvements in quality performance year over year to further incentivize plans to continue to develop programs to improve quality.

One commenter recommended non-payment rewards for high quality plans. This commenter recommended permitting a special election period for plans with a 4.5 star rating in those states where no plan achieves a 5 star rating.

Another commenter expressed concern that the demonstration design appears to leave plans that serve low income and under-educated service areas at a disadvantage.

A number of other commenters were concerned about the transition from the demonstration to the statutory requirements. Commenters recommended that CMS either extend the demonstration or create a five or six year transition from the demonstration to current law to provide plans additional time to improve their quality ratings and prevent sizeable reductions in bonus payments the year after the demonstration concludes. Some commenters asserted that the demonstration is a time-limited, transitional program quite adequate to allow plans to adjust to the payment system envisioned under the ACA, and a longer term demonstration policy could encourage plans to become complacent once they obtain a three star quality rating.

Response: We appreciate the support and have taken these comments into consideration in revising the demonstration. Due to the general support we have received for the demonstration, and the request that we recognize and reward high quality plans, we will modify the demonstration design to further incent more rapid and larger year-to-year quality improvement. The revised demonstration is intended to further increase the incentive for plans to improve their quality star ratings. CMS will apply the QBP percentage to both the applicable amount and the specified amount when calculating the blended benchmark and will not cap the blended rate at

the level of the pre-Affordable Care Act rate for plans with 3 to 5 stars. This nationwide three-year demonstration will be in effect from 2012 to 2014.

Under the demonstration the QBP percentage for each star rating will be as follows:

Stars Rating	QBP Percentage for 2012/2013	QBP Percentage for 2014
Less than 3 stars	0%	0%
3 stars	3%	3%
3.5 stars	3.5%	3.5%
4 stars	4%	5%
4.5 stars	4%	5%
5 stars	5%	5%

The design of the demonstration is intended to provide a strong incentive to improve performance at every star rating level, and to provide additional time for plans to achieve quality improvement. The three year duration was established in recognition of the multi-year time lag between the contract year measured for quality and payment year. An evaluation of the demonstration will be performed at its conclusion to determine how effective it was to incentivize increased quality on a national basis, and as a learning tool to see what other incentives may be more useful and productive in the future.

Comment: One commenter requested CMS clarify whether the qualifying county bonus payments would also be added to the entire blended benchmark under the demonstration.

Response: The revised demonstration applies the quality bonus percentage to each part of the blended benchmark. Specifically, the Applicable Amount is determined by establishing the appropriate pre-ACA county rate and multiplying that amount by the specific transition blend percentage for that county, the product of which is then multiplied by the (1 + plan specific quality bonus percentage). To establish the Specified Amount, the appropriate county fee for service transition blend percentage is multiplied by the sum of the Applicable Percentage and the plan specific quality bonus percentage, the product of which is then multiplied by the county appropriate fee-for-service rate. The Applicable Amount is then added to the Specified Amount to establish the final county rate to be applied.

The formula would therefore appear as follows: [(county specific transition blend percentage × pre-ACA county rate) × (1 + plan specific quality bonus percentage)] + [county specific fee-for-service transition blend percentage × (applicable percentage + plan specific quality bonus percentage) × county FFS rate] = final rate.

More details on the calculation of the rates can be found in the risk2012.csv file in the rate calculation data files posted on the CMS website.

Comment: A number of commenters expressed their support for applying the quality bonus percentages to the entire blended county rate for 3-4.5 star plans.

Response: We appreciate the support and have taken these comments into consideration in revising the demonstration. CMS will apply the QBP percentage to the entire 2012 blended county rate for plans with 3 to 5 stars. More specifically, we will apply the QBP percentage to both the applicable amount and the specified amount.

Comment: A number of commenters that expressed support for the quality bonus demonstration also declared that they do not support the imposition of caps on the benchmarks, stating their belief that if the caps were applied it would defeat the purpose of the demonstration. Another commenter suggested that if the ACA caps were to be applied their application should be based on a sliding scale with the lowest cap being on 3 star plans and no cap on the 4.5 and 5 star plans.

Response: We appreciate these comments and have taken them into consideration in revising the demonstration. We agree that caps would inhibit more rapid and larger year-to-year quality improvements in quality scores, because in some cases the benchmark would be capped before the bonus payment for quality would apply. Therefore, CMS will not cap the blended rate at the level of the pre-affordable Care Act rate for plans with 3 to 5 stars.

Comment: A number of commenters felt that the quality bonus percentage demonstration should allow for special provisions for specific types of plans like PACE and SNPs because of the special populations and quality issues they experience, and the special quality standards they must meet in order to qualify to become one of these specialized plans. A few other commenters also felt that the demonstration should be applied to Puerto Rico differently from the mainland such that Puerto Rican star ratings should be compared to other plans on the island rather than nationally for the duration of the demonstration, and that an exception to the ACA rule requiring a county to have been a rural floor county in 2004 should be made in determining qualifying counties to receive double bonus payments in Puerto Rico as Puerto Rican counties were precluded from receiving rural floor payments because of a territorial exception in the law which limited payment rate increases to 20% above the payment rates for the previous year.

Response: We appreciate these comments and have taken them into consideration in revising the demonstration. The purpose of the demonstration is to test whether using a scaled approach that makes quality bonus percentages available to additional rating levels instead of the current law two-level rule (four and five star plans) leads to more rapid and larger program-wide increases in plan quality scores during the three-year period of the demonstration. In light of the fact that the demonstration is being conducted nationwide and that all MA plans are participating in the demonstration, carving out special provisions for each plan type and population would have been contrary to CMS's intent to provide a strong incentive for all plans to improve performance and quality at every star rating level. We also note that at this point PACE organizations do not receive star ratings and they will be paid the pre-ACA rate.

Comment: Two commenters disagreed with CMS's proposal to implement the same rules for use of rebate dollars for 2012 that applied for 2011, under which MA organizations could continue to use rebate dollars only for the purposes set forth in section 1854(b)(1)(C)(ii), and one questioned CMS's authority to adopt this limitation given the fact that the statutory language containing these limitations was no longer in place for 2012, and suggested that at a minimum CMS should go through rulemaking to adopt this policy in regulations..

Response: First, as to the substance of our proposal to impose the limitations` at issue, we recognize that the statutory language setting forth these limitations is no longer in place for 2012, and were not relying on this inapplicable language in our proposal. Rather, we proposed, as part of the Advance Notice process, that rebate dollars continue to be used in one of the three ways that were specified in this language. We believe this approach provides MA organizations with more flexibility than would have been provided for 2012 under the statutory provision enacted on March 23, 2010 that was subsequently repealed in the reconciliation bill, while continuing to ensure that rebate dollars were used for appropriate, MA plan-related purposes. It is not clear what uses of rebate dollars the commenters contemplate other than providing additional plan benefits, buying down cost-sharing, or buying down premiums, including Part B premiums. This last option is tantamount to providing cash to enrollees, as a smaller amount is deducted from Social Security checks.

With respect to the procedural issue of how we are implementing this proposal, section 1853(b)(2) provides that CMS "shall provide for notice to [MA] organizations of proposed changes to be made in the methodology. . .used in previous [year] and shall provide [MA] organizations an opportunity to comment on such proposed changes." Section 1853(b)(1), in turn, provides for a final notice in which the "risk and other factors to be used in adjusting" payment will be published. This notice and comment process has been in place with respect to payment issues since 1985, when CMS first began contracting with private health plans on a capitation basis, under procedures set forth in section 1876(a)(1)(F) of the Act that are identical to those in section 1853(b)(2). All major changes in payment policy have been implemented through this process. For example, when section 1853(a)(3) was first implemented in 2000 with the initial risk adjustment methodology developed by CMS, this initial methodology was implemented through this section 1853(b) notice and comment process. All subsequent changes to the risk adjustment methodology, including the establishment of a "budget neutrality factor" to make risk adjustment budget neutral, and the subsequent decision by CMS to phase out budget neutrality (which was ratified by Congress in the DRA) have all been implemented through the section 1853(b) notice process. Other changes involving MA payment have been implemented through this process as well. Given that Congress specifically provided for this approach in the case of changes involving MA payment, Congress was specifying that this process was to be used to implement such changes, and that in its judgment this process gives MA organization a sufficient opportunity for input on changes affecting their payments. This belief is buttressed by the fact that Congress has on several occasions ratified in statute methodologies that CMS

established through this 1853(b) process (e.g., the initial phase in of risk adjustment and the plan to phase out budget neutrality). Because of the time needed to respond to plan comments, and prepare the notice by the 45 day deadline established by Congress, CMS has historically allowed a two-week comment period on proposed changes discussed in the Advance Notice.

Section C. Changes to the Medicare Advantage Ratebook

Comment: Several commenters noted that CMS uses a 2,000 member threshold to reflect a credibility theory for calculating FFS costs that contribute to the AGA factor and recommended that CMS consider using this same 2,000 member threshold member for the proposed small county adjustment.

Response: In the instructions for developing the bid pricing tools, CMS establishes a guideline for full credibility for MA plans of 24,000 base period member months or roughly 2,000 members. This standard is applied against one year of plan experience. In developing the Average Geographic Adjusters (AGA), five years of FFS data is used. Using five years of data requires fewer members to be considered fully credible than using one year. We studied the impact of using different levels of full credibility and determined that using 1,000 members significantly reduced the severity of fluctuations in the FFS rate development attributable to counties with low enrollment. CMS will use a 1,000 member threshold for the small county adjustment.

Comment: One commenter expressed concern about the proposed exclusion of Hospice claims for beneficiaries in Hospice status from the FFS costs used in the calculation of the AGA, stating that doing so would create two separate FFS amounts, and questioned the agency's authority for making this change.

Response: The development of the FFS USPCC has excluded Hospice claims since rates were developed on an adjusted average per capita cost basis. Excluding claims for beneficiaries in Hospice status from the AGA calculation aligns the calculation of the AGAs with how they are applied.

Comment: Several commenters felt that a delay in applying these changes to Puerto Rico rates is unnecessary, and CMS should not phase-in any changes resulting from a change in the methodology. Several commenters requested additional information regarding the data, time periods, assumptions and calculations used to produce the Puerto Rico adjustment. One commenter asserted that the proposed adjustment is not enough.

Response: We appreciate the effort and amount of detail submitted by the commenters on this issue. CMS conducted a detailed analysis of the FFS costs in Puerto Rico to ascertain the impact of the unique characteristics of beneficiaries in Puerto Rico before proposing an adjustment to the methodology used to calculate the Puerto Rico rates. As described in the Advance Notice, we tabulated the 2009 FFS costs in Puerto Rico for the cohort of Part A and/or Part B

beneficiaries as well as for beneficiaries enrolled in both Part A and Part B. We identified that the per capita costs for beneficiaries enrolled in both Part A and Part B were higher than those enrolled in Part A and/or Part B for all counties with Part B FFS enrollment of at least 100 members and most counties with less than 100 members. Medicare enrollment, cost and use in Puerto Rico is different than in the states. A far greater proportion of beneficiaries enroll in Medicare Advantage plans (67% in Puerto Rico vs 24% nationally) and those that do remain in fee-for-service are much less likely to enroll in Part B (46% in Puerto Rico vs 91% nationally). While most mainland beneficiaries are automatically enrolled in Part B, and must opt out to decline it, Puerto Rican beneficiaries are required to opt-in to Part B coverage. In addition, Medicare fee-for-service payment rates tend to be lower. Given these differences, we believe that establishing the FFS rate in Puerto Rico based on enrollees in both Part A and Part B is a reasonable approach. As with the other the other changes that affect the AGA calculation and to limit significant annual fluctuations, either upward or downward, we will reflect the new approach for tabulating FFS claims and enrollees beginning with the 2009 FFS tabulation. We have revised our estimate of the impact. This change will result in an average increase of .4% in the blended benchmark for Puerto Rico counties in 2012.

Comment: One commenter suggested that the calculation of the AGA be modified to increase the weight of expenditure data for the latest years used in this calculation instead of weighting them equally in determining the 2012 county rates.

Response: While we are concerned that introducing a new data with greater weight may introduce additional volatility into the AGA calculation, we will consider this comment in the development of future AGAs.

Comment: One commenter requested that CMS evaluate the impact on the Minnesota market place before implementing a change to the way Cost Plan claims are treated in the FFS cost calculations.

Response: We appreciate the commenter's concerns, however, CMS conducted a detailed analysis on the impact of implementing this adjustment on all counties before proposing this adjustment to the methodology. As with the other changes that affect the AGA calculation and to limit significant annual fluctuations, either upward or downward, we will reflect the new approach of excluding all FFS claims for Cost Plan enrollees beginning with the 2009 FFS tabulation.

Comment: One commenter inquired about what specific Cost Plan beneficiary information was included or excluded the 2000-2008 FFS data CMS released in prior years.

Response: Enrollees in Cost Plans were excluded from the enrollment tabulations but claims that were paid on fee-for-service basis for Cost Plan enrollees were included in the FFS tabulations through 2008.

Section D. IME Phase Out

Comment: One commenter said that the way the language reads in the Advance Notice, it appears that we are adjusting the specified amount by the IME phase-out amount and also making another IME phase-out adjustment to the ratebook rates (which are the blended rates). The commenter said that it appears that CMS is double counting this adjustment.

Response: The statute requires CMS to take into account the IME phase-out amount when computing the applicable amount and the specified amount of the new blended benchmark rate. Since the IME phase-out is reflected in both components, the blended rate excludes the IME phase-out appropriately.

Section E. Adjustment to FFS Per Capita Costs for VA-DoD Costs

Comment: A number of commenters offered support for the proposal to implement the VA-DoD adjustment, but requested that CMS publish a list of counties that will be impacted.

Response: We appreciate the support for implementing this adjustment. The county level VA-DoD adjustments can be found in the risk2012.csv file in the rate calculation data files posted on the CMS website.

Section F. Clinical Trials

Comment: Some commenters said that payment for clinical trials for MA plan enrollees through original Medicare creates a barrier to participation by such enrollees because it creates uncertainty as to who will pay for cost sharing. The commenters said that where enrollees face uncertainty with respect to financial obligation for cost sharing, they are less likely to participate in clinical trials.

Response: As we discussed in the 2011 Advance Notice, MA organizations are responsible for reducing cost sharing for clinical trials to the amount that their MA plan members would have for similar services provided by in-network providers. In effect, MA plan enrollees no longer have uncertainty as to the amount of cost sharing they will pay for clinical trials since it will be no different than the cost sharing they have when accessing in-network services of a similar kind.

Comment: Some commenters said that the administrative burden on members of having original Medicare pay clinical trial claims for MA plan enrollees, and then having such enrollees submit clinical trial cost sharing claims to MA organizations, is too great. The commenters said that this burden often discourages such enrollees from participating in clinical trials.

Response: Clinical trial sponsors/providers are permitted to submit original Medicare "paid" clinical trial claims to MA organizations on behalf of MA plan enrollees in order to obtain reimbursement for the difference between original Medicare cost sharing liabilities and in-

network MA plan cost sharing liabilities. Such sponsors/providers need only collect cost sharing from such enrollees once both original Medicare and MA organizations have paid.

Comment: Some commenters said that CMS should require MA organizations to cover all routine patient care costs associated with clinical trial enrollment.

Response: CMS requires MA organizations, in accordance with 42 CFR §422.109(c)(2), to provide coverage for: 1) services to diagnose conditions covered by clinical trial services, 2) most services furnished as follow-up care to clinical trial services, and; 3) services already covered by the MA organization. In requiring MA organizations to provide in-network cost sharing for clinical trial services, CMS is requiring that MA plan members have coverage for clinical trial services that is consistent with coverage they have for all other services.

Comment: Some commenters recommended that CMS adjust MA capitation rates to take into account participation by MA plan members in clinical trials. They said that CMS should have sufficient data to make such an adjustment after a decade of experience of having original Medicare pay for clinical trial services for MA enrollees. Commenters implied that this would somehow reduce the confusion surrounding cost sharing for beneficiaries.

Response: Although it is true that Medicare has nearly a decade of experience in paying for clinical trials for MA enrollees, the experience is nevertheless insufficient to make statistically valid adjustments to MA capitation rates. Also note that even if CMS were to adjust CMS capitation rates, MA organizations would still be permitted to impose cost sharing for clinical trial services similar to the cost sharing they impose on other MA plan-covered services.

Comment: Some commenters said that the Medicare coverage policy on clinical trials has removed the cost-sharing barrier for all Medicare beneficiaries with the exception of MA plan enrollees.

Response: While it may be true that original Medicare beneficiaries with Medigap or Medicare supplemental coverage with first dollar coverage do not pay any cost sharing when accessing Medicare-covered clinical trial services, it is also the case that such beneficiaries do not face cost sharing when accessing any Medicare-covered service. To the same extent that original Medicare beneficiaries without Medigap or supplemental coverage and MA plan enrollees generally do have cost sharing when accessing covered services, other than preventive services, cost sharing liabilities for clinical trial services are consistent and do not create a barrier to participation.

Comment: One commenter suggested referencing both Chapter 4 of the Medicare Managed Care Manual and the 2011 Payment Notice/Call Letter as a means of providing background on the fact that MA organizations are required to continue paying the difference between original Medicare cost sharing and in-network cost sharing when MA plan members access clinical trial services.

Response: As indicated above, the policy of requiring MA organizations to pay the difference between original Medicare cost sharing and in-network cost sharing for clinical trial services is unchanged from 2011. Also see section 10.13 – Clinical Trials – of updated Chapter 4 – Benefits and Beneficiary Protections – of the Medicare Managed Care Manual which was issued for comment by HPMS memorandum dated February 10, 2011.

Section G. ESRD Payments

G1. ESRD State Rates

Comment: A commenter questioned the methodology used to determine the ESRD state rates and has requested clarification.

Response: The 2012 ESRD state rates are based on 2006 – 2009 Medicare fee-for-service spending by beneficiaries in dialysis status. Consistent with the calibration of the ESRD risk adjustment model, the spending and enrollment is limited to beneficiaries with Medicare as primary and who have coverage for Medicare Parts A and B.

Comment: A commenter inquired about the lack of a 2% minimum update to the ESRD rates, and is requesting clarification as to how the 2% will be calculated for final 2012 ESRD rates.

Response: One intent of the Affordable Care Act was to more closely align MA payment rates with fee-for-service costs. In keeping with this intent, the ESRD state rates will be based on fee-for-service costs.

G2. Functioning Graft

Comment: One commenter expressed concern over this statement in the Advance Notice: "For 2012, CMS will pay Functioning Graft enrollees based on the blended benchmark for the county minus the amount of any rebate dollars (if any) allocated to reduce plan enrollees' Part B premium and/or Part D basic premium where the blended benchmark depends on the quality bonus payment (QBP) for the contract within which the person is enrolled." The commenter was concerned it would have different premiums for functioning graft enrollees in the plan.

Response: We are continuing our policy to pay functioning graft enrollees based on the county rate and the beneficiary's risk score; however, we are clarifying that the county rate(s) used for 2012 payment will include the changes to the benchmarks by the Affordable Care Act as well as the quality bonus payment (QBP) structure. In the Advance Notice we said, as with CMS' current functioning graft payment rules, the amount by which the plan reduces enrollees' Part B premium is a foregone revenue that remains in the Treasury, allowing CMS and SSA to decrease the enrollee's Part B premium by this amount. The amount by which the plan reduces the basic Part D premium is reflected in CMS' Part D payment to the plan.

Section H. Employer Group Waiver Plan Bidding

Comment: In the Advance Notice we announced our concerns about the level of EGWP bids relative to individual market bids and invited comments on ways to address our concerns. We have provided a summary of these comments below:

One commenter recommended one of three approaches with respect to Part C bidding for EGWPs: 1) Redesign our BPT so that where only a basic original Medicare benefit design is offered, then only administrative expenses for original Medicare benefits can be included; 2) Eliminate EGWP bids and use the average bid/rebate for each county, or; 3) Make an MAO's EGWP bid in a county equal to that MAO's bid in that county for non-EGWPs – in counties where both EGWP and non-EGWPs are offered by that MAO.

Another commenter said that EGWP bids differed from non-EGWP bids because EGWP enrollees often reside in more wide-spread geographic areas than do non-EGWP enrollees, creating higher utilization in EGWPs due to plan type (HMO for non-EGWP vs. PPO for EGWP), and other factors. This commenter recommended that CMS comprehensively study EGWP bidding before proposing policy changes.

A third commenter said that two factors lead to higher EGWP bids. The first factor, the commenter said, is that EGWPs offer "richer" benefits in the form of first dollar coverage and therefore cost sharing does not disincentivize enrollees from receiving medical services that are of marginal benefit. The second factor, the commenter said, is that enrollees with higher expected utilization are more likely to seek continued enrollment in EGWPs than are individuals with lower expected utilization.

A fourth commenter said that higher EGWP bids might be due to lower market force such plans can exert on providers due to the greater geographic dispersion of enrollees, less effective medical management programs, and the greater proportion of utilization of out-of-network providers.

One commenter cited first dollar coverage as the primary reason for higher EGWP bids.

Another commenter said that higher EGWP bids were due, primarily, to adverse enrollee selection and an imprecise risk-adjustment methodology. This commenter suggested that CMS provide its methodology for deriving the data displayed on page 20 in the "EGWP vs. Non-EGWP" bidding table. Finally, one commenter cited induced utilization due to "richer" benefits as the primary reason for higher EGWP bids.

Response: We thank all commenters for their thoughts on this issue. We will consider them as we continue to develop our EGWP bidding policy for the 2013 MA plan year.

Section I. CMS-HCC Risk Adjustment Model

Comment: A few commenters suggested that the new enrollee factor for C-SNPs should apply to all existing Medicare beneficiaries who are newly enrolling in a C-SNP instead of being applied only to those who are new to Medicare, while one commenter requested that a new enrollee factor be calculated for beneficiaries new to D-SNP plans as well.

Response: Current law requires the implementation of the new enrollee model for C-SNPs to apply only to new Medicare beneficiaries. CMS is not planning to develop a set of risk scores for continuing Medicare enrollees who are new to C-SNPs. Risk scores reflect prior year diagnoses, and given the strict rules about documenting reported diagnoses, CMS does not consider it appropriate that we impute prior year diagnoses. Many beneficiaries who are enrolled in MA plans develop conditions in the payment year that they did not have previously, and the risk model is designed to accurately predict risk across subgroups of beneficiaries, including groups of high-risk beneficiaries. As documented in our evaluation, the current model works well within subgroups of risk, including high-risk groups. As we further document, it is not clear that C-SNP enrollees are necessarily higher risk or more sick than similar FFS enrollees.

CMS is not considering applying similar new enrollee risk scores to Dual or Institutional SNP enrollees. We believe that absent explicit statutory authority we cannot pay Dual or Institutional SNPs differently from regular MA plans. Further, we are not considering applying differential new enrollee risk scores to all SNP enrollees. We believe that for Dual-eligible and Institutional SNPs' our evidence shows that the new enrollee risk scores in the CMS-HCC model are adequate to address the aggregate risk faced by these plans because the current new enrollee risk score model captures the additional costs due to Medicaid, disabled and institutional status. As discussed in previous Announcements, in creating the C-SNP model, CMS found that the increment to the new enrollee risk scores for C-SNPs is a result of chronic disease. This research also found that the increment was the same for each category (non-Medicaid, Medicaid, originally disabled) across all age/sex groups, indicating that there no further increments are needed for the costs predicted by Medicaid, original entitlement, or institutional status. These findings indicate that the predicted costs of Medicaid enrollees, originally disabled, and institutionalized enrollees are fully accounted for in the current new enrollee model.

Comment: One commenter expressed their support for CMS's decision not to implement a new Risk Adjustment Model, stating that doing so maintains stability and improved predictability in the risk adjustment methodology and MA payment rates while material revisions to the MA payment model are being implemented.

Response: We appreciate the support.

Comment: A few commenters expressed concern regarding CMS's decision to delay implementation of the version of the CMS-HCC model initially proposed in the 2011 Advance Notice, opining that CMS's decision to retain the current CMS-HCC model will significantly,

negatively and disproportionally impact Medicare payments to PACE organizations, especially in light of the fact that a large portion of PACE enrollees are diagnosed with dementia. These commenters also set forth their belief that the decision to delay implementation of the clinically revised HCC model disadvantages PACE provider organizations and PACE beneficiaries relative to most Medicare Advantage plans as a result of the differences in the populations enrolled in PACE and MA. A few commenters also recommended that CMS implement the proposed model for 2012.

Response: We appreciate these commenters support for implementing the clinically updated model. In light of the comments CMS received in this regard, CMS has reconsidered its decision to not implement the new model entirely, and noted above, and has decided to implement this model for PACE organizations in 2012.

Comment: Several commenters expressed their confusion regarding CMS's decision not to implement the updated version of the CMS-HCC model initially proposed in the 2011 Advance Notice, stating that the new model would provide significant improvement to risk adjustment, especially in light of the fact that it would have included diagnoses related to dementia for the first time. These commenters also recommended that an explanation be provided for not doing so, and for CMS to reconsider this decision for 2013.

Response: We appreciate the commenters' input and will take these comments into consideration when preparing the 2013 Advance Notice. We reiterate that our decision to implement the new model for PACE organizations only in 2012 was to provide some continuity in payment methodology for MA organizations in 2012, given other changes that are taking place.

Comment: One commenter expressed a concern that CMS has not improved risk adjustment for 2012, stating that even if CMS had implemented the new risk adjustment model as proposed in 2011 for 2012, it would not have provided meaningful improvement, and requested that CMS make additional improvements for 2012 and future years in order to decrease plan cherry-picking of healthier beneficiaries, improve the plans' incentive to focus on costs, reduce unnecessary costs and stop overpaying for low risk beneficiaries and underpaying for high risk beneficiaries.

Response: We direct the commenter to the evaluation that we are publishing at http://www.cms.gov/MedicareAdvtgSpecRateStats/06_Risk_adjustment.asp#TopOfPage, as it more thoroughly explains the risk adjustment model's performance, clears up many misconceptions about the model's ability to accurately predict costs for MA beneficiaries, and more thoroughly discusses the positive and noteworthy impact of the model changes initially proposed in 2011.

Comment: One commenter inquired as to whether CMS has reviewed those diagnoses currently excluded from the current risk adjustment model to see if including more diagnoses in the model would result in greater accuracy in risk scores for beneficiaries in SNPs as these plans were developed to serve individuals that have more specialized needs.

Response: Our model development process involves thorough assessment of the ability of each HCC to predict Medicare costs. We direct the commenter to the evaluation that we are publishing herewith at http://www.cms.gov/MedicareAdvtgSpecRateStats/06_Risk_adjustment.asp#TopOfPage, as it more thoroughly explains the processes through which the model is created, including the methodologies used to ascertain which HCC's are included within the model. In addition, the evaluation addresses model performance for C-SNPs. Please refer to the following publications for information on model development and performance: http://www.cms.gov/HealthCareFinancingReview/Downloads/04summerpg119.pdf

Section J. Recalibration of the ESRD Risk Adjustment Model

Comment: A commenter asked if the Part C and ESRD models are following different HCC models this year.

Response: The ESRD model has a different set of HCCs than the age/disabled CMS-HCC model for Payment Year 2012. The 2012 ESRD HCC model incorporates both a data recalibration and clinical update.

Comment: A commenter asked CMS to share the regression output and summary statistics from the current model and from the recalibrated model.

Response: We appreciate the support. In order to derive the model output (dollar coefficients) from the regression model, multiply the factors by the denominator. Several articles have presented information on model performance, such as R^2. Please see Pope, G.C. et.al. *Risk Adjustment of Medicare Capitation Payments Using the CMS-HCC Model*. Health Care Financing Review 25(4): 119-141, Summer 2004 at http://www.cms.gov/HealthCareFinancingReview/Downloads/04summerpg119.pdf. Robst, J, Levy, J.M., Ingber, M.J. *Diagnosis-Based Risk Adjustment for Medicare Prescription Drug Plan Payments.* Health Care Financing Review 28(4): 15-30, Summer 2007 at http://www.cms.gov/HealthCareFinancingReview/downloads/07Summerpg15.pdf.

Comment: One commenter requested more information on how the ESRD model was developed.

Response: CMS recalibrated the ESRD risk adjustment model using data from FFS claims, specifically, 2006 diagnoses were used to predict 2007 expenditures. In addition to using more recent data years in recalibrating the model, CMS also undertook a clinical update that involved reviewing the assignment of all ICD-9 diagnoses codes to diagnosis groupings that are used as the building blocks of the condition categories (CC). In consultation with a panel of outside clinicians, CMS reviewed the ICD-9 codes grouped with other clinically similar ICD-9 codes. These diagnosis groupings were then mapped to condition categories based on similar clinical

characteristics and severity, and cost implications. Both the panel of clinicians and analyses of cost data informed the creation of condition categories.

Coefficients for condition categories were estimated by regressing the total expenditure for A/B benefits for each FFS ESRD beneficiary onto their demographic factors and condition categories, as indicated by their diagnoses. Resulting dollar coefficients represent the marginal (additional) cost of the condition or demographic factor (e.g., age/sex group, Medicaid status, disability status). The inclusion of condition categories is based on each category's ability to predict costs for Medicare Parts A and B benefits. Condition categories that don't predict costs well –because the coefficient is small, the t-value is low, the number of beneficiaries with a certain condition is small so the coefficient is unstable, or the condition doesn't have well specified diagnostic coding – are not included in the model. Further, the ESRD model excludes HCCs and interaction terms for kidney-related conditions.

In a final step, hierarchies were imposed on the condition categories, assuring that more advanced and costly forms of a condition are reflected in a higher coefficient.

Please note that, since there are new ICD-9 codes that map to HCCs in the revised ESRD model for 2012, these new ICD-9 codes should be submitted for dates of services in 2011.

Section K. Adjustment for MA Coding Pattern Differences

Comment: Several commenters supported CMS's decision to maintain the level of the 2011 adjustment for 2012, stating that doing so maintains stability and improved predictability in the risk adjustment methodology and MA payment rates while material revisions to the MA payment model are being implemented.

Response: We appreciate the support for maintaining the current coding pattern adjustment.

Comment: One commenter stated that the adjustment should not be applied to the "Specified" portion of the rates as this amount is a percent of FFS costs, and questions why the adjustment is applied to the risk scores.

Response: The DRA requires the Secretary, in risk adjusting payments to plans, to reflect an adjustment for differences in *coding patterns* between Medicare Advantage plans and FFS providers under Part A and B, to the extent that the Secretary has identified such differences. The reason for applying this adjustment to beneficiaries' risk scores is because these coding pattern differences influence the risk scores of beneficiaries enrolled in MA plans, and not the rates.

Comment: One commenter asked how CMS will take into account the RADV audits in developing the coding intensity adjustment for 2012 and future years.

Response: As we have noted in previous Advance Notices and Rate Announcements, the MA coding adjustment factor is not intended to adjust for inaccurate coding, but for the impact on

risk scores of coding patterns that differ from FFS coding, the basis of the CMS-HCC model and the Part C normalization factor. RADV audits, on the other hand, have the purpose of validating that diagnosis codes submitted for risk adjustment are documented in the medical record and, therefore, are correctly reported for the beneficiary in question.

Comment: One commenter expressed confusion about the amount of the adjustment and requested an explanation of the methodology used to create adjuster being applied in 2012.

Response: The methodology for creating the 3.41% coding adjustment being applied in 2012 is described in detail in the 2010 Final Rate Announcement which can be found at: http://www.cms.gov/MedicareAdvtgSpecRateStats/Downloads/Announcement2010.pdf

Section L. Frailty Adjustment

Comment: Several commenters asked that CMS pay frailty at an individual level. These commenters asked that CMS pay this frailty adjuster to the nursing home certifiable population enrolled in the plan. Some of these commenters also asked that CMS only survey those enrollees who are nursing home certifiable. Another commenter asked that CMS apply frailty for beneficiaries who qualify for the home and community based program within a state.

Response: Because ADL data are collected via survey for a subset of a plan's membership, it is not possible to pay frailty calculated at an individual level for all enrollees in a plan. In addition, because the survey is developed based on a random sample of enrollees, allowing plans to select enrollees to be surveyed would violate the principle of randomization, which would mean that the frailty score could not be generalized to the entire plan. The frailty model is calibrated using a similar methodology of a randomized sample across the FFS population. Therefore, frailty factors reflect the proper weights for this survey approach to measuring frailty in a population. As to the home and community based program, we believe that the differences in eligibility criteria by state for these programs could make comparison between FIDE SNPs difficult.

Comment: Several commenters asked that CMS pay frailty to the under 55 population that has frailty similar to PACE.

Response: When we developed the frailty model, we determined that it did not help predict unexplained costs of beneficiaries under age 55.

Comment: Several commenters asked CMS to consider collecting data from state level assessments of frailty. One commenter stated that a plan should qualify for frailty if a member has been accepted into a SNP by virtue of a State approved assessment tool.

Response: CMS will continue to evaluate alternative sources of data, including state level assessments, to determine frailty. We believe, however, that the HOS survey, because it can be sampled at the PBP level, provides our best estimate of a plan's frailty score. In addition, the

survey is standardized, unlike the state level assessments, which can vary from one state to the next.

Comment: One commenter noted that the intent of the Affordable Care Act provision was to pay frailty to the integrated dual eligible programs that had previously existed outside of PACE before 2004.

Response: The statute directs CMS to look at a plan's level of frailty in comparison to PACE. We believe that our policy is consistent with the statute.

Comment: Several commenters asked CMS to consider using alternative measures of frailty, noting that researchers have identified five core frailty measures in "Untangling the Concepts of Frailty, Disability and Comorbidities," including generalized weakness, poor endurance, weight loss and/or undernourishment, low activity (including being homebound), and fear of falling and/or unsteady gait."[1] These commenters also noted that "there is a growing consensus in the geriatric community that frailty, disability and comorbidity are "'distinct clinical entities that are causally related.'"

Response: CMS recognizes that frailty has many aspects, including the five core frailty measures mentioned by the commenters. However, we disagree that there is, in fact, a consensus about how to define frailty. A recent study notes the following:

> "No clear consensual definition regarding frailty seems to emerge from the literature after 30 years of research in the topic, and a large array of models and criteria has been proposed to define the syndrome. Controversy continues to exist on the choice of the components to be included in the frailty definition. Two main definitions based on clusters of components are found in literature: a physical phenotype of frailty, operationalized in 2001 by providing a list of 5 measurable items of functional impairments, which coexists with a multidomain phenotype, based on a frailty index constructed on the accumulation of identified deficits based on comprehensive geriatric assessment. The physical phenotype considers disability and comorbidities such as dementia as distinct entities and therefore outcomes of the frailty syndrome, whereas comorbidity and disability can be components of the multidomain phenotype. Expanded models of physical frailty (models that included clusters other than the original 5 items such as dementia) increased considerably the predicting capacity of poor clinical outcomes when compared with the predictive capacity of the physical phenotype"[2]

CMS will continue to conduct research into ways to refine our frailty methodology. We have concerns about the feasibility of collecting detailed data on the five aspects of frailty without causing undue burden on plans. Given this potential burden, and consistent with studies we have conducted on this topic, we believe that ADLs provide an adequate measure of frailty that can be obtained based on available survey data.

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[1]Fried, L et. al., Untangling the Concepts of Disability, Frailty, and Comorbidity: Implications for Improving Targeting and Care", Journal of Gerontology, Medical Sciences, 2004, Vol. 59, No. 3, 255-263.

[2]Abellan van Kan G, Rolland Y, Houles M, Gillette-Guyonnet S, Soto M, Vellas B.The assessment of frailty in older adults. Clin Geriatr Med. 2010 May;26(2):275-86.

Comment: One commenter stated that CMS should identify frailty individuals based on those who qualify for $0 cost sharing based on the Part D Best Available Evidence policy.

Response: CMS does not believe that $0 cost sharing would indicate frailty, and we would not be able to distinguish frailty levels for these individuals without survey data.

Comment:
CMS received 14 comments on the application of frailty adjusted payments to FIDE SNPs. The comments expressed a range of views including support for applying frailty adjustment to any FIDE SNPs within the PACE range to not applying frailty to FIDE SNPs unless the frailty adjustment was available across the entire MA program. Some commenters also noted that certain states require Medicaid managed care plans to accept all enrollees, so enrollees will be less frail than PACE enrollees. According to these commenters, not using the range of frailty scores will result in FIDE SNPs separating their pans into nursing home certifiable and non-nursing home certifiable populations.

Response: We agree with the commenters that recommend using the minimum score of the PACE range of frailty scores to determine whether FIDE SNPs have frailty similar to PACE for the purpose of implementing this provision of the ACA.

In order to compare FIDE SNP frailty scores to PACE frailty scores for 2012, we will first establish a PACE organization range of frailty based upon those PACE organizations with at least 100 respondents to the 2011 HOS survey. Once the PACE range is established, those FIDE SNPs that have a frailty score above the minimum PACE score will receive a frailty add-on to their beneficiaries risk scores. Low enrollment (30 or fewer respondents to the HOS/HOS-M) or new FIDE SNPs (those who were not eligible to participate in the 2011 HOS because they were not eligible due to the length of time the plan was in operation) will receive a frailty score equal to the 2012 average FIDE SNP frailty score as determined by the data received from 2011 HOS survey. For comparison purposes, both the PACE range of frailty and the FIDE SNP frailty scores will be based upon the frailty factors used to calculate the frailty scores for payment to the FIDE SNP plans as published in this Notice.

Section M. Normalization Factors

Comment: Many commenters requested a more detailed explanation of the methodology and calculations used to determine the normalization factors. These commenters also expressed concern about the increase in the normalization for 2012 being significantly higher than historical changes. A few commenters also inquired if CMS is accounting for the influx of the baby boomer population into Medicare when deriving this factor.

Response: The formula for calculating normalization factors used to adjust risk scores takes into account the following factors:

(1) The annual trend, calculated over a rolling set of annual risk scores. (2) The number of years between the denominator year and the payment year.

In the case of both the Part C and Part D, each year's normalization factor may change marginally due to updating the annual trend and, to a larger degree, as a result of any change in the gap between the denominator year and the payment year. The change in the normalization factor to account for coding trends between the denominator year and the payment year should not affect a plan's risk score, as long as the plan's coding trend is consistent with the average trend.

When we project the normalization factor for the payment year, we use the most recent fee-for-service data available. For 2012 the most recent year is 2010, which we believe is current enough to reflect recent trends. We have decided to calculate an annual trend over as many as five years of risk scores specifically to smooth this trend.

Normalization Factor for the CMS-HCC Model
The final 2012 CMS-HCC Part C model normalization factor is 1.079.

- The Part C normalization factor is used to normalize the following risk scores: Aged/disabled community, aged/disabled institutional and aged/disabled new enrollee.
- Population used to calculate annual trend: FFS beneficiaries.

CMS estimates an annual trend using a linear function applied to the following years' risk scores:

2006: 0.984
2007: 1.000
2008: 1.009
2009: 1.031
2010: 1.046

The linear annual trend over these five years (2006-2010) is 0.0154. This annual trend is applied for the years between the denominator year (2007) and the payment year (2012) by taking it to the fifth power. The normalization factor is obtained as follows: $1.0154^5 = 1.079$.

Section N. ACA Evaluation

Comment: Several commenters expressed the belief that it was Congress's intent for this evaluation to be included in the Advance Notice so that plans would have an opportunity to comment. Several of these commenters are requesting that CMS publish the evaluation prior to the Announcement thereby giving plans time to submit comments, while others are requesting for a comment period after it is published in the Rate Announcement. A few plans stated that they believe Congress intended for CMS to implement changes to risk adjustment as a result of

the evaluation and do not believe that CMS has not improved risk adjustment for 2012. One commenter encouraged CMS to undertake a comprehensive survey of all SNPs to inform the risk adjustment methodology regarding frailty and comorbitities.

Response: The statute at 1853(a)(1)(C)(iii)(IV) of the Act states that the Secretary shall publish the evaluation as part of the "announcement under subsection (b)." We interpret this to mean that the evaluation should be published in the Announcement of Calendar Year (CY) 2012 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter. As also provided in statute, we will evaluate the risk adjustment system in order to assess its ability to account for higher medical and care coordination costs associated with frailty, individuals with multiple, comorbid chronic conditions, and individuals with a diagnosis of mental illness, and also to account for costs that may be associated with higher concentrations of beneficiaries with those conditions. The risk adjustment evaluation can be found on the CMS website at http://www.cms.gov/MedicareAdvtgSpecRateStats/06_Risk_adjustment.asp#TopOfPage.

Comment: One commenter requested that CMS recognize problems in the 10 decile analysis for high risk chronically ill beneficiaries stating that the model inappropriately treats high spending chronically ill beneficiaries as healthy causing them to be assigned to a lower than "true" risk decile.

Response: We measure model predictive strength by comparing predicted costs to actual

costs. We typically group beneficiaries into risk deciles, meaning that we create ten equal-sized groups of beneficiaries, ranging from the group with the highest predicted costs to the group with the lowest predicted costs. For each risk-based group, we then create ratios of predicted costs to actual costs. Using predictive ratios, we find that the CMS-HCC model performs well. Comparing predictive ratios across beneficiaries grouped by actual costs (as the comment implies) is not an actuarially sound way to look at the ability of the model to accurately predict costs. If one looks at the cost data retrospectively (after the fact) the result will always be that high cost beneficiaries are under-predicted as high cost is largely due to random events. Determining whether the costs associated with beneficiaries predicted to be high, medium or low cost is the only actuarially sound way to evaluate the risk adjustment model.

Section O. Encounter Data Collection

Comment: At least three plans commented on the burden brought about by changing the submission guidelines for Encounter Data. Some confusion also exists on how frequently plans have to submit data and what the deadlines are around these submissions.

Response: CMS is in the process of creating an encounter data managed care manual discussing issues related to these comments. We plan to release the manual early this summer.

Comment: One commenter asked CMS to clarify its statement that it intends to reimburse Medicare Cost plans for the cost of gathering and submitting encounter data. They asked us to clarify whether we would pay for creation of data systems that could be used for other purposes.

Response: Consistent with our long-standing policy, we will not reimburse full cost for the creation or enhancement of data systems that can be used for other purposes. Reasonable costs for such system's development or enhancement may, however, be claimed (where appropriate) under normal administrative and general cost reimbursement rules found in §417.564.

Comment: Some MAO plans commented that CMS should consider delaying the deployment of the new ED requirements due to the significant increase in resources needed for ED and ICD-10 within a short timeframe.

Response: CMS appreciates that the system implementation timeline for encounter data and ICD-10 may place additional burden on some of the Medicare Advantage Organizations (MAO) and Third Party Administrators (TPA). The Plans were informed of the implementation of Encounter Data through the 2011 Advanced Notice published February 2010, technical requirements were provided in the April 2010 Rate Announcement, and additional information regarding the implementation schedule and requirements were discussed during the National Encounter Data meeting held on October 29, 2010. Given the amount of notice and the extensive industry consultation, CMS does not propose to delay implementation of encounter data requirements.

Comment: Some MA plans commented on what CMS intends to do with the data it receives through the new ED requirements.

Response: We intend to use the data in accordance with our regulation at 42 CFR 422.310(f), which states CMS uses the data to determine the risk adjustment factors used to adjust payments, … for updating risk adjustment models, calculating Medicare DSH percentages, conducting quality review and improvement activities, and for Medicare coverage purposes.

Section P. Risk Adjustment Processing System (RAPS) File Changes

Comment: One commenter asked why CMS is planning to make new changes to the RAPS file format for use in 10/2013. The commenter asked CMS to clarify whether 2013 RAPS or encounter data will be used to calculate payments. The commenter asked for more detail regarding the proposed change and timing.

Response: CMS is planning to make changes to the RAPS file format to accommodate ICD 10 codes starting in 2013. We plan to run both the RAPS and encounter systems until the encounter data is complete and accurate enough to support risk adjustment payment and model development.

Section Q. Risk Adjustment Data Validation (RADV)

Comment: Several commenters objected to CMS's plans to continue contract-level Risk Adjustment Data Validation (RADV) audits in 2012 and recommend that CMS hold-off conducting further contract-specific RADV audits until the Agency addresses questions already submitted to CMS.

Response: On Tuesday, December 21, 2010, CMS posted a description of the Agency's proposed draft RADV sampling and payment error calculation methodology on our website at http://www.cms.gov/HealthPlansGenInfo/ and invited public comment on this document. To date, we have received comments on a variety of RADV topics. We are thoroughly evaluating all comments and anticipate making changes to our draft, based on input we received. We anticipate the final revised RADV sampling and payment error calculation methodology paper will be issued in the near future. CMS also plans to issue a question and answer document that summarizes the comments received on the RADV methodology and the Agency's response to those comments.

Section R. Prospective Coverage Gap Discount Program (CGDP) Payments

Comment: One commenter asked CMS to clarify our use of the term "fill fees" in this section of the Advance Notice.

Response: In this section of the Advance Notice, "fill fees" refers to dispensing fees and vaccine administration fees, both of which are excluded from the manufacturer discounts provided under the CGDP.

Comment: In the Advance Notice, we requested public comment regarding the prospective CGDP payments for fill fees. The calculation methodology proposed in the Advance Notice did not apply a downward adjustment to the prospective CGDP payments to reflect that manufacturer discounts under the CGDP do not include fill fees. A few commenters recommended that CMS apply an adjustment to the prospective CGDP payments for fill fees. They indicated that applying such an adjustment would improve the accuracy of the prospective payments since manufacturer discounts under the CGDP do not include fill fees. Two commenters agreed with our proposed methodology and indicated that no adjustment should be applied because fill fees vary significantly and will have a minimal impact on the prospective CGDP payments. One commenter expressed a concern that excluding fill fees from the prospective CGDP payments would be a change from 2011. The commenter asserted such a change would create significant administrative burden due to changes to Part D sponsors' accounting and IT systems. Overall, commenters asked that CMS make any adjustments for fill fees as simple as possible.

Response: We do not believe that it is necessary to adjust the prospective CGDP payments for fill fees. We agree with commenters that fill fees are small relative to manufacturer discounts

under the CGDP and therefore will have little impact on the prospective CGDP payments. Consistent with the guidance in the May 21, 2010 HPMS memo, "Medicare Coverage Gap Discount Program Beginning in 2011: Revised Part D Sponsor Guidance and Responses to Summary Public Comments on the Draft Guidance", any prospective CGDP payments that exceed the manufacturer discounts made available under the CGDP will be recouped by CMS during the CGDP reconciliation process.

Section S. Cost Sharing for Applicable Beneficiaries in the Coverage Gap

Comment: One commenter requested clarification regarding whether Part D sponsors should assume that in general, generic drugs are non-applicable and brand drugs are applicable when developing their Part D bids.

Response: While in general applicable drugs are brand drugs and non-applicable drugs are generic drugs, Part D sponsors should not use this assumption when developing their Part D bids. There are cases where a brand drug may be considered a non-applicable drug and a generic drug may be considered an applicable drug. Therefore, the Part D bids should be developed consistent with the definition of applicable drug in Section 1860D-14A(g)(2) of the Social Security Act and the Instructions for Completing the Prescription Drug Plan Bid Pricing Tool for Contract Year 2012.

Comment: One commenter expressed concern that the term "manufacturer discounts" could be confused with discounts unrelated to the CGDP. The commenter recommended use of the term "manufacturer coverage gap discount" to provide greater clarity for Part D sponsors when implementing the CGDP.

Response: CMS appreciates this comment and will consider the use of this term in future guidance regarding the CGDP.

Section T. Update of the Rx-HCC Model

Comment: One commenter inquired as to whether or not CMS will recalibrate the RxHCC model every year in light of the changes in the percentage of generic coverage for non-LIS beneficiaries.

Response: CMS anticipates a need to recalibrate the RxHCC model on a regular basis to factor in the impact of the new Medicare Part D benefit structure. The Advance Notice will announce the details of any future changes, such as recalibrations, to the RxHCC model.

Comment: One commenter appreciates and concurs with CMS' update of the RxHCC model. In addition, the commenter requests that greater transparency be shown via providing the details used in recalibration of the model – specifically, regression model output and summary statistics from the current and recalibrated RxHCC models to show improved payment accuracy.

Response: We appreciate the support. In order to derive the model output (dollar coefficients) from the regression model, multiply the factors by the denominator. Several articles have presented information on model performance, such as R^2. Please see Pope, G.C. et.al. *Risk Adjustment of Medicare Capitation Payments Using the CMS-HCC Model*. Health Care Financing Review 25(4): 119-141, Summer 2004 at http://www.cms.gov/HealthCareFinancingReview/Downloads/04summerpg119.pdf. Robst, J, Levy, J.M., Ingber, M.J. *Diagnosis-Based Risk Adjustment for Medicare Prescription Drug Plan Payments.* Health Care Financing Review 28(4): 15-30, Summer 2007 at http://www.cms.gov/HealthCareFinancingReview/downloads/07Summerpg15.pdf.

Section U. De Minimis Premium Policy

Comment: One commenter supported CMS' approach in regards to the *de minimis* premium policy and requested greater freedom for plans that target the low income premium subsidy level in their bid to make premium concessions.

Response: CMS appreciates the support. The *de minimis* amount is determined yearly based on the outcome of the plan bidding process. The impacts of setting the *de minimis* amounts at varying levels are considered each year, including the ability for plans to meet the low income premium target and offer a zero premium plan to LIS beneficiaries. We also consider the number of reassignments resulting from varying *de minimis* levels. CMS will continue this approach of analyzing plan bids and determining impacts prior to announcing the *de minimis* amount in August.

Section V. Payment Reconciliation

Comment: In general, commenters supported the risk corridors proposed for 2012. One Part D sponsor indicated that the continuation of the risk corridors is important because the sponsor experiences significant variations in risk sharing each year. Commenters asked that we continue to review our risk sharing data and make appropriate adjustments to the risk percentages to reduce payments recouped from Part D sponsors and better align risk sharing with the cost containment efforts of Part D sponsors. One commenter indicated that widening the risk corridors will discourage irrational pricing intended to shift downside risk to CMS.

Response: We appreciate the support and will continue to review our risk sharing data each year to assess whether any changes should be made to the risk corridors.

Section W. Medicare Part D Benefit Parameters: Annual Adjustments for Defined Standard Benefit in 2012

Comment: One commenter requests that CMS display the maximum total drug costs that a member may incur at the TrOOP threshold, or alternatively, to explain how the Estimated Total Covered Part D Spending for Applicable Beneficiaries for 2012 ($6,730.39) was developed.

Response: We note that the "Estimated Total Covered Part D Spending for Applicable Beneficiaries" is more accurately called "Estimated Total Covered Part D Spending at Out-of-Pocket Threshold for Applicable Beneficiaries" and are thus modifying the term in the Part D Benefit Parameters chart. This value of $6,730.39 for 2012 is an estimate of the average amount of total drug spending for an applicable beneficiary to attain the out-of-pocket threshold in the defined standard benefit. The purpose of providing this value is to enable enhanced alternative plans to map enhanced alternative coverage to the defined standard benefit, which is necessary for purposes of calculating the covered plan paid amounts (CPP) reported on the prescription drug event (PDE) records. The value is based on PDE data showing the historical average applicable and non-applicable drug spending in the coverage gap. The calculation for Estimated Total Covered Part D Spending at Out-of-Pocket Threshold for Applicable Beneficiaries for 2012 is shown on page 43 of the Advance Notice and Rate Announcement for 2012.

Comment: One commenter requested that the Part D Benefit Parameters chart reflect $0 cost sharing for dual eligibles receiving home and community based services.

Response: Section 3309 of the Affordable Care Act extended the elimination of Part D cost sharing to full benefit dual eligibles who would be institutionalized individuals (or an institutionalized couple) if the individuals were not receiving home and community-based services (HCBS) under Title XIX of the Act. The effective date for this requirement will be no earlier than January 1, 2012. We have proposed an implementation date of January 1, 2012 in our November 15, 2010 proposed rule. Should this proposed effective date be finalized in our final rule, the Final Updated Part D Benefit Parameters for Defined Standard Benefit, Low-Income Subsidy, and Retiree Drug Subsidy will reflect zero cost sharing for these individuals. We have included a placeholder in the chart in Attachment IV in consideration of this comment.

Attachment IV. Final Updated Part D Benefit Parameters for Defined Standard Benefit, Low-Income Subsidy, and Retiree Drug Subsidy

Annual Percentage Increases

	Annual percentage trend for 2011	Prior year revisions	Annual percentage increase for 2011
Applied to all parameters but (1)	4.67%	-1.27%	3.34%
CPI (all items, U.S. city average): Applied to (1)	1.42%	-0.43%	0.98%

Part D Benefit Parameters

	2011	2012
Standard Benefit		
Deductible	$310	$320
Initial Coverage Limit	$2,840	$2,930
Out-of-Pocket Threshold	$4,550	$4,700
Total Covered Part D Spending at Out-of-Pocket Threshold for Non-Applicable Beneficiaries (2)	$6,447.50	$6,657.50
Estimated Total Covered Part D Spending at Out-of-Pocket Threshold for Applicable Beneficiaries (3)	$6,483.72	$6,730.39
Minimum Cost-Sharing in Catastrophic Coverage Portion of the Benefit		
Generic/Preferred Multi-Source Drug	$2.50	$2.60
Other	$6.30	$6.50
Full Subsidy-Full Benefit Dual Eligible (FBDE) Individuals		
Deductible	$0.00	$0.00
Copayments for Institutionalized Beneficiaries [category code 3]	$0.00	$0.00
Copayments for Beneficiaries Receiving Home and Community-Based Services (4) [category code 3] (if effective date is January 1, 2012 as proposed)	--	$0.00
Maximum Copayments for Non-Institutionalized Beneficiaries		
Up to or at 100% FPL [category code 2]		
Up to Out-of-Pocket Threshold (1)	$1.10	$1.10
Generic/Preferred Multi-Source Drug (5)	$3.30	$3.30
Other (5)	$0.00	$0.00
Above Out-of-Pocket Threshold		
Over 100% FPL [category code 1]		
Up to Out-of-Pocket Threshold	$2.50	$2.60
Generic/Preferred Multi-Source Drug	$6.30	$6.50
Other		
Above Out-of-Pocket Threshold	$0.00	$0.00
Full Subsidy-Non-FBDE Individuals		
Eligible for QMB/SLMB/QI, SSI or applied and income at or below 135% FPL and resources ≤ $6,680 (individuals) or ≤ $10,020 (couples) (6) [category code 1]		
Deductible	$0.00	$0.00
Maximum Copayments up to Out-of-Pocket Threshold		
Generic/Preferred Multi-Source Drug	$2.50	$2.60
Other	$6.30	$6.50
Maximum Copayments above Out-of-Pocket Threshold	$0.00	$0.00
Partial Subsidy		
Applied and income below 150% FPL and resources below $11,140 (individual) or $22,260 (couple) [category code 4]		
Deductible	$63.00	$65.00
Coinsurance up to Out-of-Pocket Threshold	15%	15%
Maximum Copayments above Out-of-Pocket Threshold		
Generic/Preferred Multi-Source Drug	$2.50	$2.60
Other	$6.30	$6.50
Retiree Drug Subsidy Amounts		
Cost Threshold	$310	$320
Cost Limit	$6,300	$6,500

(1) CPI adjustment applies to copayments for non-institutionalized beneficiaries up to or at 100% FPL.

(2) For beneficiaries who are *not* considered an "applicable beneficiary" as defined at section 1860D-14A(g)(1) and therefore are not eligible for the coverage gap discount program (i.e. LIS beneficiaries), this is the amount of total drug spending required to attain out-of-pocket threshold in the defined standard benefit if the beneficiary does not have prescription drug coverage through a group health plan, insurance, government-funded health program or

similar third party arrangement. Enhanced alternative plans must use this value when mapping enhanced alternative coverage plans to the defined standard benefit, for the purposes of calculating the covered plan paid amounts (CPP) reported on the prescription drug event (PDE) records.

(3) For beneficiaries who are considered an "applicable beneficiary" as defined at section 1860D-14A(g)(1) and therefore are eligible for the coverage gap discount program (i.e. non-LIS beneficiaries), this is the estimated average amount of total drug spending required to attain the out-of-pocket threshold in the defined standard benefit if beneficiary does not have prescription drug coverage through a group health plan, insurance, government-funded health program or similar third party arrangement. Enhanced alternative plans must use this value when mapping enhanced alternative coverage to the defined standard benefit, for purposes of calculating the covered plan paid amounts (CPP) reported on the prescription drug event (PDE) records.

(4) Per section 1860D-14(a)(1)(D)(i), full-benefit dual eligibles who would be institutionalized individuals (or couple) if the individual (or couple) was not receiving home and community-based services qualify for zero cost-sharing as of an effective date (no earlier than January 1, 2012) specified by the Secretary. We proposed an effective date of January 1, 2012, and should our proposed rule be finalized with an effective January of 1, 2012, cost sharing for this population would be zero beginning January 1, 2012. (5) The increases to the LIS deductible, generic/preferred multi-source drugs and other drugs copayments are applied to the unrounded 2011 values of $63.12, $1.10, and $3.31, respectively.

(6) The actual amount of resources allowable will be updated for contract year 2012.

Attachment V. Medicare Part D Benefit Parameters for the Defined Standard Benefit: Annual Adjustments for 2012

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) directs CMS to update the statutory parameters for the defined standard Part D drug benefit each year. These parameters include the standard deductible, initial coverage limit, and catastrophic coverage threshold, and minimum copayments for costs above the annual out-of-pocket threshold. In addition, CMS is statutorily required to update the parameters for the low income subsidy benefit and the cost threshold and cost limit for qualified retiree prescription drug plans eligible for the Retiree Drug Subsidy. Included in this notice are (i) the methodologies for updating these parameters, (ii) the updated parameter amounts for the Part D defined standard benefit and low-income subsidy benefit for 2012, and (iii) the updated cost threshold and cost limit for qualified retiree prescription drug plans.

As required by statute, the parameters for the defined standard benefit formula are indexed to the percentage increase in average per capita total Part D drug expenses for Medicare beneficiaries. Accordingly, the actuarial value of the drug benefit increases along with any increase in drug expenses, and the defined standard Part D benefit continues to cover a constant share of drug expenses from year to year.

All of the Part D benefit parameters are updated using one of two indexing methods specified by statute: (i) the annual percentage increase in average expenditures for Part D drugs per eligible beneficiary, and (ii) the annual percentage increase in the Consumer Price Index (CPI) (all items, U.S. city average).

I. Annual Percentage Increase in Average Expenditures for Part D Drugs Per Eligible Beneficiary

Section 1860D-2(b)(6) of the Social Security Act defines the "annual percentage increase" as "the annual percentage increase in average per capita aggregate expenditures for covered Part D drugs in the United States for Part D eligible individuals, as determined by the Secretary for the 12-month period ending in July of the previous year using such methods as the Secretary shall specify." The following parameters are updated using the "annual percentage increase":

Deductible: From $310 in 2011 and rounded to the nearest multiple of $5.

Initial Coverage Limit: From $2,840 in 2011 and rounded to the nearest multiple of $10.

Out-of-Pocket Threshold: From $4,550 in 2011 and rounded to the nearest multiple of $50.

Minimum Cost-Sharing in the Catastrophic Coverage Portion of the Benefit: From $2.50 per generic or preferred drug that is a multi-source drug, and $6.30 for all other drugs in 2011, and rounded to the nearest multiple of $0.05.

Maximum Copayments below the Out-of-Pocket Threshold for certain Low Income Full Subsidy Eligible Enrollees: From $2.50 per generic or preferred drug that is a multi-source drug, and $6.30 for all other drugs in 2011, and rounded to the nearest multiple of $0.05.

Deductible for Low Income (Partial) Subsidy Eligible Enrollees: From $63[3] in 2011 and rounded to the nearest $1.

Maximum Copayments above the Out-of-Pocket Threshold for Low Income (Partial) Subsidy Eligible Enrollees: From $2.50 per generic or preferred drug that is a multi-source drug, and $6.30 for all other drugs in 2011, and rounded to the nearest multiple of $0.05.

II. Annual Percentage Increase in Consumer Price Index, All Urban Consumers (all items, U.S. city average)

Section 1860D-14(a)(4) of the Social Security Act specifies that the annual percentage increase in the CPI, All Urban Consumers (all items, U.S. city average) as of September of the previous year is used to update the maximum copayments below the out-of-pocket threshold for full benefit dual eligible enrollees with incomes that do not exceed 100% of the Federal poverty line. These copayments are increased from $1.10 per generic or preferred drug that is a multi-source drug, and $3.30 for all other drugs in 2011[4], and rounded to the nearest multiple of $0.05 and $0.10, respectively.

III. Calculation Methodology

Annual Percentage Increase

For the 2007 and 2008 contract years, the annual percentage increases, as defined in section 1860D-2(b)(6) of the Social Security Act, were based on the National Health Expenditure (NHE) prescription drug per capita estimates because sufficient Part D program data was not available. Beginning with the 2009 contract year, the annual percentage increases are based on Part D

[3] Consistent with the statutory requirements of 1860D-14(a)(4)(B) of the Social Security Act, the update for the deductible for low income (partial) subsidy eligible enrollees is applied to the unrounded 2011 value of $63.12.

[4] Consistent with the statutory requirements of 1860D-14(a)(4)(A) of the Social Security Act, the copayments are increased from the unrounded 2011 values of $1.10 per generic or preferred drug that is a multi-source drug, and $3.31 for all other drugs.

program data. For the 2012 contract year benefit parameters, Part D program data is used to calculate the annual percentage trend as follows:

$$\frac{August\,2010 - July\,2011}{August\,2009 - July\,2010} = \frac{\$2{,}924.44}{\$2{,}793.88} = 1.0467$$

In the formula, the average per capita cost for August 2009 – July 2010 ($2,793.88) is calculated from actual Part D prescription drug event (PDE) data and the average per capita cost for August 2010 – July 2011 ($2,924.44) is calculated based on actual Part D PDE data incurred from August – December, 2010 and projected through July, 2011.

The 2012 benefit parameters reflect the 2011 annual percentage trend as well as a revision to the prior estimates for prior years' annual percentage increases. Based on updated NHE prescription drug per capita costs and PDE data, the annual percentage increases are now estimated as summarized by Table III-2.

Table III-2. Revised Prior Years' Annual Percentage Increases

Year	Prior Estimates of Annual Percentage Increases	Revised Annual Percentage Increases
2007	6.48%	6.74%
2008	5.12%	5.36%
2009	4.42%	4.44%
2010	3.22%	3.07%
2011	4.63%	2.96%

Accordingly, the 2012 benefit parameters reflect a multiplicative update of -1.27% for prior year revisions. In summary, the 2011 parameters outlined in section I are updated by 3.34% for 2012 as summarized by Table III-3.

Table III-3. Annual Percentage Increase

Annual percentage trend for July 2011	4.67%
Prior year revisions	−1.27%
Annual percentage increase for 2012	3.34%

Note: Percentages are multiplicative, not additive. Values are carried to additional decimal places and may not agree to the rounded values presented above.

Annual Percentage Increase in Consumer Price Index, All Urban Consumers (all items, U.S. city average)

The annual percentage increase in the CPI as of September of the previous year referenced in section 1860D-14(a)(4)(A)(ii) is interpreted to mean that, for contract year 2012, the September 2011 CPI should be used in the calculation of the index. To ensure that plan sponsors and CMS have sufficient time to incorporate the cost-sharing requirements into benefit, marketing material and systems development, the methodology to calculate this update includes an estimate of the September 2011 CPI based on the projected amount included in the President's FY2012 Budget. The September 2010 value is from the Bureau of Labor Statistics. The annual percentage trend in CPI for contract year 2012 is calculated as follows:

$$\frac{\text{Projected September 2011 CPI}}{\text{Actual September 2010 CPI}} \textit{ or } \frac{221.550}{218.439} = 1.0142$$

(Source: President's FY2012 Budget and Bureau of Labor Statistics, Department of Labor)

The 2012 benefit parameters reflect the 2011 annual percentage trend in the CPI, as well as a revision to the prior estimate for the 2010 annual percentage increase. The 2011 parameter update reflected an annual percentage trend in CPI of 1.58%. Based on the actual reported CPI for September 2010, the September 2010 CPI increase is now estimated to be 1.14%. Thus, the 2012 update reflects a multiplicative -0.43% correction for prior year revisions. In summary, the cost sharing items outlined in section II are updated by 0.98% for 2012 as summarized by Table III-4.

Table III-4. Cumulative Annual Percentage Increase in CPI

Annual percentage trend for September 2011	1.42%
Prior year revisions	-0.43%
Annual percentage increase for 2011	0.98%

Note: Percentages are multiplicative, not additive. Values are carried to additional decimal places and may not agree to the rounded values presented above.

Estimated Total Covered Part D Spending at Out-of-Pocket Threshold for Applicable Beneficiaries

For 2012, the Total Covered Part D Spending at OOP Threshold for Applicable Beneficiaries is $6,730.39. The Total Covered Part D Spending at OOP Threshold for Applicable Beneficiaries is calculated as the ICL plus 100% beneficiary cost sharing in the coverage gap divided by the weighted gap coinsurance factor. This value is calculated assuming 100% cost sharing in the deductible phase, 25% in the initial coverage phase, and in the coverage gap, 86% for non-applicable (generic) drugs and 100% for applicable (brand) drugs.

Total Covered Part D Spending at OOP Threshold for Applicable Beneficiaries is calculated for 2012 as follows:

$$\text{ICL} + \frac{\text{100\% beneficiary cost sharing in the gap}}{\text{weighted gap coinsurance factor}} \quad \textit{or} \quad \$2930 + \frac{\$3727.50}{98.082\%} = \$6{,}730.39$$

where 100% of the beneficiary cost sharing in the gap is the estimated total drug spending in the gap assuming 100% coinsurance.

100% beneficiary cost sharing in the gap is calculated as follows for 2012:

OOP threshold – OOP costs up to the ICL *or* $4,700 − $972.50 = $3,727.50

Weighted gap coinsurance factor is calculated for 2012 as follows:

(Brand GDCB % for non-LIS × 100% cost sharing for applicable drugs) + (Generic GDCB % for non-LIS × 86% cost sharing for non-applicable drugs) *or* (86.3% × 100%) + (13.7% × 86%) = 98.082%

where:

- Brand GDCB % for non-LIS is the percentage of gross covered drug costs below the out-of-pocket threshold for applicable beneficiaries attributable to applicable (brand) drugs as reported on the 2010 PDE records;
- Gap cost sharing for applicable drugs is the coinsurance incurred by applicable beneficiaries for applicable (brand) drugs in coverage gap;
- Generic GDCB % for non-LIS is the percentage of gross covered drug costs below the out-of-pocket threshold for applicable beneficiaries attributable to non-applicable (generic) drugs as reported on the 2010 PDE records; and
- Gap cost sharing for non-applicable drugs is the coinsurance incurred by applicable beneficiaries for non-applicable (generic) drugs in coverage gap.

IV. Retiree Drug Subsidy Amounts

As outlined in §423.886(b)(3) of the regulations implementing the Part D benefit, the cost threshold and cost limit for qualified retiree prescription drug plans that end in years after 2006 are adjusted in the same manner as the annual Part D deductible and out-of-pocket threshold are adjusted under §423.104(d)(1)(ii) and (d)(5)(iii)(B), respectively. Specifically, they are adjusted by the "annual percentage increase" as defined previously in this document and the cost threshold is rounded the nearest multiple of $5 and the cost limit is rounded to the nearest multiple of $50. The cost threshold and cost limit are defined as $310 and $6,300, respectively, for plans that end in 2010, and, as $310 and $6,300, respectively, for plans that end in 2011. For 2012, the cost threshold is $320 and the cost limit is $6,500.

Attachment VI. ESRD, and Rx-HCC Risk Adjustment Factors

Tables

Table 1. ESRD Model Continuing Enrollee Dialysis Relative Factors

Variable	Relative Factors
Female	
0-34 Years	0.598
35-44 Years	0.598
45-54 Years	0.598
55-59 Years	0.606
60-64 Years	0.619
65-69 Years	0.686
70-74 Years	0.702
75-79 Years	0.717
80-84 Years	0.739
85-89 Years	0.745
90-94 Years	0.745
95 Years or Over	0.745
Male	
0-34 Years	0.589
35-44 Years	0.589
45-54 Years	0.589
55-59 Years	0.599
60-64 Years	0.609
65-69 Years	0.661
70-74 Years	0.686
75-79 Years	0.695
80-84 Years	0.736
85-89 Years	0.752
90-94 Years	0.752
95 Years or Over	0.752
Medicaid, Originally Disabled, and Originally ESRD Interactions with Age and Sex	
Medicaid_Female_Aged	0.052
Medicaid_Female_NonAged (Age <65)	0.057
Medicaid_Male_Aged	0.065
Medicaid_Male_NonAged (Age <65)	0.033
Originally Disabled_Female[2]	0.049
Originally Disabled_Male[2]	0.045
Originally ESRD_Female[3]	-0.062
Originally ESRD_Male[3]	-0.045

Disease Group	Description Label	RelativeFactors
HCC1	HIV/AIDS	0.171
HCC2	Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock	0.077
HCC6	Opportunistic Infections	0.080
HCC8	Metastatic Cancer and Acute Leukemia	0.251
HCC9	Lung and Other Severe Cancers	0.172
HCC10	Lymphoma and Other Cancers	0.106
HCC11	Colorectal, Bladder, and Other Cancers	0.058
HCC12	Breast, Prostate, and Other Cancers and Tumors	0.031
HCC17	Diabetes with Acute Complications	0.202
HCC18	Diabetes with Chronic Complications	0.087
HCC19	Diabetes without Complication	0.075
HCC21	Protein-Calorie Malnutrition	0.037
HCC22	Morbid Obesity	0.132
HCC23	Other Significant Endocrine and Metabolic Disorders	0.004
HCC27	End-Stage Liver Disease	0.201
HCC28	Cirrhosis of Liver	0.085
HCC29	Chronic Hepatitis	0.053
HCC33	Intestinal Obstruction/Perforation	0.057
HCC34	Chronic Pancreatitis	0.039
HCC35	Inflammatory Bowel Disease	0.056
HCC39	Bone/Joint/Muscle Infections/Necrosis	0.068
HCC40	Rheumatoid Arthritis and Inflammatory Connective Tissue Disease	0.075
HCC46	Severe Hematological Disorders	0.148
HCC47	Disorders of Immunity	0.031
HCC48	Coagulation Defects and Other Specified Hematological Disorders	0.076
HCC51	Dementia With Complications	0.127

Disease Group	Description Label	RelativeFactors
HCC52	Dementia Without Complication	0.060
HCC54	Drug/Alcohol Psychosis	-
HCC55	Drug/Alcohol Dependence	-
HCC57	Schizophrenia	0.136
HCC58	Major Depressive, Bipolar, and Paranoid Disorders	0.084
HCC70	Quadriplegia	0.206
HCC71	Paraplegia	0.206
HCC72	Spinal Cord Disorders/Injuries	0.105
HCC73	Amyotrophic Lateral Sclerosis and Other Motor Neuron Disease	-
HCC74	Cerebral Palsy	0.068
HCC75	Polyneuropathy	0.056
HCC76	Muscular Dystrophy	-
HCC77	Multiple Sclerosis	0.069
HCC78	Parkinson's and Huntington's Diseases	0.055
HCC79	Seizure Disorders and Convulsions	0.069
HCC80	Coma, Brain Compression/Anoxic Damage	0.118
HCC82	Respirator Dependence/Tracheostomy Status	0.295
HCC83	Respiratory Arrest	0.114
HCC84	Cardio-Respiratory Failure and Shock	0.062
HCC85	Congestive Heart Failure	0.072
HCC86	Acute Myocardial Infarction	0.092
HCC87	Unstable Angina and Other Acute Ischemic Heart Disease	0.092
HCC88	Angina Pectoris	0.044
HCC96	Specified Heart Arrhythmias	0.071
HCC99	Cerebral Hemorrhage	0.077
HCC100	Ischemic or Unspecified Stroke	0.077
HCC103	Hemiplegia/Hemiparesis	0.076
HCC104	Monoplegia, Other Paralytic Syndromes	0.076
HCC106	Atherosclerosis of the Extremities with Ulceration or Gangrene	0.279
HCC107	Vascular Disease with Complications	0.084
HCC108	Vascular Disease	0.051
HCC110	Cystic Fibrosis	0.065
HCC111	Chronic Obstructive Pulmonary Disease	0.065
HCC112	Fibrosis of Lung and Other Chronic Lung Disorders	0.054
HCC114	Aspiration and Specified Bacterial Pneumonias	0.081
HCC115	Pneumococcal Pneumonia, Empyema, Lung Abscess	0.015
HCC122	Proliferative Diabetic Retinopathy and Vitreous Hemorrhage	-
HCC124	Exudative Macular Degeneration	-
HCC157	Pressure Ulcer of Skin with Necrosis Through to Muscle, Tendon, or Bone	0.171
HCC158	Pressure Ulcer of Skin with Full Thickness Skin Loss	0.171
HCC159	Pressure Ulcer of Skin with Partial Thickness Skin Loss	0.171
HCC160	Pressure Pre-Ulcer Skin Changes or Unspecified Stage	0.171
HCC161	Chronic Ulcer of Skin, Except Pressure	0.118
HCC162	Severe Skin Burn or Condition	0.049
HCC166	Severe Head Injury	0.118
HCC167	Major Head Injury	0.015
HCC169	Vertebral Fractures without Spinal Cord Injury	0.050
HCC170	Hip Fracture/Dislocation	0.040
HCC173	Traumatic Amputations and Complications	0.041
HCC176	Complications of Specified Implanted Device or Graft	-
HCC186	Major Organ Transplant or Replacement Status	0.159
HCC188	Artificial Openings for Feeding or Elimination	0.047
HCC189	Amputation Status, Lower Limb/Amputation Complications	0.114
Disease Interactions		
SEPSIS_CARD_RESP_FAIL	Sepsis*Cardiorespiratory Failure	0.100
CANCER_IMMUNE	Cancer*Immune Disorders	0.093
DIABETES_CHF	Diabetes*Congestive Heart Failure	0.020
CHF_COPD	Congestive Heart Failure*Chronic Obstructive Pulmonary Disease	0.018
COPD_CARD_RESP_FAIL	Chronic Obstructive Pulmonary Disease*Cardiorespiratory Failure	0.013
NonAged (Age <65)/Disease Interactions		
NONAGED_HCC6	NonAged, Opportunistic Infections	0.074
NONAGED_HCC34	NonAged, Chronic Pancreatitis	0.116
NONAGED_HCC46	NonAged, Severe Hematological Disorders	0.038
NONAGED_HCC54	NonAged, Drug/Alcohol Psychosis	0.166
NONAGED_HCC55	NonAged, Drug/Alcohol Dependence	0.166
NONAGED_HCC110	NonAged, Cystic Fibrosis	0.369
NONAGED_HCC176	NonAged, Complications of Specified Implanted Device or Graft	0.046

NOTES:
1. The CMS ESRD Dialysis Denominator used to calculate the relative factors is $75,564.91.

[2] Originally Disabled indicates beneficiary originally entered Medicare due to a condition other than ESRD.

[3] Originally ESRD indicates beneficiary originally entered Medicare due to ESRD. Beneficiaries that are Originally ESRD cannot be Originally Disabled.

The estimate for HCC 160 is based on pressure ulcer, any stage, for all anatomical sites codes. The estimated coefficient for HCC 160 is also assigned to HCCs 157, 158, and 159 in the constrained regression because the ICD9 codes for the stages of pressure ulcers are not implemented until FY09.

In the "disease interactions," the variables are defined as follows:
Sepsis = HCC 2.
Cardiorespiratory Failure = HCCs 82-84.
Cancer = HCCs 8-12.
Immune Disorders = HCC 47.
Diabetes = HCCs 17, 18, 19.
Congestive Heart Failure = HCC 85.
Chronic Obstructive Pulmonary Disease = HCCs 110-111.

SOURCE: RTI International analysis of 2006/2007 Medicare 100% ESRD sample claims and enrollment data.

Table 2. ESRD Model Demographic Relative Factors for New Enrollees in Dialysis Status

	Non-Medicaid & Non-Originally Disabled	Medicaid & Non-Originally Disabled	Non-Medicaid & Originally Disabled	Medicaid & Originally Disabled
Female				
0-34 Years	0.848	0.966	1.075	1.193
35-44 Years	0.848	0.966	1.075	1.193
45-54 Years	0.848	0.966	1.075	1.193
55-59 Years	0.883	1.001	1.110	1.228
60-64 Years	0.902	1.020	1.128	1.246
65-69 Years	1.021	1.120	1.248	1.347
70-74 Years	1.065	1.165	1.292	1.392
75-79 Years	1.123	1.222	1.350	1.449
80-84 Years	1.128	1.227	1.354	1.454
85 Years or Over	1.142	1.241	1.369	1.468
Male				
0-34 Years	0.735	0.842	0.957	1.065
35-44 Years	0.775	0.883	0.998	1.105
45-54 Years	0.811	0.919	1.034	1.141
55-59 Years	0.843	0.951	1.066	1.173
60-64 Years	0.867	0.975	1.090	1.197
65-69 Years	0.974	1.088	1.197	1.311
70-74 Years	1.030	1.144	1.253	1.367
75-79 Years	1.072	1.186	1.295	1.409
80-84 Years	1.105	1.219	1.327	1.441
85 Years or Over	1.120	1.234	1.342	1.456

NOTES:

1. The CMS ESRD Dialysis Denominator used to calculate the relative factors is $75,564.91.

2. Originally disabled terms refer to people originally entitled to Medicare for reasons of disability other than ESRD.

SOURCE: RTI International analysis of 2006/2007 Medicare 100% ESRD sample claims and enrollment data.

Table 3. ESRD Kidney Transplant CMS-HCC Model Relative Factors for Transplant Beneficiaries

	Beneficiaries	**Kidney Transplant** *Actual Dollars*	**Kidney Transplant Relative Risk Factor**
Month 1	8,412	36,618.30	5.815
Months 2 and 3	16,188	5,540.51	0.880
Total (Actual Months 1-3)		**47,569.19**	

NOTES:

1. Kidney transplant is identified by DRG 302 for discharge dates through September 30, 2007 and by MS-DRG 652 for discharge dates from October 1, 2007 on.

2. The transplant month payments were computed by aggregating the costs for each of the three monthly payments.

3. The transplant factor is calculated in this manner: (kidney transplant month's dollars/Dialysis Denominator)*12. The CMS ESRD Dialysis Denominator value used was $75,564.91.

SOURCE: RTI International analysis of 2006/2007 Medicare 100% ESRD sample claims and enrollment data.

Table 4. ESRD Model Functioning Graft Relative Factors for Community Population

Variable	Relative Factor
Functioning Graft Factors	
Aged 65+, with duration since transplant of 4-9 months	2.635
Aged <65, with duration since transplant of 4-9 months	2.582
Aged 65+, with duration since transplant of 10 months or more	1.268
Aged <65, with duration since transplant of 10 months or more	1.170
Female	
0-34 Years	0.198
35-44 Years	0.212
45-54 Years	0.274
55-59 Years	0.359
60-64 Years	0.416
65-69 Years	0.283
70-74 Years	0.346
75-79 Years	0.428
80-84 Years	0.517
85-89 Years	0.632
90-94 Years	0.755
95 Years or Over	0.775
Male	
0-34 Years	0.079
35-44 Years	0.119
45-54 Years	0.165
55-59 Years	0.292
60-64 Years	0.332
65-69 Years	0.309
70-74 Years	0.378
75-79 Years	0.464
80-84 Years	0.565
85-89 Years	0.647
90-94 Years	0.776
95 Years or Over	0.963
Medicaid and Originally Disabled Interactions with Age and Sex	
Medicaid_Female_Aged	0.213
Medicaid_Female_NonAged (Age <65)	0.104
Medicaid_Male_Aged	0.210
Medicaid_Male_NonAged (Age <65)	0.113
Originally Disabled_Female_Age ≥65	0.244
Originally Disabled_Male_Age ≥65	0.171

Disease Group	Description Label	Relative Factor
HCC1	HIV/AIDS	0.492
HCC2	Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock	0.520
HCC6	Opportunistic Infections	0.557
HCC8	Metastatic Cancer and Acute Leukemia	2.425
HCC9	Lung and Other Severe Cancers	1.006
HCC10	Lymphoma and Other Cancers	0.695
HCC11	Colorectal, Bladder, and Other Cancers	0.330
HCC12	Breast, Prostate, and Other Cancers and Tumors	0.180
HCC17	Diabetes with Acute Complications	0.344
HCC18	Diabetes with Chronic Complications	0.344
HCC19	Diabetes without Complication	0.124
HCC21	Protein-Calorie Malnutrition	0.653
HCC22	Morbid Obesity	0.342
HCC23	Other Significant Endocrine and Metabolic Disorders	0.240
HCC27	End-Stage Liver Disease	1.003
HCC28	Cirrhosis of Liver	0.425
HCC29	Chronic Hepatitis	0.313
HCC33	Intestinal Obstruction/Perforation	0.337
HCC34	Chronic Pancreatitis	0.257
HCC35	Inflammatory Bowel Disease	0.279
HCC39	Bone/Joint/Muscle Infections/Necrosis	0.423
HCC40	Rheumatoid Arthritis and Inflammatory Connective Tissue Disease	0.376
HCC46	Severe Hematological Disorders	1.078
HCC47	Disorders of Immunity	0.306
HCC48	Coagulation Defects and Other Specified Hematological Disorders	0.258

Disease Group	Description Label	Relative Factor
HCC51	Dementia With Complications	0.616
HCC52	Dementia Without Complication	0.343
HCC54	Drug/Alcohol Psychosis	0.358
HCC55	Drug/Alcohol Dependence	0.358
HCC57	Schizophrenia	0.471
HCC58	Major Depressive, Bipolar, and Paranoid Disorders	0.318
HCC70	Quadriplegia	1.075
HCC71	Paraplegia	0.868
HCC72	Spinal Cord Disorders/Injuries	0.441
HCC73	Amyotrophic Lateral Sclerosis and Other Motor Neuron Disease	1.016
HCC74	Cerebral Palsy	0.036
HCC75	Polyneuropathy	0.281
HCC76	Muscular Dystrophy	0.460
HCC77	Multiple Sclerosis	0.482
HCC78	Parkinson's and Huntington's Diseases	0.555
HCC79	Seizure Disorders and Convulsions	0.252
HCC80	Coma, Brain Compression/Anoxic Damage	0.533
HCC82	Respirator Dependence/Tracheostomy Status	1.732
HCC83	Respiratory Arrest	0.769
HCC84	Cardio-Respiratory Failure and Shock	0.326
HCC85	Congestive Heart Failure	0.361
HCC86	Acute Myocardial Infarction	0.283
HCC87	Unstable Angina and Other Acute Ischemic Heart Disease	0.283
HCC88	Angina Pectoris	0.210
HCC96	Specified Heart Arrhythmias	0.276
HCC99	Cerebral Hemorrhage	0.371
HCC100	Ischemic or Unspecified Stroke	0.333
HCC103	Hemiplegia/Hemiparesis	0.481
HCC104	Monoplegia, Other Paralytic Syndromes	0.212
HCC106	Atherosclerosis of the Extremities with Ulceration or Gangrene	1.313
HCC107	Vascular Disease with Complications	0.417
HCC108	Vascular Disease	0.288
HCC110	Cystic Fibrosis	0.388
HCC111	Chronic Obstructive Pulmonary Disease	0.388
HCC112	Fibrosis of Lung and Other Chronic Lung Disorders	0.294
HCC114	Aspiration and Specified Bacterial Pneumonias	0.691
HCC115	Pneumococcal Pneumonia, Empyema, Lung Abscess	0.212
HCC122	Proliferative Diabetic Retinopathy and Vitreous Hemorrhage	0.223
HCC124	Exudative Macular Degeneration	0.248
HCC134	Dialysis Status	—
HCC135	Acute Renal Failure	—
HCC136	Chronic Kidney Disease, Stage 5	—
HCC137	Chronic Kidney Disease, Severe (Stage 4)	—
HCC138	Chronic Kidney Disease, Moderate (Stage 3)	—
HCC139	Chronic Kidney Disease, Mild or Unspecified (Stages 1-2 or Unspecified)	—
HCC140	Unspecified Renal Failure	—
HCC141	Nephritis	—
HCC157	Pressure Ulcer of Skin with Necrosis Through to Muscle, Tendon, or Bone	1.071
HCC158	Pressure Ulcer of Skin with Full Thickness Skin Loss	1.071
HCC159	Pressure Ulcer of Skin with Partial Thickness Skin Loss	1.071
HCC160	Pressure Pre-Ulcer Skin Changes or Unspecified Stage	1.071
HCC161	Chronic Ulcer of Skin, Except Pressure	0.473
HCC162	Severe Skin Burn or Condition	0.458
HCC166	Severe Head Injury	0.533
HCC167	Major Head Injury	0.141
HCC169	Vertebral Fractures without Spinal Cord Injury	0.441
HCC170	Hip Fracture/Dislocation	0.363
HCC173	Traumatic Amputations and Complications	0.379
HCC176	Complications of Specified Implanted Device or Graft	0.668
HCC186	Major Organ Transplant or Replacement Status	0.203
HCC188	Artificial Openings for Feeding or Elimination	0.609
HCC189	Amputation Status, Lower Limb/Amputation Complications	0.804

Disease Group	Description Label	Relative Factor
Disease Interactions		
SEPSIS_CARD_RESP_FAIL	Sepsis*Cardiorespiratory Failure	0.634
CANCER_IMMUNE	Cancer*Immune Disorders	1.101
DIABETES_CHF	Diabetes*Congestive Heart Failure	0.237
CHF_COPD	Congestive Heart Failure*Chronic Obstructive Pulmonary Disease	0.255
CHF_RENAL	Congestive Heart Failure*Renal Disease	—
COPD_CARD_RESP_FAIL	Chronic Obstructive Pulmonary Disease*Cardiorespiratory Failure	0.420
NonAged (Age <65)/Disease Interactions		
NONAGED_HCC6	NonAged, Opportunistic Infections	0.564
NONAGED_HCC34	NonAged, Chronic Pancreatitis	0.757
NONAGED_HCC46	NonAged, Severe Hematological Disorders	0.818
NONAGED_HCC54	NonAged, Drug/Alcohol Psychosis	0.432
NONAGED_HCC55	NonAged, Drug/Alcohol Dependence	0.147
NONAGED_HCC110	NonAged, Cystic Fibrosis	2.397
NONAGED_HCC176	NonAged, Complications of Specified Implanted Device or Graft	—

NOTES:

1. The coefficients estimated for this model are the Functioning Graft add-on factors for being in a month after the 3 months accounted for in the Transplant segment of the ESRD system. Early months post-transplant incur higher Medicare spending than later months. The model differentiates the six months, months 4-9, from months further from the transplant period.

2. Originally disabled terms refer to people originally entitled to Medicare for reasons of disability other than ESRD.

3. The Denominator used to calculate the relative factors is $8,034.71.

In the "disease interactions," the variables are defined as follows:

Sepsis = HCC 2.
Cardiorespiratory Failure = HCCs 82-84.
Cancer = HCCs 8-12.
Immune Disorders = HCC 47.
Diabetes = HCCs 17, 18, 19.
Congestive Heart Failure = HCC 85.
Chronic Obstructive Pulmonary Disease = HCCs 110-111.
Renal Disease = HCCs 134-141.

SOURCE: RTI International analysis of 2006/2007 100% ESRD sample claims and enrollment data and 2006/2007 Medicare 5% sample.

Table 5. ESRD Model Functioning Graft Relative Factors for Institutionalized Population

Variable	Relative Factor
Functioning Graft Factors	
Aged 65+, with duration since transplant of 4-9 months	2.635
Aged <65, with duration since transplant of 4-9 months	2.582
Aged 65+, with duration since transplant of 10 months or more	1.268
Aged <65, with duration since transplant of 10 months or more	1.170
Female	
0-34 Years	0.783
35-44 Years	0.723
45-54 Years	0.700
55-59 Years	0.805
60-64 Years	0.773
65-69 Years	1.004
70-74 Years	0.947
75-79 Years	0.874
80-84 Years	0.792
85-89 Years	0.699
90-94 Years	0.594
95 Years or Over	0.465
Male	
0-34 Years	0.994
35-44 Years	0.658
45-54 Years	0.687
55-59 Years	0.814
60-64 Years	0.877
65-69 Years	1.148
70-74 Years	1.195
75-79 Years	1.168
80-84 Years	1.104
85-89 Years	1.046
90-94 Years	0.928
95 Years or Over	0.842
Medicaid and Originally Disabled Interactions with Age and Sex	
Medicaid	0.126
Originally Disabled_Age ≥65	0.026

Disease Group	Description Label	Relative Factor
HCC1	HIV/AIDS	1.374
HCC2	Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock	0.471
HCC6	Opportunistic Infections	0.541
HCC8	Metastatic Cancer and Acute Leukemia	0.928
HCC9	Lung and Other Severe Cancers	0.610
HCC10	Lymphoma and Other Cancers	0.363
HCC11	Colorectal, Bladder, and Other Cancers	0.255
HCC12	Breast, Prostate, and Other Cancers and Tumors	0.165
HCC17	Diabetes with Acute Complications	0.434
HCC18	Diabetes with Chronic Complications	0.434
HCC19	Diabetes without Complication	0.187
HCC21	Protein-Calorie Malnutrition	0.343
HCC22	Morbid Obesity	0.353
HCC23	Other Significant Endocrine and Metabolic Disorders	0.248
HCC27	End-Stage Liver Disease	0.637
HCC28	Cirrhosis of Liver	0.343
HCC29	Chronic Hepatitis	0.343
HCC33	Intestinal Obstruction/Perforation	0.302
HCC34	Chronic Pancreatitis	0.175
HCC35	Inflammatory Bowel Disease	0.250
HCC39	Bone/Joint/Muscle Infections/Necrosis	0.386
HCC40	Rheumatoid Arthritis and Inflammatory Connective Tissue Disease	0.222
HCC46	Severe Hematological Disorders	0.638
HCC47	Disorders of Immunity	0.436
HCC48	Coagulation Defects and Other Specified Hematological Disorders	0.197
HCC51	Dementia With Complications	

Disease Group	Description Label	Relative Factor
HCC52	Dementia Without Complication	—
HCC54	Drug/Alcohol Psychosis	0.051
HCC55	Drug/Alcohol Dependence	0.051
HCC57	Schizophrenia	0.274
HCC58	Major Depressive, Bipolar, and Paranoid Disorders	0.274
HCC70	Quadriplegia	0.497
HCC71	Paraplegia	0.497
HCC72	Spinal Cord Disorders/Injuries	0.191
HCC73	Amyotrophic Lateral Sclerosis and Other Motor Neuron Disease	0.294
HCC74	Cerebral Palsy	—
HCC75	Polyneuropathy	0.256
HCC76	Muscular Dystrophy	0.247
HCC77	Multiple Sclerosis	—
HCC78	Parkinson's and Huntington's Diseases	0.110
HCC79	Seizure Disorders and Convulsions	0.173
HCC80	Coma, Brain Compression/Anoxic Damage	0.103
HCC82	Respirator Dependence/Tracheostomy Status	1.567
HCC83	Respiratory Arrest	0.611
HCC84	Cardio-Respiratory Failure and Shock	0.346
HCC85	Congestive Heart Failure	0.226
HCC86	Acute Myocardial Infarction	0.394
HCC87	Unstable Angina and Other Acute Ischemic Heart Disease	0.394
HCC88	Angina Pectoris	0.366
HCC96	Specified Heart Arrhythmias	0.227
HCC99	Cerebral Hemorrhage	0.175
HCC100	Ischemic or Unspecified Stroke	0.175
HCC103	Hemiplegia/Hemiparesis	0.063
HCC104	Monoplegia, Other Paralytic Syndromes	0.063
HCC106	Atherosclerosis of the Extremities with Ulceration or Gangrene	0.773
HCC107	Vascular Disease with Complications	0.257
HCC108	Vascular Disease	0.146
HCC110	Cystic Fibrosis	0.323
HCC111	Chronic Obstructive Pulmonary Disease	0.323
HCC112	Fibrosis of Lung and Other Chronic Lung Disorders	0.252
HCC114	Aspiration and Specified Bacterial Pneumonias	0.239
HCC115	Pneumococcal Pneumonia, Empyema, Lung Abscess	0.194
HCC122	Proliferative Diabetic Retinopathy and Vitreous Hemorrhage	0.366
HCC124	Exudative Macular Degeneration	0.178
HCC134	Dialysis Status	—
HCC135	Acute Renal Failure	—
HCC136	Chronic Kidney Disease, Stage 5	—
HCC137	Chronic Kidney Disease, Severe (Stage 4)	—
HCC138	Chronic Kidney Disease, Moderate (Stage 3)	—
HCC139	Chronic Kidney Disease, Mild or Unspecified (Stages 1-2 or Unspecified)	—
HCC140	Unspecified Renal Failure	—
HCC141	Nephritis	—
HCC157	Pressure Ulcer of Skin with Necrosis Through to Muscle, Tendon, or Bone	0.284
HCC158	Pressure Ulcer of Skin with Full Thickness Skin Loss	0.284
HCC159	Pressure Ulcer of Skin with Partial Thickness Skin Loss	0.284
HCC160	Pressure Pre-Ulcer Skin Changes or Unspecified Stage	0.284
HCC161	Chronic Ulcer of Skin, Except Pressure	0.226
HCC162	Severe Skin Burn or Condition	—
HCC166	Severe Head Injury	0.103
HCC167	Major Head Injury	—
HCC169	Vertebral Fractures without Spinal Cord Injury	0.179
HCC170	Hip Fracture/Dislocation	—
HCC173	Traumatic Amputations and Complications	0.067
HCC176	Complications of Specified Implanted Device or Graft	0.668
HCC186	Major Organ Transplant or Replacement Status	0.203
HCC188	Artificial Openings for Feeding or Elimination	0.658
HCC189	Amputation Status, Lower Limb/Amputation Complications	0.384
Disease Interactions		
CHF_COPD	Congestive Heart Failure*Chronic Obstructive Pulmonary Disease	0.159
CRFAIL_COPD	Cardiorespiratory Failure*Chronic Obstructive Pulmonary Disease	0.524
SEPSIS_PRESSURE_ULCER	Sepsis*Pressure Ulcer	0.538
SEPSIS_ARTIF_OPENINGS	Sepsis*Artificial Openings for Feeding or Elimination	0.453

Disease Group	Description Label	Relative Factor
ARTIF_OPENINGS_PRESSURE_ULCER	Artificial Openings for Feeding or Elimination*Pressure Ulcer	0.361
DIABETES_CHF	Diabetes*Congestive Heart Failure	0.143
COPD_ASP_SPEC_BACT_PNEUM	Chronic Obstructive Pulmonary Disease*Aspiration and Specified Bacterial Pneumonias	0.249
ASP_SPEC_BACT_PNEUM_PRES_ULCER	Aspiration and Specified Bacterial Pneumonias*Pressure Ulcer	0.325
SEPSIS_ASP_SPEC_BACT_PNEUM	Sepsis*Aspiration and Specified Bacterial Pneumonias	0.387
SCHIZOPHRENIA_COPD	Schizophrenia*Chronic Obstructive Pulmonary Disease	0.187
SCHIZOPHRENIA_CHF	Schizophrenia*Congestive Heart Failure	0.220
SCHIZOPHRENIA_SEIZURES	Schizophrenia*Seizure Disorders and Convulsions	0.303
NonAged (Age <65)/Disease Interactions		
NONAGED_HCC85	NonAged, Congestive Heart Failure	0.320
NONAGED_PRESSURE_ULCER	NonAged, Pressure Ulcer	0.421
NONAGED_HCC161	NonAged, Chronic Ulcer of the Skin, Except Pressure Ulcer	0.337
NONAGED_HCC39	NonAged, Bone/Joint Muscle Infections/Necrosis	0.624
NONAGED_HCC77	NonAged, Multiple Sclerosis	0.344
NONAGED_HCC6	NonAged, Opportunistic Infections	0.914

NOTES:

1. The coefficients estimated for this model are the Functioning Graft add-on factors for being in a month after the 3 months accounted for in the Transplant segment of the ESRD system. Early months post-transplant incur higher Medicare spending than later months. The model differentiates the six months, months 4-9, from months further from the transplant period.

2. Originally disabled terms refer to people originally entitled to Medicare for reasons of disability other than ESRD.

3. The Denominator used to calculate the relative factors is $8,034.71.

In the "Disease interactions" and "NonAged interactions," the variables are defined as follows:

Sepsis = HCC 2.
Cardiorespiratory Failure = HCCs 82-84.
Diabetes = HCCs 17, 18, 19.
Congestive Heart Failure = HCC 85.
Chronic Obstructive Pulmonary Disease = HCCs 110-111.
Pressure Ulcer = HCCs 157-160.
Artificial Openings for Feeding or Elimination = HCC 188.
Aspiration and Specified Bacterial Pneumonias = HCC 114.
Schizophrenia = HCC 57.
Seizure Disorders and Convulsions = HCC 79.
Chronic Ulcer of Skin, except Pressure = HCC 161.
Bone/Joint/Muscle Infections/Necrosis = HCC 39.
Multiple Sclerosis = HCC 77.
Opportunistic Infections = HCC 6.

SOURCE: RTI International analysis of 2006/2007 100% ESRD sample claims and enrollment data and 2006/2007 Medicare 5% sample.

Table 6. ESRD Model Demographic Relative Factors for Functioning Graft New Enrollees Duration Since Transplant of 4-9 Months

	Non-Medicaid & Non-Originally Disabled	Medicaid & Non-Originally Disabled	Non-Medicaid & Originally Disabled	Medicaid & Originally Disabled
Female				
0-34 Years	3.033	3.362	–	–
35-44 Years	3.180	3.509	–	–
45-54 Years	3.388	3.717	–	–
55-59 Years	3.554	3.883	–	–
60-64 Years	3.659	3.988	–	–
65 Years	3.133	3.644	3.753	4.263
66 Years	3.174	3.646	3.821	4.292
67 Years	3.210	3.682	3.857	4.328
68 Years	3.229	3.701	3.876	4.347
69 Years	3.256	3.727	3.902	4.373
70-74 Years	3.368	3.862	3.955	4.449
75-79 Years	3.571	3.994	4.130	4.553
80-84 Years	3.745	4.169	4.304	4.728
85-89 Years	3.908	4.332	4.467	4.891
90-94 Years	4.000	4.423	4.559	4.982
95 Years or Over	3.875	4.298	4.434	4.858
Male				
0-34 Years	2.824	3.241	–	–
35-44 Years	3.030	3.446	–	–
45-54 Years	3.212	3.628	–	–
55-59 Years	3.403	3.819	–	–
60-64 Years	3.533	3.950	–	–
65 Years	3.174	3.726	3.738	4.289
66 Years	3.232	3.783	3.751	4.302
67 Years	3.262	3.813	3.781	4.332
68 Years	3.290	3.842	3.809	4.361
69 Years	3.311	3.863	3.830	4.382
70-74 Years	3.449	4.000	3.965	4.515
75-79 Years	3.685	4.195	4.124	4.635
80-84 Years	3.904	4.414	4.343	4.853
85-89 Years	4.074	4.584	4.513	5.023
90-94 Years	4.249	4.759	4.688	5.198
95 Years or Over	4.315	4.826	4.754	5.265

NOTES:
1. The table entries are derived from the Graft New Enrollee model. 2. Originally Disabled terms refer to people originally entitled to Medicare for reasons of disability other than ESRD. In this model, Originally Disabled is defined only for beneficiaries age 65 and greater.

3. The Denominator used to calculate the relative factors is $8,034.71.

SOURCE: RTI International analysis of 2006/2007 100% ESRD sample claims and enrollment data and 2006/2007 Medicare 5% sample.

Table 7. ESRD Model Demographic Relative Factors for Functioning Graft New Enrollees Duration Since Transplant of 10 Months or More

	Non-Medicaid & Non-Originally Disabled	Medicaid & Non-Originally Disabled	Non-Medicaid & Originally Disabled	Medicaid & Originally Disabled
Female				
0-34 Years	1.621	1.951	–	–
35-44 Years	1.768	2.098	–	–
45-54 Years	1.976	2.306	–	–
55-59 Years	2.142	2.472	–	–
60-64 Years	2.247	2.577	–	–
65 Years	1.766	2.277	2.386	2.896
66 Years	1.808	2.279	2.454	2.925
67 Years	1.844	2.315	2.490	2.961
68 Years	1.862	2.334	2.509	2.980
69 Years	1.889	2.360	2.535	3.006
70-74 Years	2.001	2.495	2.588	3.082
75-79 Years	2.204	2.627	2.763	3.186
80-84 Years	2.378	2.802	2.938	3.361
85-89 Years	2.541	2.965	3.101	3.524
90-94 Years	2.633	3.056	3.192	3.615
95 Years or Over	2.508	2.931	3.067	3.491
Male				
0-34 Years	1.412	1.829	–	–
35-44 Years	1.618	2.035	–	–
45-54 Years	1.800	2.217	–	–
55-59 Years	1.991	2.408	–	–
60-64 Years	2.122	2.538	–	–
65 Years	1.807	2.359	2.371	2.922
66 Years	1.865	2.416	2.384	2.935
67 Years	1.895	2.446	2.414	2.965
68 Years	1.924	2.475	2.442	2.994
69 Years	1.944	2.496	2.463	3.015
70-74 Years	2.082	2.633	2.598	3.149
75-79 Years	2.318	2.829	2.757	3.268
80-84 Years	2.537	3.047	2.976	3.486
85-89 Years	2.707	3.217	3.146	3.657
90-94 Years	2.882	3.392	3.321	3.831
95 Years or Over	2.948	3.459	3.387	3.898

NOTES:
1. The table entries are derived from the Graft New Enrollee model. 2. Originally Disabled terms refer to people originally entitled to Medicare for reasons of disability other than ESRD. In this model, Originally Disabled is defined only for beneficiaries age 65 and greater.

3. The Denominator used to calculate the relative factors is $8,034.71.

SOURCE: RTI International analysis of 2006/2007 100% ESRD sample claims and enrollment data and 2006/2007 Medicare 5% sample.

Table 8. List of Disease Hierarchies for the Revised ESRD Model

DISEASE HIERARCHIES

Hierarchical Condition Category (HCC)	If the Disease Group is Listed in this column…	…Then drop the HCC(s) listed in this column
	Hierarchical Condition Category (HCC) LABEL	
8	Metastatic Cancer and Acute Leukemia	9,10,11,12
9	Lung and Other Severe Cancers	10,11,12
10	Lymphoma and Other Cancers	11,12
11	Colorectal, Bladder, and Other Cancers	12
17	Diabetes with Acute Complications	18,19
18	Diabetes with Chronic Complications	19
27	End-Stage Liver Disease	28,29,80
28	Cirrhosis of Liver	29
46	Severe Hematological Disorders	48
51	Dementia With Complications	52
54	Drug/Alcohol Psychosis	55
57	Schizophrenia	58
70	Quadriplegia	71,72,103,104,169
71	Paraplegia	72,104,169
72	Spinal Cord Disorders/Injuries	169
82	Respirator Dependence/Tracheostomy Status	83,84
83	Respiratory Arrest	84
86	Acute Myocardial Infarction	87,88
87	Unstable Angina and Other Acute Ischemic Heart Disease	88
99	Cerebral Hemorrhage	100
103	Hemiplegia/Hemiparesis	104
106	Atherosclerosis of the Extremities with Ulceration or Gangrene	107,108,161,189
107	Vascular Disease with Complications	108
110	Cystic Fibrosis	111,112
111	Chronic Obstructive Pulmonary Disease	112
114	Aspiration and Specified Bacterial Pneumonias	115
134	Dialysis Status	135,136,137,138,139,140,141
135	Acute Renal Failure	136,137,138,139,140,141
136	Chronic Kidney Disease, Stage 5	137,138,139,140,141
137	Chronic Kidney Disease, Severe (Stage 4)	138,139,140,141
138	Chronic Kidney Disease, Moderate (Stage 3)	139,140,141
139	Chronic Kidney Disease, Mild or Unspecified (Stages 1-2 or Unspecified)	140,141
140	Unspecified Renal Failure	141
157	Pressure Ulcer of Skin with Necrosis Through to Muscle, Tendon, or Bone	158,159,160,161
158	Pressure Ulcer of Skin with Full Thickness Skin Loss	159,160,161
159	Pressure Ulcer of Skin with Partial Thickness Skin Loss	160,161
160	Pressure Pre-Ulcer Skin Changes or Unspecified Stage	161
166	Severe Head Injury	80,167

How Payments are Made with a Disease Hierarchy EXAMPLE: If a beneficiary triggers HCCs 140 (Unspecified Renal Failure) and 141 (Nephritis), then HCC 141 will be dropped. In other words, payment will always be associated with the HCC in column 1, if a HCC in column 3 also occurs during the same collection period. Therefore, the organization's payment will be based on HCC 140 rather than HCC 141.

Table 9. Community and Institutional Relative Factors for the Revised CMS-HCC Risk Adjustment Model

Variable	Disease Group	Community Factor	Institutional Factor
Female			
0-34 Years		0.198	0.783
35-44 Years		0.212	0.723
45-54 Years		0.274	0.700
55-59 Years		0.359	0.805
60-64 Years		0.416	0.773
65-69 Years		0.283	1.004
70-74 Years		0.346	0.947
75-79 Years		0.428	0.874
80-84 Years		0.517	0.792
85-89 Years		0.632	0.699
90-94 Years		0.755	0.594
95 Years or Over		0.775	0.465
Male			
0-34 Years		0.079	0.994
35-44 Years		0.119	0.658
45-54 Years		0.165	0.687
55-59 Years		0.292	0.814
60-64 Years		0.332	0.877
65-69 Years		0.309	1.148
70-74 Years		0.378	1.195
75-79 Years		0.464	1.168
80-84 Years		0.565	1.104
85-89 Years		0.647	1.046
90-94 Years		0.776	0.928
95 Years or Over		0.963	0.842
Medicaid and Originally Disabled Interactions with Age and Sex			
Medicaid_Female_Aged		0.213	
Medicaid_Female_Disabled		0.104	
Medicaid_Male_Aged		0.210	
Medicaid_Male_Disabled		0.113	
Originally Disabled_Female		0.244	
Originally Disabled_Male		0.171	
Medicaid and Originally Disabled			
Medicaid			0.126
Originally Disabled			0.026

Disease Coefficients	Description Label	Community Factor	Institutional Factor
HCC1	HIV/AIDS	0.492	1.374
HCC2	Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock	0.520	0.471
HCC6	Opportunistic Infections	0.557	0.541
HCC8	Metastatic Cancer and Acute Leukemia	2.425	0.928
HCC9	Lung and Other Severe Cancers	1.006	0.610
HCC10	Lymphoma and Other Cancers	0.695	0.363
HCC11	Colorectal, Bladder, and Other Cancers	0.330	0.255
HCC12	Breast, Prostate, and Other Cancers and Tumors	0.180	0.165
HCC17	Diabetes with Acute Complications	0.344	0.434
HCC18	Diabetes with Chronic Complications	0.344	0.434
HCC19	Diabetes without Complication	0.124	0.187
HCC21	Protein-Calorie Malnutrition	0.653	0.343
HCC22	Morbid Obesity	0.342	0.353
HCC23	Other Significant Endocrine and Metabolic Disorders	0.240	0.248
HCC27	End-Stage Liver Disease	1.003	0.637
HCC28	Cirrhosis of Liver	0.425	0.343
HCC29	Chronic Hepatitis	0.313	0.343
HCC33	Intestinal Obstruction/Perforation	0.337	0.302
HCC34	Chronic Pancreatitis	0.257	0.175
HCC35	Inflammatory Bowel Disease	0.279	0.250

Disease Coefficients	Description Label	Community Factor	Institutional Factor
HCC39	Bone/Joint/Muscle Infections/Necrosis	0.423	0.386
HCC40	Rheumatoid Arthritis and Inflammatory Connective Tissue Disease	0.376	0.222
HCC46	Severe Hematological Disorders	1.078	0.638
HCC47	Disorders of Immunity	0.306	0.436
HCC48	Coagulation Defects and Other Specified Hematological Disorders	0.258	0.197
HCC51	Dementia With Complications	0.616	—
HCC52	Dementia Without Complication	0.343	—
HCC54	Drug/Alcohol Psychosis	0.358	0.051
HCC55	Drug/Alcohol Dependence	0.358	0.051
HCC57	Schizophrenia	0.471	0.274
HCC58	Major Depressive, Bipolar, and Paranoid Disorders	0.318	0.274
HCC70	Quadriplegia	1.075	0.497
HCC71	Paraplegia	0.868	0.497
HCC72	Spinal Cord Disorders/Injuries	0.441	0.191
HCC73	Amyotrophic Lateral Sclerosis and Other Motor Neuron Disease	1.016	0.294
HCC74	Cerebral Palsy	0.036	—
HCC75	Polyneuropathy	0.281	0.256
HCC76	Muscular Dystrophy	0.460	0.247
HCC77	Multiple Sclerosis	0.482	—
HCC78	Parkinson's and Huntington's Diseases	0.555	0.110
HCC79	Seizure Disorders and Convulsions	0.252	0.173
HCC80	Coma, Brain Compression/Anoxic Damage	0.533	0.103
HCC82	Respirator Dependence/Tracheostomy Status	1.732	1.567
HCC83	Respiratory Arrest	0.769	0.611
HCC84	Cardio-Respiratory Failure and Shock	0.326	0.346
HCC85	Congestive Heart Failure	0.361	0.226
HCC86	Acute Myocardial Infarction	0.283	0.394
HCC87	Unstable Angina and Other Acute Ischemic Heart Disease	0.283	0.394
HCC88	Angina Pectoris	0.210	0.366
HCC96	Specified Heart Arrhythmias	0.276	0.227
HCC99	Cerebral Hemorrhage	0.371	0.175
HCC100	Ischemic or Unspecified Stroke	0.333	0.175
HCC103	Hemiplegia/Hemiparesis	0.481	0.063
HCC104	Monoplegia, Other Paralytic Syndromes	0.212	0.063
HCC106	Atherosclerosis of the Extremities with Ulceration or Gangrene	1.313	0.773
HCC107	Vascular Disease with Complications	0.417	0.257
HCC108	Vascular Disease	0.288	0.146
HCC110	Cystic Fibrosis	0.388	0.323
HCC111	Chronic Obstructive Pulmonary Disease	0.388	0.323
HCC112	Fibrosis of Lung and Other Chronic Lung Disorders	0.294	0.252
HCC114	Aspiration and Specified Bacterial Pneumonias	0.691	0.239
HCC115	Pneumococcal Pneumonia, Empyema, Lung Abscess	0.212	0.194
HCC122	Proliferative Diabetic Retinopathy and Vitreous Hemorrhage	0.223	0.366
HCC124	Exudative Macular Degeneration	0.248	0.178
HCC134	Dialysis Status	0.617	0.538
HCC135	Acute Renal Failure	0.617	0.538
HCC136	Chronic Kidney Disease, Stage 5	0.227	0.304
HCC137	Chronic Kidney Disease, Severe (Stage 4)	0.227	0.304
HCC138	Chronic Kidney Disease, Moderate (Stage 3)	0.227	0.304
HCC139	Chronic Kidney Disease, Mild or Unspecified (Stages 1-2 or Unspecified)	0.227	0.304
HCC140	Unspecified Renal Failure	0.227	0.304
HCC141	Nephritis	0.075	0.235
HCC157	Pressure Ulcer of Skin with Necrosis Through to Muscle, Tendon, or Bone	1.071	0.284
HCC158	Pressure Ulcer of Skin with Full Thickness Skin Loss	1.071	0.284

Disease Coefficients	Description Label	Community Factor	Institutional Factor
HCC159	Pressure Ulcer of Skin with Partial Thickness Skin Loss	1.071	0.284
HCC160	Pressure Pre-Ulcer Skin Changes or Unspecified Stage	1.071	0.284
HCC161	Chronic Ulcer of Skin, Except Pressure	0.473	0.226
HCC162	Severe Skin Burn or Condition	0.458	—
HCC166	Severe Head Injury	0.533	0.103
HCC167	Major Head Injury	0.141	—
HCC169	Vertebral Fractures without Spinal Cord Injury	0.441	0.179
HCC170	Hip Fracture/Dislocation	0.363	—
HCC173	Traumatic Amputations and Complications	0.379	0.067
HCC176	Complications of Specified Implanted Device or Graft	0.555	0.369
HCC186	Major Organ Transplant or Replacement Status	1.032	1.120
HCC188	Artificial Openings for Feeding or Elimination	0.609	0.658
HCC189	Amputation Status, Lower Limb/Amputation Complications	0.804	0.384
Disease Interactions			
SEPSIS CARD RESP FAIL	Sepsis*Cardiorespiratory Failure	0.634	
CANCER IMMUNE	Cancer*Immune Disorders	1.101	
DIABETES CHF	Diabetes*Congestive Heart Failure	0.237	0.143
CHF COPD	Congestive Heart Failure*Chronic Obstructive Pulmonary Disease	0.255	0.159
CHF RENAL	Congestive Heart Failure*Renal Disease	0.201	
COPD CARD RESP FAIL	Chronic Obstructive Pulmonary Disease*Cardiorespiratory Failure	0.420	
CRFAIL COPD	Cardiorespiratory Failure*Chronic Obstructive Pulmonary Disease		0.524
SEPSIS PRESSURE ULCER	Sepsis*Pressure Ulcer		0.538
SEPSIS ARTIF OPENINGS	Sepsis*Artificial Openings for Feeding or Elimination		0.453
ARTIF OPENINGS PRESSURE ULCER	Artificial Openings for Feeding or Elimination*Pressure Ulcer		0.361
COPD ASP SPEC BACT PNEUM	Chronic Obstructive Pulmonary Disease*Aspiration and Specified Bacterial Pneumonias		0.249
ASP SPEC BACT PNEUM PRES ULCER	Aspiration and Specified Bacterial Pneumonias*Pressure Ulcer		0.325
SEPSIS ASP SPEC BACT PNEUM	Sepsis*Aspiration and Specified Bacterial Pneumonias		0.387
SCHIZOPHRENIA COPD	Schizophrenia*Chronic Obstructive Pulmonary Disease		0.187
SCHIZOPHRENIA CHF	Schizophrenia*Congestive Heart Failure		0.220
SCHIZOPHRENIA SEIZURES	Schizophrenia*Seizure Disorders and Convulsions		0.303
Disabled/Disease Interactions			
DISABLED HCC6	Disabled, Opportunistic Infections	0.564	
DISABLED HCC34	Disabled, Chronic Pancreatitis	0.757	
DISABLED HCC46	Disabled, Severe Hematological Disorders	0.818	
DISABLED HCC54	Disabled, Drug/Alcohol Psychosis	0.432	
DISABLED HCC55	Disabled, Drug/Alcohol Dependence	0.147	
DISABLED HCC110	Disabled, Cystic Fibrosis	2.397	
DISABLED HCC176	Disabled, Complications of Specified Implanted Device or Graft	0.495	
DISABLED HCC85	Disabled, Congestive Heart Failure		0.320
DISABLED PRESSURE ULCER	Disabled, Pressure Ulcer		0.421
DISABLED HCC161	Disabled, Chronic Ulcer of the Skin, Except Pressure Ulcer		0.337
DISABLED HCC39	Disabled, Bone/Joint Muscle Infections/Necrosis		0.624
DISABLED HCC77	Disabled, Multiple Sclerosis		0.344
DISABLED HCC6	Disabled, Opportunistic Infections		0.914

NOTES

1. The relative risk scores in this table were calculated by dividing the parameter estimates by the Part C national average predicted expenditures (CMS Part C Denominator). The Part C Denominator value used is $8,034.71.

2. The relative factor for HCC 160 is based on pressure ulcer, any stage, for all anatomical sites codes. The relative factor for HCC 160 is also assigned to HCCs 157, 158, and 159 in the constrained regression because the ICD9 codes for the stages of pressure ulcers are not implemented until FY09.

In the "disease interactions," the variables are defined as follows:

Artificial Openings for Feeding or Elimination = HCC 188.
Aspiration and Specified Bacterial Pneumonias = HCC 114.
Bone/Joint/Muscle Infections/Necrosis = HCC 39.
Cancer = HCCs 8-12.
Cardiorespiratory Failure = HCCs 82-84.
Chronic Obstructive Pulmonary Disease = HCCs 110-111.
Chronic Ulcer of Skin, except Pressure = HCC 161.
Congestive Heart Failure = HCC 85.
Diabetes = HCCs 17, 18, 19.
Immune Disorders = HCC 47.
Multiple Sclerosis = HCC 77.
Opportunistic Infections = HCC 6.
Pressure Ulcer = HCCs 157-160.
Renal Disease = HCCs 134-141.
Schizophrenia = HCC 57.
Seizure Disorders and Convulsions = HCC 79.
Sepsis = HCC 2.

SOURCE: RTI International analysis of 2006/2007 Medicare 5% sample.
SOURCE: RTI International analysis of 2006/2007 Medicare 100% institutional sample.

Table 10. Revised CMS-HCC Model Relative Factors for Aged and Disabled New Enrollees

	Non-Medicaid & Non-Originally Disabled	Medicaid & Non-Originally Disabled	Non-Medicaid & Originally Disabled	Medicaid & Originally Disabled
Female				
0-34 Years	0.453	0.784	-	-
35-44 Years	0.601	0.932	-	-
45-54 Years	0.810	1.141	-	-
55-59 Years	0.977	1.308	-	-
60-64 Years	1.082	1.414	-	-
65 Years	0.501	1.014	1.124	1.637
66 Years	0.543	1.016	1.192	1.665
67 Years	0.579	1.052	1.228	1.702
68 Years	0.598	1.071	1.247	1.721
69 Years	0.624	1.098	1.274	1.747
70-74 Years	0.737	1.233	1.327	1.823
75-79 Years	0.941	1.366	1.503	1.928
80-84 Years	1.116	1.542	1.678	2.104
85-89 Years	1.280	1.706	1.842	2.268
90-94 Years	1.372	1.797	1.934	2.359
95 Years or Over	1.247	1.672	1.809	2.234
Male				
0-34 Years	0.243	0.662	-	-
35-44 Years	0.450	0.869	-	-
45-54 Years	0.633	1.052	-	-
55-59 Years	0.825	1.244	-	-
60-64 Years	0.956	1.375	-	-
65 Years	0.542	1.096	1.109	1.663
66 Years	0.601	1.155	1.122	1.676
67 Years	0.631	1.185	1.152	1.706
68 Years	0.659	1.213	1.181	1.735
69 Years	0.680	1.234	1.202	1.756
70-74 Years	0.818	1.372	1.337	1.890
75-79 Years	1.056	1.569	1.497	2.010
80-84 Years	1.275	1.788	1.717	2.230
85-89 Years	1.446	1.960	1.888	2.401
90-94 Years	1.622	2.135	2.063	2.577
95 Years or Over	1.689	2.202	2.130	2.644

NOTES:

1. For payment purposes, a new enrollee is a beneficiary who did not have 12 months of Part B eligibility in the data collection year. The CMS-HCC new enrollee model is not based on diagnosis, but includes factors for different age and gender combinations by Medicaid and the original reason for Medicare entitlement.
2. The relative risk scores in this table were calculated by dividing the parameter estimates by the Part C national average predicted expenditures (CMS Part C Denominator). The Part C Denominator value used is $8,034.71.

SOURCE: RTI International analysis of 2006/2007 Medicare 5% sample.

Table 11. List of Disease Hierarchies for the Revised CMS-HCC Model

DISEASE HIERARCHIES

Hierarchical Condition Category (HCC)	If the Disease Group is Listed in this column…	…Then drop the HCC(s) listed in this column
	Hierarchical Condition Category (HCC) LABEL	
8	Metastatic Cancer and Acute Leukemia	9,10,11,12
9	Lung and Other Severe Cancers	10,11,12
10	Lymphoma and Other Cancers	11,12
11	Colorectal, Bladder, and Other Cancers	12
17	Diabetes with Acute Complications	18,19
18	Diabetes with Chronic Complications	19
27	End-Stage Liver Disease	28,29,80
28	Cirrhosis of Liver	29
46	Severe Hematological Disorders	48
51	Dementia With Complications	52
54	Drug/Alcohol Psychosis	55
57	Schizophrenia	58
70	Quadriplegia	71,72,103,104,169
71	Paraplegia	72,104,169
72	Spinal Cord Disorders/Injuries	169
82	Respirator Dependence/Tracheostomy Status	83,84
83	Respiratory Arrest	84
86	Acute Myocardial Infarction	87,88
87	Unstable Angina and Other Acute Ischemic Heart Disease	88
99	Cerebral Hemorrhage	100
103	Hemiplegia/Hemiparesis	104
106	Atherosclerosis of the Extremities with Ulceration or Gangrene	107,108,161,189
107	Vascular Disease with Complications	108
110	Cystic Fibrosis	111,112
111	Chronic Obstructive Pulmonary Disease	112
114	Aspiration and Specified Bacterial Pneumonias	115
134	Dialysis Status	135,136,137,138,139,140,141
135	Acute Renal Failure	136,137,138,139,140,141
136	Chronic Kidney Disease, Stage 5	137,138,139,140,141
137	Chronic Kidney Disease, Severe (Stage 4)	138,139,140,141
138	Chronic Kidney Disease, Moderate (Stage 3)	139,140,141
139	Chronic Kidney Disease, Mild or Unspecified (Stages 1-2 or Unspecified)	140,141
140	Unspecified Renal Failure	141
157	Pressure Ulcer of Skin with Necrosis Through to Muscle, Tendon, or Bone	158,159,160,161
158	Pressure Ulcer of Skin with Full Thickness Skin Loss	159,160,161
159	Pressure Ulcer of Skin with Partial Thickness Skin Loss	160,161
160	Pressure Pre-Ulcer Skin Changes or Unspecified Stage	161
166	Severe Head Injury	80,167

How Payments are Made with a Disease Hierarchy EXAMPLE: If a beneficiary triggers HCCs 140 (Unspecified Renal Failure) and 141 (Nephritis), then HCC 141 will be dropped. In other words, payment will always be associated with the HCC in column 1, if a HCC in column 3 also occurs during the same collection period. Therefore, the organization's payment will be based on HCC 140 rather than HCC 141.

Table 12. Comparison of Current and Revised CMS-HCC Risk Adjustment Model HCCs

Current Model			Revised Model	
HCC	**Description**	**Category Short Name**	**HCC**	**Description**
HCC1	HIV/AIDS	Infection	HCC1	HIV/AIDS
HCC2	Septicemia/Shock		*HCC2*	*Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock*
HCC5	Opportunistic Infections		HCC6	Opportunistic Infections
HCC7	Metastatic Cancer and Acute Leukemia	Neoplasm	HCC8	Metastatic Cancer and Acute Leukemia
HCC8	Lung, Upper Digestive Tract, and Other Severe Cancers		HCC9	Lung and Other Severe Cancers
HCC9	Lymphatic, Head and Neck, Brain, and Other Major Cancers		HCC10	Lymphoma and Other Cancers
HCC10	Breast, Prostate, Colorectal and Other Cancers and Tumors		**HCC11**	**Colorectal, Bladder, and Other Cancers**
			HCC12	Breast, Prostate, and Other Cancers and Tumors
HCC15	Diabetes with Renal or Peripheral Circulatory Manifestation	Diabetes	HCC17	Diabetes with Acute Complications
HCC16	Diabetes with Neurologic or Other Specified Manifestation		*HCC18*	*Diabetes with Chronic Complications*
HCC17	Diabetes with Acute Complications		HCC19	Diabetes without Complication
HCC18	Diabetes with Ophthalmologic or Unspecified Manifestation			
HCC19	Diabetes without Complication			
HCC21	Protein-Calorie Malnutrition	Metabolic	HCC21	Protein-Calorie Malnutrition
			HCC22	**Morbid Obesity**
			HCC23	**Other Significant Endocrine and Metabolic Disorders**
HCC25	End-Stage Liver Disease	Liver	HCC27	End-Stage Liver Disease
HCC26	Cirrhosis of Liver		HCC28	Cirrhosis of Liver
HCC27	Chronic Hepatitis		HCC29	Chronic Hepatitis
HCC31	Intestinal Obstruction/Perforation	Gastrointestinal	HCC33	Intestinal Obstruction/Perforation
HCC32	Pancreatic Disease		*HCC34*	*Chronic Pancreatitis*
HCC33	Inflammatory Bowel Disease		HCC35	Inflammatory Bowel Disease
HCC37	Bone/Joint/Muscle Infections/Necrosis	Musculoskeletal	HCC39	Bone/Joint/Muscle Infections/Necrosis
HCC38	Rheumatoid Arthritis and Inflammatory Connective Tissue Disease		HCC40	Rheumatoid Arthritis and Inflammatory Connective Tissue Disease
HCC44	Severe Hematological Disorders	Blood	HCC46	Severe Hematological Disorders
HCC45	Disorders of Immunity		HCC47	Disorders of Immunity
			HCC48	**Coagulation Defects and Other Specified Hematological Disorders**
		Cognitive	**HCC51**	**Dementia With Complications**
			HCC52	**Dementia Without Complication**
HCC51	Drug/Alcohol Psychosis	Substance Abuse	HCC54	Drug/Alcohol Psychosis
HCC52	Drug/Alcohol Dependence		HCC55	Drug/Alcohol Dependence

Current Model			Revised Model	
HCC	**Description**	**Category Short Name**	**HCC**	**Description**
HCC54	Schizophrenia	Psychiatric	HCC57	Schizophrenia
HCC55	Major Depressive, Bipolar, and Paranoid Disorders		HCC58	Major Depressive, Bipolar, and Paranoid Disorders
HCC67	Quadriplegia, Other Extensive Paralysis	Spinal	*HCC70*	*Quadriplegia*
HCC68	Paraplegia		HCC71	Paraplegia
HCC69	Spinal Cord Disorders/Injuries		HCC72	Spinal Cord Disorders/Injuries
HCC70	Muscular Dystrophy	Neurological	**HCC73**	**Amyotrophic Lateral Sclerosis and Other Motor Neuron Disease**
HCC71	Polyneuropathy		**HCC74**	**Cerebral Palsy**
HCC72	Multiple Sclerosis		HCC75	Polyneuropathy
HCC73	Parkinson's and Huntington's Diseases		HCC76	Muscular Dystrophy
HCC74	Seizure Disorders and Convulsions		HCC77	Multiple Sclerosis
HCC75	Coma, Brain Compression/Anoxic Damage		HCC78	Parkinson's and Huntington's Diseases
			HCC79	Seizure Disorders and Convulsions
			HCC80	Coma, Brain Compression/Anoxic Damage
HCC77	Respirator Dependence/Tracheostomy Status	Arrest	HCC82	Respirator Dependence/Tracheostomy Status
HCC78	Respiratory Arrest		HCC83	Respiratory Arrest
HCC79	Cardio-Respiratory Failure and Shock		HCC84	Cardio-Respiratory Failure and Shock
HCC80	Congestive Heart Failure	Heart	HCC85	Congestive Heart Failure
HCC81	Acute Myocardial Infarction		HCC86	Acute Myocardial Infarction
HCC82	Unstable Angina and Other Acute Ischemic Heart Disease		HCC87	Unstable Angina and Other Acute Ischemic Heart Disease
HCC83	Angina Pectoris/Old Myocardial Infraction		*HCC88*	*Angina Pectoris*
HCC92	Specified Heart Arrhythmias		HCC96	Specified Heart Arrhythmias
HCC95	Cerebral Hemorrhage	Cerebrovascular Disease	HCC99	Cerebral Hemorrhage
HCC96	Ischemic or Unspecified Stroke		HCC100	Ischemic or Unspecified Stroke
HCC100	Hemiplegia/Hemiparesis		HCC103	Hemiplegia/Hemiparesis
HCC101	Cerebral Palsy and Other Paralytic Syndromes		*HCC104*	*Monoplegia, Other Paralytic Syndromes*
HCC104	Vascular Disease with Complications	Vascular	**HCC106**	**Atherosclerosis of the Extremities with Ulceration or Gangrene**
HCC105	Vascular Disease		HCC107	Vascular Disease with Complications
			HCC108	Vascular Disease
HCC107	Cystic Fibrosis	Lung	HCC110	Cystic Fibrosis
HCC108	Chronic Obstructive Pulmonary Disease		HCC111	Chronic Obstructive Pulmonary Disease
HCC111	Aspiration and Specified Bacterial Pneumonias		**HCC112**	**Fibrosis of Lung and Other Chronic Lung Disorders**
HCC112	Pneumococcal Pneumonia, Empyema, Lung Abscess		HCC114	Aspiration and Specified Bacterial Pneumonias
			HCC115	Pneumococcal Pneumonia, Empyema, Lung Abscess
HCC119	Proliferative Diabetic Retinopathy and Vitreous Hemorrhage	Eye	HCC122	Proliferative Diabetic Retinopathy and Vitreous Hemorrhage
			HCC124	**Exudative Macular Degeneration**
HCC130	Dialysis Status	Kidney	HCC134	Dialysis Status

Current Model			Revised Model	
HCC	**Description**	**Category Short Name**	**HCC**	**Description**
HCC131	Renal Failure		*HCC135*	*Acute Renal Failure*
HCC132	Nephritis		*HCC136*	*Chronic Kidney Disease, Stage 5*
			HCC137	*Chronic Kidney Disease, Severe (Stage 4)*
			HCC138	*Chronic Kidney Disease, Moderate (Stage 3)*
			HCC139	*Chronic Kidney Disease, Mild or Unspecified (Stages 1-2 or Unspecified)*
			HCC140	*Unspecified Renal Failure*
			HCC141	Nephritis
HCC148	Decubitus Ulcer of Skin	Skin	**HCC157**	**Pressure Ulcer of Skin with Necrosis Through to Muscle, Tendon, or Bone**
HCC149	Chronic Ulcer of Skin, Except Decubitus		**HCC158**	**Pressure Ulcer of Skin with Full Thickness Skin Loss**
HCC150	Extensive Third-Degree Burns		**HCC159**	**Pressure Ulcer of Skin with Partial Thickness Skin Loss**
			HCC160	Pressure Pre-Ulcer Skin Changes or Unspecified Stage
			HCC161	Chronic Ulcer of Skin, Except Pressure
			HCC162	*Severe Skin Burn or Condition*
HCC154	Severe Head Injury	Injury	HCC166	Severe Head Injury
HCC155	Major Head Injury		HCC167	Major Head Injury
HCC157	Vertebral Fractures w/o Spinal Cord Injury		HCC169	Vertebral Fractures without Spinal Cord Injury
HCC158	Hip Fracture/Dislocation		HCC170	Hip Fracture/Dislocation
HCC161	Traumatic Amputation		*HCC173*	*Traumatic Amputations and Complications*
HCC164	Major Complications of Medical Care and Trauma	Complications	*HCC176*	*Complications of Specified Implanted Device or Graft*
HCC174	Major Organ Transplant Status	Transplant	HCC186	Major Organ Transplant or Replacement Status
HCC176	Artificial Openings for Feeding or Elimination	Openings	HCC188	Artificial Openings for Feeding or Elimination
HCC177	Amputation Status, Lower Limb/Amputation Complications	Amputation	HCC189	Amputation Status, Lower Limb/Amputation Complications
		Disabled/Disease Interactions		
D-HCC5	Disabled_Opportunistic Infections		D_HCC6	Disabled, Opportunistic Infections
D-HCC44	Disabled_Severe Hematological Disorders		**D_HCC34**	**Disabled, Chronic Pancreatitis**
D-HCC51	Disabled_Drug/Alcohol Psychosis		D_HCC46	Disabled, Severe Hematological Disorders
D-HCC52	Disabled_Drug/Alcohol Dependence		D_HCC54	Disabled, Drug/Alcohol Psychosis
D-HCC107	Disabled_Cystic Fibrosis		D_HCC55	Disabled, Drug/Alcohol Dependence
			D_HCC110	Disabled, Cystic Fibrosis
			D_HCC176	**Disabled, Complications of Specified Implanted Device or Graft**
		DiseaseInteractions		
INT1	DM_CHF		**SEPSIS CARD RESP FAIL**	**Sepsis*Cardiorespiratory Failure**
INT2	DM_CVD		**CANCER IMMUNE**	**Cancer*Immune Disorders**
INT3	CHF COPD		DIABETES CHF	Diabetes*Congestive Heart Failure

Current Model			Revised Model	
HCC	**Description**	**Category Short Name**	**HCC**	**Description**
INT4	COPD CVD CAD		CHF COPD	Congestive Heart Failure*Chronic Obstructive Pulmonary Disease
INT5	RF CHF		CHF RENAL	Congestive Heart Failure*Renal Disease
INT6	RF CHF DM		**COPD CARD RESP FAIL**	**Chronic Obstructive Pulmonary Disease*Cardiorespiratory Failure**

Current Model NOTES:
Beneficiaries with three-way interaction RF_CHF_DM are excluded from the two-way interactions DM_CHF and RF_CHF.
DM is diabetes mellitus (HCCs 15-19).
CHF is congestive heart failure (HCC 80).
COPD is chronic obstructive pulmonary disease (HCC 108).
CVD is cerebrovascular disease (HCCs 95-96, 100-101).
CAD is coronary artery disease (HCCs 81-83).
RF is renal failure (HCC 131).

Revised Model NOTES:
New HCCs, demographic factors, or interactions (compared to the current model HCCs) are bolded.
Substantially revised HCCs, demographic factors, or interactions (compared to the current model HCCs) are in italics.
In the "disease interactions", the variables are defined as follows:
Sepsis = HCC 2.
Cardiorespiratory Failure = HCCs 82-84.
Cancer = HCCs 8-12.
Immune Disorders = HCC 47.
Diabetes = HCCs 17, 18, 19.
Congestive Heart Failure = HCC 85.
Chronic Obstructive Pulmonary Disease = HCCs 110-111.
Renal Disease = HCCs 134-141.

Table 13. PACE and FIDE-SNP Frailty Factors

ADL	FIDE-SNP Factors (Non-Medicaid)	PACE Recalibrated Factors (Non-Medicaid)	FIDE-SNP Factors (Medicaid)	PACE Recalibrated Factors (Medicaid)
0	-0.093	-0.079	-0.180	-0.201
1-2	0.112	0.118	0.035	0.000
3-4	0.201	0.187	0.155	0.105
5-6	0.381	0.335	0.200	0.121

Table 14. RxHCC Model Relative Factors for Continuing Enrollees

		Continuing Enrollee (CE) RxHCC Model Segments				
Variable	**Disease Group**	Community, Non-Low Income, Age>=65	Community, Non-Low Income, Age<65	Community, Low Income, Age>=65	Community, Low Income, Age<65	Institutional
Female						
0-34 Years		-	0.260	-	0.397	1.525
35-44 Years		-	0.471	-	0.587	1.546
45-54 Years		-	0.579	-	0.659	1.461
55-59 Years		-	0.568	-	0.630	1.384
60-64 Years		-	0.570	-	0.606	1.331
65 Years		0.410	-	0.440	-	1.422
66 Years		0.410	-	0.440	-	1.422
67 Years		0.410	-	0.440	-	1.422
68 Years		0.410	-	0.440	-	1.422
69 Years		0.410	-	0.440	-	1.422
70-74 Years		0.406	-	0.430	-	1.343
75-79 Years		0.413	-	0.428	-	1.287
80-84 Years		0.423	-	0.423	-	1.234
85-89 Years		0.432	-	0.414	-	1.181
90-94 Years		0.430	-	0.391	-	1.110
95 Years or Over		0.405	-	0.322	-	0.965
Male						
0-34 Years		-	0.240	-	0.426	1.552
35-44 Years		-	0.395	-	0.552	1.512
45-54 Years		-	0.522	-	0.592	1.443
55-59 Years		-	0.517	-	0.560	1.350
60-64 Years		-	0.531	-	0.531	1.299
65 Years		0.416	-	0.360	-	1.360
66 Years		0.416	-	0.360	-	1.360
67 Years		0.416	-	0.360	-	1.360
68 Years		0.416	-	0.360	-	1.360
69 Years		0.416	-	0.360	-	1.360
70-74 Years		0.407	-	0.352	-	1.316
75-79 Years		0.398	-	0.347	-	1.274
80-84 Years		0.392	-	0.336	-	1.246
85-89 Years		0.394	-	0.336	-	1.225
90-94 Years		0.419	-	0.357	-	1.182
95 Years or Over		0.423	-	0.350	-	1.079
Originally Disabled Interactions with Sex						
Originally Disabled		-	-	-	-	0.027
Originally Disabled_Female		0.070	-	0.100	-	-
Originally Disabled_Female_Age 65		-	-	-	-	-

Variable	Disease Group	Community, Non-Low Income, Age>=65	Community, Non-Low Income, Age<65	Community, Low Income, Age>=65	Community, Low Income, Age<65	Institutional
Originally Disabled_Female_Age 66-69		-	-	-	-	-
Originally Disabled_Female_Age 70-74		-	-	-	-	-
Originally Disabled_Female_Age 75+		-	-	-	-	-
Originally Disabled_Male		0.021	-	0.089	-	-
Originally Disabled_Male_Age 65		-	-	-	-	-
Originally Disabled_Male_Age 66-69		-	-	-	-	-
Originally Disabled_Male_Age 70-74		-	-	-	-	-
Originally Disabled_Male_Age 75+		-	-	-	-	-

Disease Coefficients	Description Label	Community, Non-Low Income, Age>=65	Community, Non-Low Income, Age<65	Community, Low Income, Age>=65	Community, Low Income, Age<65	Institutional
RXHCC1	HIV/AIDS	1.599	2.337	2.082	2.496	1.058
RXHCC5	Opportunistic Infections	0.118	0.130	0.082	0.176	0.083
RXHCC8	Chronic Myeloid Leukemia	1.651	2.073	2.059	2.329	1.037
RXHCC9	Multiple Myeloma and Other Neoplastic Disorders	1.095	1.278	0.997	1.192	0.546
RXHCC10	Breast, Lung, and Other Cancers and Tumors	0.206	0.209	0.233	0.249	0.101
RXHCC11	Prostate and Other Cancers and Tumors	0.039	0.052	0.114	0.062	0.082
RXHCC14	Diabetes with Complications	0.251	0.188	0.270	0.266	0.154
RXHCC15	Diabetes without Complication	0.175	0.152	0.209	0.218	0.110
RXHCC18	Diabetes Insipidus and Other Endocrine and Metabolic Disorders	0.247	0.577	0.183	0.612	0.124
RXHCC19	Pituitary, Adrenal Gland, and Other Endocrine and Metabolic Disorders	0.045	0.065	0.029	0.059	0.061
RXHCC20	Thyroid Disorders	0.038	0.095	0.045	0.102	0.037
RXHCC21	Morbid Obesity	0.042	0.016	0.037	0.048	0.067
RXHCC23	Disorders of Lipoid Metabolism	0.119	0.131	0.139	0.178	0.063
RXHCC25	Chronic Viral Hepatitis	0.077	0.041	0.216	0.109	—
RXHCC30	Chronic Pancreatitis	0.091	0.174	0.045	0.074	0.021
RXHCC31	Pancreatic Disorders and Intestinal Malabsorption, Except Pancreatitis	0.034	0.075	0.034	0.074	0.021
RXHCC32	Inflammatory Bowel Disease	0.268	0.257	0.186	0.309	0.075
RXHCC33	Esophageal Reflux and Other Disorders of Esophagus	0.136	0.114	0.158	0.172	0.074
RXHCC38	Aseptic Necrosis of Bone	0.056	0.166	0.043	0.229	0.068
RXHCC40	Psoriatic Arthropathy	0.321	0.449	0.560	0.992	0.374
RXHCC41	Rheumatoid Arthritis and Other Inflammatory Polyarthropathy	0.172	0.264	0.193	0.383	0.095
RXHCC42	Systemic Lupus Erythematosus, Other Connective Tissue Disorders, and Inflammatory Spondylopathies	0.125	0.249	0.158	0.261	0.086
RXHCC45	Osteoporosis, Vertebral and Pathological Fractures	0.093	0.162	0.123	0.178	0.028
RXHCC47	Sickle Cell Anemia	0.140	0.089	0.131	0.425	0.035
RXHCC48	Myelodysplastic Syndromes, Except High-Grade	0.209	0.371	0.293	0.226	0.420
RXHCC49	Immune Disorders	0.151	0.255	0.128	0.271	0.142
RXHCC50	Aplastic Anemia and Other Significant Blood Disorders	0.045	0.089	0.058	0.072	0.035
RXHCC54	Alzheimer`s Disease	0.471	0.264	0.304	0.181	0.015
RXHCC55	Dementia, Except Alzheimer`s Disease	0.253	0.098	0.141	0.048	—
RXHCC58	Schizophrenia	0.433	0.574	0.633	0.940	0.334
RXHCC59	Bipolar Disorders	0.364	0.442	0.419	0.664	0.287
RXHCC60	Major Depression	0.274	0.350	0.302	0.430	0.202
RXHCC61	Specified Anxiety, Personality, and Behavior Disorders	0.163	0.224	0.215	0.430	0.172
RXHCC62	Depression	0.139	0.177	0.143	0.226	0.115
RXHCC63	Anxiety Disorders	0.057	0.127	0.086	0.179	0.115
RXHCC65	Autism	0.180	0.325	0.486	0.648	0.172

Disease Coefficients	Description Label	Community, Non-Low Income, Age>=65	Community, Non-Low Income, Age<65	Community, Low Income, Age>=65	Community, Low Income, Age<65	Institutional
RXHCC66	Profound or Severe Mental Retardation/Developmental Disability	0.028	0.325	0.486	0.393	—
RXHCC67	Moderate Mental Retardation/Developmental Disability	0.028	0.173	0.396	0.288	—
RXHCC68	Mild or Unspecified Mental Retardation/Developmental Disability	0.011	0.051	0.234	0.141	—
RXHCC71	Myasthenia Gravis, Amyotrophic Lateral Sclerosis and Other Motor Neuron Disease	0.185	0.306	0.156	0.308	0.059
RXHCC72	Spinal Cord Disorders	0.064	0.170	0.071	0.094	—
RXHCC74	Polyneuropathy	0.089	0.215	0.081	0.179	0.059
RXHCC75	Multiple Sclerosis	0.448	0.796	0.485	1.313	0.121
RXHCC76	Parkinson`s Disease	0.420	0.501	0.290	0.286	0.154
RXHCC78	Intractable Epilepsy	0.364	0.640	0.347	0.897	0.123
RXHCC79	Epilepsy and Other Seizure Disorders, Except Intractable Epilepsy	0.221	0.269	0.166	0.363	0.077
RXHCC80	Convulsions	0.110	0.129	0.097	0.225	0.039
RXHCC81	Migraine Headaches	0.115	0.229	0.109	0.197	0.144
RXHCC83	Trigeminal and Postherpetic Neuralgia	0.095	0.179	0.105	0.151	0.081
RXHCC86	Pulmonary Hypertension and Other Pulmonary Heart Disease	0.253	0.395	0.286	0.338	0.122
RXHCC87	Congestive Heart Failure	0.177	0.091	0.242	0.106	0.098
RXHCC88	Hypertension	0.168	0.077	0.215	0.094	0.063
RXHCC89	Coronary Artery Disease	0.146	0.083	0.130	0.045	0.017
RXHCC93	Atrial Arrhythmias	0.062	0.046	0.022	—	0.013
RXHCC97	Cerebrovascular Disease, Except Hemorrhage or Aneurysm	0.065	—	0.049	—	—
RXHCC98	Spastic Hemiplegia	0.146	0.241	0.055	0.146	0.013
RXHCC100	Venous Thromboembolism	0.014	0.048	—	0.083	—
RXHCC101	Peripheral Vascular Disease	0.057	0.030	0.091	0.063	—
RXHCC103	Cystic Fibrosis	0.199	0.692	0.219	1.320	0.114
RXHCC104	Chronic Obstructive Pulmonary Disease and Asthma	0.199	0.125	0.217	0.200	0.114
RXHCC105	Pulmonary Fibrosis and Other Chronic Lung Disorders	0.113	0.125	0.096	0.199	0.038
RXHCC106	Gram-Negative/Staphylococcus Pneumonia and Other Lung Infections	—	0.079	—	0.042	0.027
RXHCC111	Diabetic Retinopathy	0.094	0.082	0.078	0.038	0.034
RXHCC113	Open-Angle Glaucoma	0.142	0.101	0.152	0.122	0.100
RXHCC120	Kidney Transplant Status	0.275	0.165	0.379	0.399	0.329
RXHCC121	Dialysis Status	0.220	0.295	0.278	0.526	0.211
RXHCC122	Chronic Kidney Disease Stage 5	0.118	0.138	0.128	0.164	0.108
RXHCC123	Chronic Kidney Disease Stage 4	0.118	0.138	0.128	0.164	0.108
RXHCC124	Chronic Kidney Disease Stage 3	0.100	0.138	0.113	0.164	0.080
RXHCC125	Chronic Kidney Disease Stage 1, 2, or Unspecified	0.040	0.059	0.035	0.070	0.041
RXHCC126	Nephritis	0.040	0.034	0.035	0.068	0.013
RXHCC142	Chronic Ulcer of Skin, Except Pressure	0.042	0.060	0.027	0.060	—
RXHCC145	Pemphigus	0.111	0.146	0.120	0.254	—
RXHCC147	Psoriasis, Except with Arthropathy	0.106	0.186	0.202	0.284	0.124
RXHCC156	Narcolepsy and Cataplexy	0.274	0.344	0.161	0.432	0.102
RXHCC166	Lung Transplant Status	0.948	0.912	0.949	1.093	0.696
RXHCC167	Major Organ Transplant Status, Except Lung, Kidney, and Pancreas	0.415	0.378	0.409	0.471	0.329
RXHCC168	Pancreas Transplant Status	0.275	0.165	0.379	0.345	0.329
Non-Aged Disease Interactions						
NonAged_RXHCC1	HIV/AIDS	-	-	-	-	1.074
NonAged_RXHCC58	Schizophrenia	-	-	-	-	0.382
NonAged_RXHCC59	Bipolar Disorders	-	-	-	-	0.238
NonAged_RXHCC60	Major Depression	-	-	-	-	0.112
NonAged_RXHCC61	Specified Anxiety, Personality, and Behavior Disorders	-	-	-	-	0.112
NonAged_RXHCC62	Depression	-	-	-	-	0.056
NonAged_RXHCC63	Anxiety Disorders	-	-	-	-	0.032

Disease Coefficients	Description Label	Community, Non-Low Income, Age>=65	Community, Non-Low Income, Age<65	Community, Low Income, Age>=65	Community, Low Income, Age<65	Institutional
NonAged_RXHCC65	Autism	-	-	-	-	0.112
NonAged_RXHCC75	Multiple Sclerosis	-	-	-	-	0.467
NonAged_RXHCC78	Intractable Epilepsy	-	-	-	-	0.199
NonAged_RXHCC79	Epilepsy and Other Seizure Disorders, Except Intractable Epilepsy	-	-	-	-	0.040
NonAged_RXHCC80	Convulsions	-	-	-	-	0.034

Note:
The relative risk scores in this table were calculated by dividing the parameter estimates by the Part D national average predicted expenditures (CMS Part D Denominator). The Part D Denominator value used was $1,107.82. This Part D Denominator is based on the combined PDP and MA-PD populations, and it includes adjustments for new model diagnoses not yet submitted by the MA-PD population.

Source: RTI Analysis of 100% 2008 PDE, 2007 NCH, 2008 HPMS, 2008 CME, and 2007-2008 Denominator.

Table 15. RxHCC Model Relative Factors for New Enrollees, Non-Low Income

Variable	Baseline – Not Concurrently ESRD, Not Originally Disabled	Concurrently ESRD, Not Originally Disabled	Originally Disabled, Not Concurrently ESRD	Originally Disabled, Concurrently ESRD
Female				
0-34 Years	0.476	0.908	-	-
35-44 Years	0.793	1.225	-	-
45-54 Years	1.061	1.493	-	-
55-59 Years	1.124	1.556	-	-
60-64 Years	1.170	1.601	-	-
65 Years	0.755	1.187	1.151	1.583
66 Years	0.751	1.183	0.899	1.330
67 Years	0.751	1.183	0.899	1.330
68 Years	0.751	1.183	0.899	1.330
69 Years	0.751	1.183	0.899	1.330
70-74 Years	0.737	1.168	0.737	1.168
75-79 Years	0.674	1.106	0.674	1.106
80-84 Years	0.646	1.078	0.646	1.078
85-89 Years	0.566	0.997	0.566	0.997
90-94 Years	0.566	0.997	0.566	0.997
95 Years or Over	0.566	0.997	0.566	0.997
Male				
0-34 Years	0.322	0.754	-	-
35-44 Years	0.608	1.040	-	-
45-54 Years	0.874	1.306	-	-
55-59 Years	0.926	1.358	-	-
60-64 Years	1.013	1.445	-	-
65 Years	0.771	1.203	1.020	1.451
66 Years	0.757	1.188	0.757	1.188
67 Years	0.757	1.188	0.757	1.188
68 Years	0.757	1.188	0.757	1.188
69 Years	0.757	1.188	0.757	1.188
70-74 Years	0.719	1.151	0.719	1.151
75-79 Years	0.638	1.070	0.638	1.070
80-84 Years	0.540	0.972	0.540	0.972
85-89 Years	0.462	0.894	0.462	0.894
90-94 Years	0.462	0.894	0.462	0.894
95 Years or Over	0.462	0.894	0.462	0.894

NOTES:

1. The Part D Denominator used to calculate relative factors is $1,107.82. This Part D Denominator is based on the combined PDP and MA-PD populations. MA-PD risk scores were adjusted to account for new model diagnoses not yet submitted for the MA-PD population.

2. Originally Disabled is defined as originally entitled to Medicare by disability only (OREC = 1).

3. Concurrently ESRD is defined as at least one month of ESRD status—dialysis (D), transplant (1, 2, 5, 6 or N), or post-graft (G, R or Y) in the payment year (2008 in the model calibration).

Source: RTI Analysis of 100% 2008 PDE SAF, 2007-2008 HPMS, 2008 CME, and 2007-2008 Denominator.

Table 16. RxHCC Model Relative Factors for New Enrollees, Low Income

Variable	Baseline – Not Concurrently ESRD and Not Originally Disabled	Concurrently ESRD, Not Originally Disabled	Originally Disabled, Not Concurrently ESRD	Originally Disabled, Concurrently ESRD
Female				
0-34 Years	0.875	1.413	-	-
35-44 Years	1.217	1.755	-	-
45-54 Years	1.253	1.792	-	-
55-59 Years	1.142	1.681	-	-
60-64 Years	1.116	1.654	-	-
65 Years	0.851	1.390	1.040	1.579
66 Years	0.587	1.126	0.742	1.280
67 Years	0.587	1.126	0.742	1.280
68 Years	0.587	1.126	0.742	1.280
69 Years	0.587	1.126	0.742	1.280
70-74 Years	0.598	1.137	0.753	1.291
75-79 Years	0.652	1.191	0.807	1.345
80-84 Years	0.684	1.222	0.839	1.377
85-89 Years	0.683	1.221	0.837	1.376
90-94 Years	0.683	1.221	0.837	1.376
95 Years or Over	0.683	1.221	0.837	1.376
Male				
0-34 Years	0.820	1.358	-	-
35-44 Years	1.093	1.632	-	-
45-54 Years	1.054	1.592	-	-
55-59 Years	0.914	1.452	-	-
60-64 Years	0.866	1.404	-	-
65 Years	0.674	1.212	0.772	1.311
66 Years	0.437	0.975	0.538	1.077
67 Years	0.437	0.975	0.538	1.077
68 Years	0.437	0.975	0.538	1.077
69 Years	0.437	0.975	0.538	1.077
70-74 Years	0.449	0.987	0.550	1.089
75-79 Years	0.477	1.016	0.477	1.016
80-84 Years	0.470	1.009	0.470	1.009
85-89 Years	0.507	1.045	0.507	1.045
90-94 Years	0.507	1.045	0.507	1.045
95 Years or Over	0.507	1.045	0.507	1.045

NOTES:

1. The Part D Denominator used to calculate relative factors is $1,107.82. This Part D Denominator is based on the combined PDP and MA-PD populations. MA-PD risk scores were adjusted to account for new model diagnoses not yet submitted for the MA-PD population.

2. Originally Disabled is defined as originally entitled to Medicare by disability only (OREC = 1).

3. Concurrently ESRD is defined as at least one month of ESRD status—dialysis (D), transplant (1, 2, 5, 6 or N), or post-graft (G, R or Y) in the payment year (2008 in the model calibration).

Source: RTI Analysis of 100% 2008 PDE SAF, 2007-2008 HPMS, 2008 CME, and 2007-2008 Denominator.

Table 17. RxHCC Model Relative Factors for New Enrollees, Institutional

Variable	Baseline – Not Concurrently ESRD	Concurrently ESRD
Female		
0-34 Years	2.095	2.326
35-44 Years	2.095	2.326
45-54 Years	2.012	2.243
55-59 Years	1.975	2.205
60-64 Years	1.917	2.148
65 Years	1.988	2.218
66 Years	1.783	2.013
67 Years	1.783	2.013
68 Years	1.783	2.013
69 Years	1.783	2.013
70-74 Years	1.616	1.846
75-79 Years	1.551	1.781
80-84 Years	1.378	1.609
85-89 Years	1.214	1.445
90-94 Years	1.214	1.445
95 Years or Over	1.214	1.445
Male		
0-34 Years	2.118	2.348
35-44 Years	2.118	2.348
45-54 Years	2.059	2.289
55-59 Years	1.938	2.169
60-64 Years	1.792	2.023
65 Years	1.790	2.020
66 Years	1.683	1.914
67 Years	1.683	1.914
68 Years	1.683	1.914
69 Years	1.683	1.914
70-74 Years	1.573	1.804
75-79 Years	1.539	1.769
80-84 Years	1.505	1.736
85-89 Years	1.293	1.523
90-94 Years	1.293	1.523
95 Years or Over	1.293	1.523

NOTES:

1. The Part D Denominator used to calculate relative factors is $1,107.82. This Part D Denominator is based on the combined PDP and MA-PD populations. MA-PD risk scores were adjusted to account for new model diagnoses not yet submitted for the MA-PD population.

2. Concurrently ESRD is defined as at least one month of ESRD status—dialysis (D), transplant (1, 2, 5, 6 or N), or post-graft (G, R or Y) in the payment year (2008 in the model calibration).3. The Part D New Enrollee Institutional sample does not have an Originally Disabled add-on (set to $0 because of regression results).

Source: RTI Analysis of 100% 2008 PDE SAF, 2007-2008 HPMS, 2008 CME, and 2007-2008 Denominator.

Table 18. List of Disease Hierarchies for the Revised RxHCC Model

DISEASE HIERARCHIES

Rx Hierarchical Condition Category (RxHCC)	If the Disease Group is Listed in this column…	…Then drop the RxHCC(s) listed in this column
	Rx Hierarchical Condition Category (RxHCC) LABEL	
8	Chronic Myeloid Leukemia	9,10,11,48,50
9	Multiple Myeloma and Other Neoplastic Disorders	10,11,48,50
10	Breast, Lung, and Other Cancers and Tumors	11
14	Diabetes with Complications	15
18	Diabetes Insipidus and Other Endocrine and Metabolic Disorders	19
30	Chronic Pancreatitis	31
40	Psoriatic Arthropathy	41,42,147
41	Rheumatoid Arthritis and Other Inflammatory Polyarthropathy	42
47	Sickle Cell Anemia	50
48	Myelodysplastic Syndromes, Except High-Grade	50
54	Alzheimer's Disease	55
58	Schizophrenia	59,60,61,62,63,65,66,67,68
59	Bipolar Disorders	60,61,62,63
60	Major Depression	61,62,63
61	Specified Anxiety, Personality, and Behavior Disorders	62,63
62	Depression	63
65	Autism	61,62,63,66,67,68
66	Profound or Severe Mental Retardation/Developmental Disability	67,68
67	Moderate Mental Retardation/Developmental Disability	68
78	Intractable Epilepsy	79,80
79	Epilepsy and Other Seizure Disorders, Except Intractable Epilepsy	80
86	Pulmonary Hypertension and Other Pulmonary Heart Disease	87,88
87	Congestive Heart Failure	88
103	Cystic Fibrosis	104,105
104	Chronic Obstructive Pulmonary Disease and Asthma	105
120	Kidney Transplant Status	121,122,123,124,125,126,168
121	Dialysis Status	122,123,124,125,126
122	Chronic Kidney Disease Stage 5	123,124,125,126
123	Chronic Kidney Disease Stage 4	124,125,126
124	Chronic Kidney Disease Stage 3	125,126
125	Chronic Kidney Disease Stage 1, 2, or Unspecified	126
166	Lung Transplant Status	167,168
167	Major Organ Transplant Status, Except Lung, Kidney, and Pancreas	168

SOURCE: RTI International.

Attachment VII: 2012 Call Letter

Table of Contents

How to Use This Call Letter

The 2012 Call Letter contains information on the Part C and Part D programs. Also, we indicate when certain sections apply to cost-reimbursed HMOs, PACE programs, and employer and union-sponsored group health plans (EGWPs).

Over the past year, CMS has committed its resources to improving the quality of plan choices for beneficiaries who elect to enroll in Medicare Advantage and prescription drug plans. As part of this effort, CMS published a proposed regulation (4144-P) on November 22, 2010 that would make revisions to the Parts C and D regulations. CMS is currently reviewing comments submitted by the public and is in the process of developing the policies for the final rule. Since this year's final Call Letter will be released close to the expected final publication of the final rule (4144-F), the content is limited to clarification of current policy and operational guidance. However, requirements contained in the final rule may be included in this year's final Call Letter, even if they have not been included in this draft Call Letter. The Call Letter is divided into three sections: Program Updates, Improving Information Sharing & Transparency with Sponsors, and Improving Beneficiary Protections. These three sections contain information about Part C and Part D. We remind sponsoring organizations to continue to familiarize themselves with statutory requirements, regulations, and guidance governing the MA and Part D programs, including the Medicare Advantage and Prescription Drug Benefit Manuals. CMS will separately issue technical and procedural clarifications regarding bid and formulary submissions, benefits, HPMS data, CMS marketing models, and other operational issues of interest to sponsoring organizations.

Also note that this year some of the calendar items have dates that are earlier than for the 2011 contract year. This is as a result of the earlier Annual Enrollment Period (AEP) as compared to years past. Items with earlier due dates are indicated in the chart. Organizations and CMS need to work together to ensure contracting deadlines are met.

We hope this information helps you implement and comply with CMS policies and procedures as you prepare either to offer a plan for the first time or continue offering plans under the MA and/or Part D programs.

If you have questions concerning this Call Letter, please contact: Heather Rudo at Heather.Rudo@cms.hhs.gov (Part C issues) and Julie Gover at Julie.Gover2@cms.hhs.gov (Part D issues).

Section 1 – Program updates

This is a combined calendar listing of side-by-side key dates and timelines for operational activities that pertain to MA, MA-PD, PDP and cost-based plans. The calendar provides important operational dates for all organizations such as the date CMS bids are due, the date that organizations must inform CMS of their contract non-renewal, and dates for beneficiary mailings. The calendar has changed slightly from the draft version of the call letter to include updated timeframes based on external comments and to meet certain requirements of ACA.

2012 MA, MA-PD, Part D and Cost-Based Plan Calendar **(All dates, unless identified as statutory, are subject to change)**					
2011 ***Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D sponsors also apply to MA and cost-based plans offering a Part D benefit.**		***Part C**	***Part D sponsors**	**Cost**	**Date earlier than last year**
January 4, 2011	Release of the 2012 MAO/MAPD/PDP/SAE Applications in the Health Plan management System (HPMS)	✓	✓	✓	
January 5 & 12, 2011	Industry training on 2012 Applications	✓	✓	✓	
February 24, 2011	2012 Applications are due to CMS	✓	✓	✓	
March 2011	CMS releases guidance concerning updates to Parent Organization designations in HPMS	✓	✓	✓	✓
March 4, 2011	Initial Submission deadline for risk adjustment data with dates of service January 1, 2010 through December 31, 2010	✓		✓	
March 25, 2011	Release of the 2012 Formulary Submission Module in HPMS	✓	✓		
March 25 2011	Release of the 2012 Medication Therapy Management Module (MTMP) in HPMS		✓		
Early April 2011	CY 2012 OOPC estimates for each plan and an OOPC model will be made available to plan sponsors in SAS to download from the CMS website that will assist plans in meeting meaningful difference and total beneficiary cost requirements prior to bid submission.	✓	✓		

2012 MA, MA-PD, Part D and Cost-Based Plan Calendar **(All dates, unless identified as statutory, are subject to change)**					
2011 ***Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D sponsors also apply to MA and cost-based plans offering a Part D benefit.**		***Part C**	***Part D sponsors**	**Cost**	**Date earlier than last year**
Early April 2011	Release additional guidance regarding potentially duplicative plans, low enrollment plans and benefits review standards for 2012 bid submission.	✓	✓		
TBD	Conference call with industry to discuss the 2012 Call Letter.	✓	✓	✓	
April 4, 2011	2012 Final Call Letter released. Announce CY 2011 MA Capitation Rates and MA and Part D Payment Policies. *(applies to Part C and Part D sponsors only)*	✓	✓	✓	
April 4, 2011	2012 MTMP submission deadline		✓		
April 8, 2011	Release of the 2012 Plan Creation, Plan Benefit Package (PBP), and Bid Pricing Tool (BPT) Software of HPMS	✓	✓		
April 12 – 13, 2011	Medicare Advantage and Part D Spring Conference	✓	✓	✓	✓
April 15, 2011	Release of the 2012 PBP online Training Module	✓	✓		
April 15, 2011	Parent Organization Update requests from sponsors due to CMS (instructional memo to be released on March 25, 2011)	✓	✓	✓	✓
April 18, 2011	2012 Formulary Submissions due from all sponsors offering Part D (11:59 p.m. EDT) Transition Attestations due to CMS *(Part D sponsors only)*	✓	✓		
April/May 2011	CMS contacts MAOs with low enrollment plans	✓	✓	✓	
May 2011	Final ANOC/EOC, LIS rider, EOB, formularies, transition notice, provider directory, and pharmacy directory models for 2012 will be available for all organizations. (Models containing significant revisions will be released for public comment prior to this date).	✓	✓		

2012 MA, MA-PD, Part D and Cost-Based Plan Calendar **(All dates, unless identified as statutory, are subject to change)**					
2011 ***Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D sponsors also apply to MA and cost-based plans offering a Part D benefit.**		***Part C**	***Part D sponsors**	**Cost**	**Date earlier than last year**
May 2, 2011	*Voluntary non-renewal*: CMS strongly encourages MA, MA-PD and cost plans to notify us of an intention to non-renew a county or counties for individuals, but continue the county for "800 series" EGWP members, by May 2, 2011.	✓		✓	
May 2, 2011	*Voluntary non-renewal*: CMS strongly encourages Part D sponsors to notify us of any type of service area reduction, or conversion to offering employer-only contracts by May 2, 2011, so that we can make the required changes in HPMS to facilitate sponsors' ability to correctly upload their bids in June.		✓		
Early to Mid May 2011	Release Medicare Marketing Guidelines for CY 2012	✓	✓	✓	
Early to Mid May	Industry training on revised Medicare Marketing Guidelines and model documents	✓	✓	✓	
May 13, 2011	Release of the 2012 Bid Upload Functionality in HPMS	✓	✓	✓	
Late-May/June 2011	CMS sends eligibility determinations to applicants based on review of the 2012 applications for new contracts or service area expansions.	✓	✓	✓	
June 3, 2011	Release of the 2010 DIR Submission Module in HPMS		✓		
June 3, 2011	2012 MTMP Annual Review completed	✓	✓	✓	
June 3, 2011	Sponsors may begin to upload agent/broker compensation information into HPMS	✓	✓	✓	
June 6, 2011	Release of the 2012 Marketing Module in HPMS	✓	✓	✓	
June 6, 2011	Release of the 2012 Actuarial Certification Module in HPMS	✓	✓	✓	

2012 MA, MA-PD, Part D and Cost-Based Plan Calendar **(All dates, unless identified as statutory, are subject to change)**					
2011 ***Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D sponsors also apply to MA and cost-based plans offering a Part D benefit.**		***Part C**	***Part D sponsors**	**Cost**	**Date earlier than last year**
June 6, 2011	Deadline for submission of CY 2012 bids for all MA plans, MA-PD plans, PDPs, cost-based plans offering a Part D benefit, "800 series" EGWP and direct contract EGWP applicants and renewing organizations; deadline for cost-based plans wishing to appear in the 2011 Medicare Options Compare to submit PBPs (11:59 p.m. PDT). Voluntary Non-Renewal. Deadline for MA, MA-PD, PDPs and Cost-Based organizations to submit a contract non-renewal, service area reduction, or Plan Benefit Package (PBP) level non-renewal notice to CMS for CY 2012.	✓	✓	✓	
June to Early September, 2011	CMS completes review and approval of 2012 bid data. Submit attestations, contracts, and final actuarial certifications	✓	✓		
June 13, 2011	Deadline for submitting Supplemental Formulary files, Free First Fill file, Partial Gap file, Excluded Drug file, Over the Counter (OTC) drug file, and Home Infusion file through HPMS	✓	✓		
Late June, 2011	Release of the 2012 SB Hardcopy Change Request Module) on HPMS	✓	✓	✓	
Late June, 2011	Submission of HITECH identifying information for MA EPs and MA-affiliated hospitals and for attestation of qualifying MA organizations not offering MA HMO plans in HPMS	✓			
Late June, 2011	Final date to submit 2011 HITECH methodology for estimating portion of MA EP salary attributable to providing Part B services	✓			

2012 MA, MA-PD, Part D and Cost-Based Plan Calendar **(All dates, unless identified as statutory, are subject to change)**					
2011 ***Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D sponsors also apply to MA and cost-based plans offering a Part D benefit.**		***Part C**	***Part D sponsors**	**Cost**	**Date earlier than last year**
June 30, 2011	Final date to submit CY 2011 marketing materials to ensure timely CMS' review and approval. NOTE: Sponsors may continue to submit CY 2011 file and use materials as these may be filed in HPMS five calendar days prior to their use.	✓	✓	✓	
June 30, 2011	MAOs offering SNPs must provide their account managers with the total number of non-special needs individuals who continued to be enrolled as of January 1, 2011.	✓			
Late June 2011	Non-Renewal. CMS to issue an acknowledgement letter to all MA, MA-PD, PDP and Medicare cost-based plans that have notified CMS they are non-renewing or reducing their service area.	✓	✓	✓	
July1, 2011	Submission date for contracting MAOs (new and expanding) to provide CMS with a ratified contract with the State in order to operate a Medicaid dual eligible SNP for CY 2012.	✓			
July 5, 2011	Plans are expected to submit non-model Low Income Subsidy (LIS) riders to the regional office for review.		✓		
July 25, 2011	Submission deadline for agent/broker compensation information via HPMS upload.	✓	✓	✓	
July 29, 2011	CMS issues further details about MAO SNP disenrollment process for ineligible or "disproportionate share" SNP enrollees.	✓			

2012 MA, MA-PD, Part D and Cost-Based Plan Calendar **(All dates, unless identified as statutory, are subject to change)**					
2011 ***Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D sponsors also apply to MA and cost-based plans offering a Part D benefit.**		***Part C**	***Part D sponsors**	**Cost**	**Date earlier than last year**
Late July/Early August, 2011	Release of the 2012 Part D national average monthly bid amount, the Medicare Part D base beneficiary premium, the Part D regional low-income premium subsidy amounts, and the Medicare Advantage regional PPO benchmarks. Rebate reallocation period begins after release of the above amounts.	✓	✓	✓	✓
August 1, 2011	Plans are expected to submit model Low Income Subsidy (LIS) riders to the regional office for review.		✓		
Mid – August, 2011	CMS will release annual non-renewal guidance, including model final non-renewal beneficiary notification letters.				✓
August 25 – August 29, 2011	If applicable, plans preview the 2012 *Medicare & You* plan data in HPMS prior to printing of the CMS publication (not applicable to EGWPs).	✓	✓	✓	✓
Late August 2011	Contracting Materials submitted to CMS	✓	✓	✓	
End of August/Early September 2011	Plan preview period of star ratings in HPMS	✓	✓		
August 31 – September 2, 2011	First CY 2012 Medicare Plan Finder (MPF) Preview and (Out-of-Pocket Cost) OOPC Preview	✓	✓	✓	✓
September, 2011	CMS begins accepting plan correction requests upon contract approval.	✓	✓	✓	
September 2, 2011	Initial Submission deadline for risk adjustment data with dates of service from July 1, 2010 through June 30, 2011	✓		✓	
September 13 – September 16, 2011	Second CY 2012 Medicare Plan Finder (MPF) Preview and (Out-of-Pocket Cost) OOPC Preview	✓	✓	✓	✓

2012 MA, MA-PD, Part D and Cost-Based Plan Calendar **(All dates, unless identified as statutory, are subject to change)**					
2011 ***Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D sponsors also apply to MA and cost-based plans offering a Part D benefit.**		***Part C**	***Part D sponsors**	**Cost**	**Date earlier than last year**
Mid-September 2011	All 2012 contracts fully executed (signed by both parties: Part C/Part D sponsor and CMS)	✓	✓	✓	
Sept 15 – Sept 30, 2011	CMS mails the 2012 *Medicare & You* handbook to Medicare beneficiaries.	✓	✓	✓	✓
September 30, 2011	The beneficiary involuntary disenrollment notification must be a personalized letter and received by SNP enrollees who are no longer eligible for the SNP plan due to changes in service area, eligibility requirements or disproportionate share by September 30, 2011.	✓			

2012 MA, MA-PD, Part D and Cost-Based Plan Calendar **(All dates, unless identified as statutory, are subject to change)**					
2011 ***Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D sponsors also apply to MA and cost-based plans offering a Part D benefit.**		***Part C**	***Part D sponsors**	**Cost**	**Date earlier than last year**
September 30, 2011	CY 2012 standardized, combined Annual Notice of Change (ANOC)/Evidence of Coverage (EOC) is due to current members of all MA plans, MA-PD plans, PDPs and cost-based plans offering Part D. MA and MA-PD plans must ensure current members receive the combined ANOC/EOC by September 30th. Plans have the option to include Pharmacy/Provider directories in this mailing. All plans offering Part D must mail their LIS riders and abridged or comprehensive formularies with the ANOC/EOC to ensure current member receipt by September 30th. Exception: Dual Eligible SNPs that are fully integrated with the State must mail an ANOC with the SB for member receipt by September 30, 2011 and then send the EOC for member receipt by December 31, 2011. Fully Integrated Dual Eligible SNPs that send a combined, standardized ANOC/EOC for member receipt by September 30, 2011 are not required to send an SB to current members. Note: With the exception of the ANOC/EOC, LIS Rider, and abridged or comprehensive formularies, no additional materials may be sent prior to the beginning of when marketing activities may begin on October 1.	✓	✓	✓	✓

2012 MA, MA-PD, Part D and Cost-Based Plan Calendar **(All dates, unless identified as statutory, are subject to change)**					
2011 ***Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D sponsors also apply to MA and cost-based plans offering a Part D benefit.**		***Part C**	***Part D sponsors**	**Cost**	**Date earlier than last year**
October 1, 2011	Plans may begin CY 2012 marketing activities. Once an organization begins marketing CY 2012 plans, the organization must cease marketing CY 2011 plans through mass media or direct mail marketing (except for age-in mailings). Organizations may still provide CY 2011 materials upon request, conduct one-on-one sales appointments and process enrollment applications. Plans are required to include information in CY 2011 marketing and enrollment materials to inform potential enrollees about the possibility of plan (benefit) changes beginning January 1, 2012. Last day for Part D sponsors to request plan benefit package (PBP) plan corrections via HPMS.	✓	✓	✓	
October 1, 2011	Deadline for cost-based, MA, MA-PD and PDP organizations to request a plan correction to the plan benefit package (PBP) Deadline for cost-based, MA and MA-PD organizations to request SB hard copy changes	✓	✓	✓	

2012 MA, MA-PD, Part D and Cost-Based Plan Calendar **(All dates, unless identified as statutory, are subject to change)**					
2011 ***Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D sponsors also apply to MA and cost-based plans offering a Part D benefit.**		***Part C**	***Part D sponsors**	**Cost**	**Date earlier than last year**
October 2, 2011	Non-Renewal. The final beneficiary non-renewal notification letter must be a personalized letter and received by PDP, MA, MA-PD enrollees by October 1, 2011. PDP, MA, MA-PD organizations may not market to beneficiaries of non-renewing plans until after October 1, 2011. The non-renewal beneficiary notification must be received by beneficiaries no later than October 2, 2011. This year October 2 is a Sunday, which is non-mail day. Therefore, plans should take this into consideration when planning their mailings in order to make sure the beneficiary letters are sent far enough in advance so that they are received by this date. Additionally, CMS strongly encourages all organizations/sponsors to mail the beneficiary notification letters far enough in advance so that all beneficiaries have them before marketing begins on October 1, 2011.	✓	✓	✓	
October 6, 2011	Plan ratings go live on Medicare Plan Finder	✓	✓		
October 6, 2011	Tentative date for 2012 plan benefit data and plan drug benefit information to be displayed on Medicare Plan Finder (not applicable to EGWPs).	✓	✓	✓	
October 15, 2011	Part D sponsors must post PA and ST criteria on their websites for the 2012 contract year.		✓		

2012 MA, MA-PD, Part D and Cost-Based Plan Calendar **(All dates, unless identified as statutory, are subject to change)**					
2011 ***Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D sponsors also apply to MA and cost-based plans offering a Part D benefit.**		***Part C**	***Part D sponsors**	**Cost**	**Date earlier than last year**
October 15, 2011	2012 Annual Election Period begins. All organizations must hold open enrollment (for EGWPs, see Chapter 2 of the Medicare Managed Care Manual, Section 30.1). Medicare Marketing Guidelines require that all plans mail a CY 2012 EOC to each new member no later than when they notify the new member of acceptance of enrollment. Organizations offering Part D must mail their Low Income Subsidy Rider (LIS) and abridged or comprehensive formularies with the EOC for new members. Organizations may but are not required to provide new members with an effective date of January 1, 2012 or later with the ANOC portion of the standardized/combined ANOC/EOC	✓	✓		✓
November 2, 2011	Cost-Based organizations must mail the personalized final beneficiary non-renewal notification in time to be received by enrollees by November 2, 2011.			✓	
November 11, 2011	Notices of Intent to Apply (NOIA) for CY 2013 due for MA, MA-PD, PDPs, and "800 series" EGWPS and Direct Contract EGWPs	✓	✓	✓	
November – December, 2011	Non-Renewal. CMS to issue "close out" information and instructions to MA plans, MA-PD plans, PDPs, and cost-based plans that are non-renewing or reducing service areas.	✓	✓	✓	
December 1, 2011	Medicare cost-based plans not offering Part D must send the combined ANOC/EOC for receipt by members by December 1, 2011.			✓	
December 1, 2011	Non-Renewal. Cost-based plans must publish notice of non-renewal.			✓	

2012 MA, MA-PD, Part D and Cost-Based Plan Calendar **(All dates, unless identified as statutory, are subject to change)**					
2011 ***Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D sponsors also apply to MA and cost-based plans offering a Part D benefit.**		***Part C**	***Part D sponsors**	**Cost**	**Date earlier than last year**
December 7, 2011	Annual Election Period Ends	✓	✓		✓
December 31, 2011	Fully Integrated Dual Eligible SNPs that did not send an EOC with the ANOC by September 30, 2011, must send the EOC by December 31, 2011.	✓			
December 31, 2011	MAO SNPs must disenroll members: 1.) who enrolled prior to January 1, 2010 under the "disproportionate share" policy (i.e., the members did not meet the special needs criteria at the time of enrollment; or 2.) who were enrolled in a C-SNP as of January 1, 2010, but no longer met the special needs criteria as of that date.	✓			
2012					
January 1, 2012	Plan Benefit Period Begins	✓	✓	✓	
January 1 – February 14, 2012	Medicare Advantage Disenrollment Period (MADP)	✓			
January 4, 2012	Release of CY 2013 MAO/MAPD/PDP/SAE/EGWP applications	✓	✓	✓	
Mid January, 2012	Industry training on CY 2013 applications	✓	✓	✓	
January 31, 2012	Final Submission deadline for risk adjustment data with dates of service January 1, 2010 through December 31, 2010	✓		✓	
February 23, 2012	Applications due for CY 2013	✓	✓	✓	
March 2, 2012	Initial Submission deadline for risk adjustment data with dates of service January 1, 2011 through December 31, 2011	✓		✓	
September 7, 2012	Initial Submission deadline for risk adjustment data with dates of service from July 1, 2011 through June 30, 2012	✓		✓	

Part D Sponsor Bids and the Platino Program

When Part D sponsors seek to offer a plan in the Commonwealth of Puerto Rico as part of the Platino program, the Part D bids must reflect only basic benefits (i.e., defined standard, actuarial equivalent standard, or basic alternative design). Any supplemental benefits required by the Commonwealth (the Platino program's coverage of excluded drugs and/or cost-sharing buy-downs) should not be included as part of the plan sponsor's Part D bid. As discussed previously in our Call Letter for calendar year 2010, the supplemental benefits are negotiated between the Commonwealth and the Part D sponsor and are never part of the Medicare Part D bid submitted to CMS. CMS does not evaluate nor approve the Commonwealth's benefits provided by the Platino program.

CMS will revise the Health Plan Management System's (HPMS) Plan Benefit Package to reflect submissions of bids specific to the Platino program for 2012. Plan sponsors will not be able to validate bids for enhanced plans that apply to Platino programs.

Coordination of Benefits (COB) User Fees

CMS is authorized to impose user fees on Part D sponsors for the transmittal of information necessary for certain benefit coordination activities between sponsors and other entities providing prescription drug coverage. CMS may review and update this user fee annually to reflect the costs associated with such COB activities for the specific year. Since this user fee reflects the annual funding needs for COB-related activities, user fees vary (increasing or decreasing) yearly to reflect those needs. For contract year 2011, the Part D COB user fee was decreased to $1.17 per enrollee per year. In April 2011, CMS will implement the MARx Redesign and Modernization project which, among other changes, will enable daily enrollment transaction processing and reporting, multiple 4Rx spans within the beneficiary enrollment history, and reinstatement of erroneous disenrollments. These changes will significantly improve the timeliness and accuracy of information on beneficiary coverages. Some of the other functions financed through these fees include the operations of the TrOOP Facilitation Contractor (supporting real-time electronic E1, Nx and FIR transactions), the Coordination of Benefits Contractor (supporting the exchange and collection of information on other insurance or liability coverages for Medicare beneficiaries), and the facilitation of information on coverage gap discount program Part D drug cost reimbursements. Our projection of the incremental on-going costs of the COB-related activities to be carried out in 2012 indicates the Part D COB user fee must be increased to $1.62 per enrollee per year for contract year 2012. The 2012 COB user fee will be collected at a monthly rate of $0.18 for the first 9 months of the coverage year (for an annual rate of $0.135 per enrollee per month) for a total user fee of $1.62 per enrollee per year. Part D sponsors should account for this COB user fee when developing their 2012 bids.

ESRD Drugs

Effective January 1, 2011, the bundled prospective payment system (PPS) for renal dialysis services provided by an end-stage renal disease (ESRD) dialysis facility includes the limited number of oral equivalents of injectable drugs and biologics used in the treatment of ESRD that were formerly reimbursed under Part D. Therefore, sponsors are reminded that the costs related to these oral drugs with injectable equivalents must be excluded from the 2012 plan bids.

Submission of Quality Improvement Projects (QIPs) and Chronic Care Improvement Programs

Each MA organization that offers one or more MA plan must, for each of those plans, have an ongoing Quality Improvement (QI) Program that meets the applicable requirements of 42 CFR §422.152. CMS will request, on an annual basis, that QIPs and CCIPs be submitted for purposes of ongoing quality improvement monitoring. CMS does not anticipate a QIP and CCIP collection for CY 2011. However, the annual collection cycle for QIPs and CCIPs will begin with CY 2012. To ensure that these projects are evaluated in a consistent manner, CMS will require all plans, including those that have been deemed by an accrediting organization, to submit the QIPs and CCIPs for CY 2012 on the appropriate templates.

Guidance describing the QIP and CCIP templates, scoring methodology, benchmarks, and any CMS identified QIP and/or CCIP topics will be forthcoming. The guidance will also specify that in future years we anticipate that the project submission date may be earlier in the calendar year to allow sufficient time for CMS review.

Proposed Initiative to Promote Enrollment in Fully Integrated SNPs

In the draft 2012 Call Letter issued February 18, 2011, CMS solicited comments on a proposed initiative to promote enrollment of dual eligible beneficiaries in MA Special Needs Plans (SNPs) that integrate Medicaid and Medicare benefits. The initiative would be launched in 2013.

We asked for comment on key features, including the appropriate definition of "high quality" plan; design flexibilities that would promote care and streamline administration; incentives to promote plan participation; and appropriate consumer protections that would be a part of any such initiative. We appreciate the constructive comments and suggestions received, as well as concerns expressed. We will take these into consideration as we continue to develop this initiative. Additional details would be made available in separate guidance.

All Dual Eligible SNPs Required to Contract with State Medicaid Agencies

As required by section 164 of MIPPA and revised by section 3205 of the Affordable Care Act, starting in Contract Year 2013, all Dual Eligible Special Needs Plans (D-SNPs) will be required

to have contracts with the State Medicaid agencies in the States within which they operate. In the draft Call Letter, we announced that CMS is working to align the D-SNP State Medicaid Agency contract submission deadline with the MA Application deadline so that SNP approval can occur simultaneously with the MA contracting process. We solicited comment on a late February contract submission date.

In their comments, numerous D-SNPs and States objected to the proposed February contract submission deadline on the grounds that State budget and procurement rules do not allow States to execute contracts in February for the following calendar year. These commenters suggested that a February contract submission deadline would create significant hardships for D-SNPs and States, and serve as a barrier to operation for D-SNPs. We are currently taking these comments into consideration and developing operational policy that both reflects State budgetary and contracting timelines, and aligns this D-SNP contract submission deadline with the MA contracting process. We intend to publish operational guidance on the D-SNP State Medicaid Agency contract submission deadline for Contract Year 2013 in the future.

Involuntary Disenrollment of Ineligible or "Disproportionate Share" SNP Enrollees

As provided under MIPPA and section 3205(c) of the Affordable Care Act, SNPs may only enroll individuals who meet the plan's specific eligibility criteria; they may no longer enroll and serve a "disproportionate share" of individuals who do not meet the targeted criteria or condition. Also pursuant to MIPPA, chronic care SNPs (C-SNPs) may only enroll and serve individuals with certain chronic conditions, as specified by CMS.

Many SNPs currently include members: (1) who enrolled prior to January 1, 2010 under the "disproportionate share" policy (i.e., the members did not meet the special needs criteria at the time of enrollment); or (2) who were enrolled in a C-SNP as of January 1, 2010, but no longer met the revised special needs criteria as of that date. In both of these circumstances, rather than require the MAO offering these SNPs to involuntarily disenroll these members effective January 1, 2011 because they no longer met the SNP's targeted criteria, CMS required the MAOs to allow these individuals to continue to be enrolled through CY 2011. However, effective CY 2012, SNPs that include members who enrolled under the two circumstances described above will be required to disenroll those individuals if they do not request enrollment in a different plan prior to January 1, 2012. MAOs will not be permitted to transition these current enrollees into other MA plans offered by the organization. However, MAOs must retain any of these enrollees whose circumstances change and who regain special needs status prior to January 1, 2012.

Please refer to Section 14 of Appendix A1 of this Call Letter for guidance regarding the process for disenrolling ineligible members by January 1, 2012. The MAO must submit disenrollment transactions to MARx for those individuals who do not meet the plan's specific eligibility criteria, pursuant to instructions that CMS will release this year.

Please refer to the renewal plan guidance provided in this Call Letter for the notification requirements for current SNP enrollees other than those described above. Enrollees who will need to be disenrolled because they lose their special needs status in 2011 must be sent a disenrollment notice that includes information about other plan options, as well as additional details about Medigap rights and/or SEP rights, as applicable.[5] MAOs must retain any of these enrollees through their period of deemed continued eligibility, and also retain enrollees whose circumstances change and who regain their special needs status during such period, as described in section 50.2.5 of the MA Enrollment and Disenrollment Guidance.

MAO and PDP Sponsor Renewal/Non-Renewal Options for CY 2012

In this Call Letter, we provide detailed guidance regarding the plan renewal and non-renewal options available to MAOs and PDP sponsors for CY 2012. In addition, we clarify aspects of our non-renewal policies with respect to section 1876 cost contract plans.

As a result of business decisions, or pre- or post-bid discussions with CMS, MAOs and PDP sponsors may choose to change their current year offerings for the following contract year. Each year, current MAOs and PDP sponsors that continue their contracts are required to complete the Health Plan Management System (HPMS) Plan Crosswalk in a way that reflects Plan Benefit Package (PBP) renewal and non-renewal decisions and delineates, for enrollment purposes, the relationships between PBPs offered under each of their contracts for the coming contract year.

MAOs and Part D sponsors must also adhere to certain notification requirements, as specified in this guidance. While most renewal options must be completed using the HPMS Plan Crosswalk, there are limited exceptions to this requirement. These exceptions are described in Appendices A-1, A-2, B-1 and B-2. CMS will also provide precise technical instructions for completing the HPMS Plan Crosswalk for each MAO or PDP sponsor renewal or non-renewal option in the HPMS Bid Submission User Manual scheduled to be released on May 13, 2011.

Overall, this renewal and non-renewal guidance is based on two underlying principles: (1) the maximization of beneficiary choice; and (2) the protection of enrollment choices beneficiaries have previously made. We believe that beneficiaries should have the opportunity to make active enrollment elections into Original Medicare, a health care plan option, or a PDP option that best fits their particular needs.

As provided under 42 CFR 422.254, 422.256, 423.265, and 423.272, CMS reviews bids to ensure that an organization's or sponsor's plans in a service area are substantially different from those of other plans offered by the organization or sponsor in the area with respect to key plan

[5] Plans should note that the notification policy in this paragraph applies to those SNP enrollees who lost special needs status in 2011 *not* to disproportionate share enrollees who were not eligible for the SNP as of January 1, 2010.

characteristics such as premiums, cost-sharing, formulary structure, or benefits offered. In addition, under 42 CFR 422.506 and 423.507, we may non-renew plans that do not meet minimum enrollment thresholds after a specified length of time. This Call Letter contains information about how these requirements will be operationalized for CY 2012.

Although many of the renewal options outlined in this guidance are permissible despite year-to-year changes in benefits, premiums, and cost-sharing, we urge organizations and sponsors to maintain comparable benefits across contract years to the greatest extent possible in order to ensure that enrollees' enrollment elections remain valid. Section 3209 of the Affordable Care Act of 2010 provides CMS with authority to deny plan bids if an organization's or sponsor's proposed PBP includes significant increases in cost sharing or decreases in benefits offered. Refer to the "CY 2012 Cost Sharing Standards" section of this Call Letter for more information about how this requirement will be operationalized for CY 2012.

Appendices A-1, A-2, B-1 and B-2 outline all permissible renewal and non-renewal options for CY 2012 for MAOs and PDP sponsors, respectively, including their method of effectuation, systems enrollment activities, enrollment procedures, and required beneficiary notifications. Appendix C is a CMS model notice that corresponds to PDP scenario 6. CMS anticipates a release of model disenrollment notices that correspond to MAO scenarios 10, 13b, and 14 later this year.

Finally, the model termination notices associated with plan terminations or entire contract non-renewals will be released in August 2011 with instructions for non-renewing plans and contracts. MAOs offering special needs plans (SNPs) should note the options for SNP transitions, such as those involving renewing SNPs with ineligible or "disproportionate share" members and other transitions potentially affected by State contracting efforts. Organizations and sponsors should note that we have eliminated some exceptions that were allowed in previous years and modified previous options available under the HPMS Plan Crosswalk. Organizations and sponsors should also be aware that approval of a bid does not necessarily mean a submitted HPMS Plan Crosswalk or crosswalk exception meets CMS requirements and will be accepted by CMS. **If a renewal or non-renewal scenario is not outlined in Appendices A-1, A-2, B-1, or B-2, it is not a permissible renewal option.** Therefore, organizations and sponsors should submit their crosswalks and crosswalk exception requests as early as possible and contact CMS staff for clarification if there is any uncertainty about whether CMS requirements will be met and the exception will be granted. Organizations and sponsors are also urged to use this guidance to determine whether their renewal or non-renewal arrangements adhere to CMS standards. If CMS requirements are met, bids as well as HPMS Plan Crosswalks and crosswalk exceptions will be approved accordingly. Organizations and sponsors that have questions about their exceptions requests should contact Sara Silver, at sara.silver@cms.hhs.gov, and Heather Kilbourne, at heather.kilbourne@cms.hhs.gov, well before the bid submission deadline.

Each renewal and non-renewal option outlined in Appendices A-2 and B-2 includes, where applicable, instructions or deadlines for requesting particular renewal options that organizations and sponsors cannot themselves effectuate in the HPMS Plan Crosswalk. Organizations and sponsors will *not* be able to make changes to their HPMS Plan Crosswalks once bids are submitted to CMS on June 6, 2011. After that point, CMS will only make changes to organizations' and sponsors' HPMS Plan Crosswalks under exceptional circumstances.

Furthermore, any renewal options that require organizations and sponsors to submit crosswalk exception requests and manual enrollment transactions must be completed both correctly and completely pursuant to instructions that CMS will release later this year. A detailed timeline for HPMS Plan Crosswalks and crosswalk exception requests submissions will be included in forthcoming instructions. However, as stated above, organizations and sponsors should prepare their renewal and non-renewal options in advance so that they are able to submit any crosswalk and crosswalk exceptions as early as possible.

The June 6, 2011 deadline for bid submissions is incorporated in the *2012 MA, MA-PD, Part D and Cost-Based Calendar* at the beginning of this Call Letter. In addition, the calendar also lists June 6, 2011 as the deadline for MA plans, MA-PD plans, PDPs and Medicare cost-based contractors and cost-based sponsors to submit a CY 2012 full contract or partial contract (PBP) non-renewal or service area reduction notice to CMS. CMS will publish an HPMS memorandum, to be released this summer, providing non-renewal and service area reduction guidance and required termination model beneficiary notices. Organizations and sponsors should refer to this forthcoming memorandum for more information about full-contract non-renewal and plan termination processes.

Section 2 – Improving Information Sharing & Transparency with Sponsors

Clarification of Parent Organization Information for MA Organizations and PDP Sponsors

CMS is increasingly focused on the relationship between MA organizations and PDP sponsors and their parent organizations in our administration of the Part C and D programs. For example, CMS makes auto-enrollment and reassignment determinations by allocating enrollees among PDP sponsors' parent organizations, not among the sponsors themselves. Also, in certain situations, CMS will look to an MA organization's parent organization to make a determination concerning its qualification for quality bonus payments. Therefore, it is crucial that all MA organizations and PDP sponsors accurately report their parent organization status to CMS and keep such information up-to-date in CMS records.

CMS considers a parent organization to be the legal entity that owns a controlling interest in a PDP sponsor or MA organization (both referred to as "contracting organizations"). More specifically, for Part C and D reporting purposes, the parent organization is the "ultimate" parent,

or the top entity in a hierarchy (which may include other parent organizations) of subsidiary organizations which is not itself a subsidiary of any corporation.

CMS is providing this clarification in part because there have been instances where contracting organizations have reported information concerning their immediate parent rather than their ultimate parent. Such inaccuracies create the risk that CMS makes incorrect program implementation determinations or conducts duplicative work.

CMS acknowledges that in fact many contracting organizations are not subsidiaries to a parent company. However, for purposes of program administration, CMS must have a parent organization name associated with each contracting organization. Therefore, when applicable, contracting organizations should identify themselves as their own "parent organization" in CMS records.

All contracting organizations are required to report parent organization information to CMS as part of their applications for qualification for a Medicare contract. CMS has also provided guidance through HPMS to organizations alerting them to their obligation to keep such information up-to-date in our records. As part of this effort, contracting organizations must pay special attention to the impact of changes of ownership among entities in their corporate ownership chain that may have an effect on the identity of the contracting organization's ultimate parent. Also, contracting organizations should always be prepared to provide the most conclusive documentation available to them of their relationship to their parent organization upon request from CMS. Such documentation may consist of financial statements, articles of incorporation, contracts, or filings with regulatory authorities.

Contracting organizations can view their parent organization assignments within the Basic Contract Management Module in HPMS. The parent organization assignment can be accessed using the following navigation path: Contract Management > Basic Contract Management > Select Contract Number > Plan Management Data. Parent organization data is also available in the General Information Report under Contract Reports and in the Plan Version of the Contract Information Data Extract. Contracting organizations do not have access rights to change the parent organization designation, but rather must report changes to CMS.

While CMS will continue to issue annual requests to contracting organizations to provide updates to CMS concerning the name of the parent organization, effective immediately, we are now requiring contracting organizations to proactively report all parent organization changes to CMS within 30 days of the effective date of such a change. All such change requests must be emailed to drugbenefitimpl@cms.hhs.gov with the subject line of "Parent Organization Update." Contracting organizations should include with the email supporting documentation, such as one or more of the items listed above. CMS may request additional supporting documentation, if

necessary. Of note, due to character limitations, CMS will not necessarily agree to all minor changes, such as requests to expand abbreviations.

Prescriber Identifiers

This section provides guidance regarding how Part D sponsors handle prescriber identifiers on Part D claims and PDE records; the first section responds to questions we have received on how sponsors should currently handle identifiers for prescribers from jurisdictions other than U.S. states and territories, where allowed under state law; the remaining sections concern permissible prescriber identifiers on Part D claims and PDE records in 2012 and 2013.

Foreign Prescriber Identifiers: In an August 13, 2010 memorandum on the use of prescriber identifiers on Medicare Part D drug claims, we reiterated the CMS guidance that specifies that the NPI is intended to uniquely identify a health care provider in standard transactions, such as health care claims. The Health Insurance Portability and Accountability Act of 1996 (HIPAA) requires that covered entities use NPIs in standard transactions by the specified compliance dates. The NPI is the only health care provider identifier that covered entities may use to identify health care providers. Although HIPAA requires pharmacies to use the NPI on HIPPA standard transactions, we recognize that pharmacies cannot always obtain the prescriber NPI at the time of dispensing. Therefore, to ensure Part D enrollees do not experience service interruptions, CMS guidance permits Part D sponsors to accept alternative prescriber identifiers, such as DEA registration numbers or state license numbers. However, we clarified that it is our intention that whatever type of prescriber identifier (i.e., NPI, DEA number, unique provider identification number (UPIN) or state license number) is used, it must be a valid number.

After this guidance was issued, we received comments indicating that a number of States permit pharmacies to fill prescriptions written by foreign (i.e., non-U.S. - licensed) prescribers. We have been asked what prescriber identifier should be required on the Part D claim and submitted on the prescription drug event (PDE) record. If a prescription has been written by a foreign prescriber, the sponsor should require the use of the license number assigned by an appropriate licensing board in the foreign jurisdiction in which the prescriber practices/resides on the claim with the State license qualifier. We understand that the use of this qualifier is not inconsistent with the National Council for Prescription Drug Programs (NCPDP) data dictionary, which defines a State license number as a number assigned and required by a State Board or other State regulatory agency. In the absence of a reference to "U.S." in the NCPDP definition and given the Webster's dictionary definition of "state" as one of the territorial and political units constituting a federal government, we believe State license is the most appropriate qualifier to use for foreign prescribers.

Permissible Prescriber Identifiers in 2012: For 2012, CMS will continue to permit Part D sponsors to report on the PDE records any one of the four currently acceptable types of

prescriber identifiers; that is NPI, DEA number, UPIN or state license number. Sponsors must ensure that these identifiers are active and valid. However, sponsors should not reject a pharmacy claim solely on the basis of an invalid prescriber identifier unless the issue can be resolved at point-of-sale. Thus, pharmacies can fill prescriptions and sponsors can pay the associated drug claims with an unvalidated prescriber ID at point-of-sale. However, sponsors are then responsible for verifying and reporting a valid prescriber ID on the PDE record and, whichever type of identifier is reported in the PDE, the identifier must be valid. Therefore, if a valid prescriber ID is not included on the Part D claim, either the sponsor, or the pharmacy if in accordance with the contractual terms of the network pharmacy agreement, must follow up retrospectively to acquire a valid ID of one of the four acceptable types before the PDE is submitted.

Follow-up may require review of the prescription, contact with the prescriber, use of the multiple sources of state and federal data on providers, or the purchase of prescriber ID validation services from a commercial vendor. Among the available state and federal sources are individual state licensing board data on licensing and sanctions, Drug Enforcement Agency registrant files, the Social Security Administration death file, OIG and state Medicaid program excluded provider lists, and the CMS National Plan & Provider Enumeration System (NPPES) database. Periodically updated files are available from these databases, in some cases directly from these agencies, or else wise through the Department of Commerce's National Technical Information Service (NTIS). In addition to these resources, we understand that multiple commercial firms compile databases and offer services for validation of prescriber identifiers, so an alternative approach would be for sponsors to purchase prescriber identifier validation services from commercial vendors who already have access to these sources of data and are currently providing these services to pharmacy, health plan, and pharmaceutical manufacturer clients. In an exception to this requirement, we agree with commenters that foreign prescriber identifiers cannot be similarly validated, and thus it will be permissible to submit foreign prescribers' license numbers obtained from the prescription or prescriber without validation against any official database.

Thus, sponsors have the option to either build their own systems or contract with commercial vendors for prescriber ID validation services. Although we impose the requirement for validation of prescriber identifiers on Part D sponsors, we expect that network pharmacies will either contractually agree to provide some of these services themselves or will fully support any retroactive review of the prescription and other pharmacy records necessary to retrospectively identify the prescriber and obtain a valid identifier. We leave the terms and conditions for responsibilities for these processes and any penalties for failure to perform to contractual negotiations between the sponsor or its agent and the network pharmacies. However, we do expect that any requirement for a pharmacy to acquire and utilize its own automated validation capability will be arrived at only through mutual agreement, since such a requirement may be impractical for many smaller pharmacy organizations.

For 2012, we will also extend the requirement for a valid prescriber identifier to be reported on the PDE record to non-standard format claims, such as requests for reimbursement ("paper" claims) submitted by Medicare beneficiaries. We received numerous questions concerning the approach sponsors are expected to use to process beneficiary submitted requests for reimbursement. For 2012, sponsors may require members to furnish the prescriber's name and address or phone number, or the pharmacy information, to assist the sponsor in obtaining the prescriber ID. However, payment to the beneficiary cannot be made dependent upon the sponsor's acquisition of the prescriber ID, itself. Consistent with current guidance, sponsors may withhold reimbursement to the beneficiary only if there is a reason to suspect fraud or if there are coverage issues. Once the prescriber or pharmacy contact information is acquired, the sponsor must process the request for reimbursement and the sponsor, or the pharmacy (if doing so is in accordance with their contract terms), must follow up retrospectively to acquire a valid ID. Follow-up may entail a review of the prescription, prescriber contact, use of state or federal data on providers, or purchase of prescriber ID validation services from a commercial vendor. In the absence of fraud, if the sponsor is unable to retrospectively acquire a valid prescriber ID, the sponsor may not seek recovery of the Part D payment from the beneficiary.

CMS will begin validating the format of all prescriber identifiers on PDEs that are coded as an NPI and will exclude from payment reconciliation PDEs with invalid NPIs. We will also be assessing each sponsor's performance regarding NPI use and validity and will be notifying plan sponsors of their performance level. While this section has specifically addressed prescriber identifiers, we remind both Medicare Advantage Organizations and Part D Sponsors that they are also required to obtain valid provider NPIs on claims. NPIs may be deactivated for reasons such as provider death or fraud related to identity theft and other forms of fraud. The NPPES database is updated monthly to reflect these changes. Therefore, in addition to verifying the reported NPI is valid, Part C and D plan sponsors must also periodically confirm the identifiers are active. In those instances when the NPI is found to have been deactivated, the sponsor must follow up with the provider to determine the reason for the deactivation.

In 2012, we will also impose additional requirements on plan sponsors with regard to Part D claims for all controlled substances (not just Schedule II drugs as described in our proposed Call Letter). Effective January 1, 2012 Part D sponsors will be required to confirm the validity of DEA numbers on Schedule II-V drug claims or map NPIs on these claims to the prescriber's DEA numbers. In addition, sponsors will be required to confirm that the controlled substance is within the prescriber's scope of practice to prescribe. As noted above, sources of state and federal data on providers are available to support sponsor efforts to ensure a prescriber ID is valid and to verify Schedule II-V drugs are within the prescriber's scope of practice. This policy does not supersede or alter pharmacy obligations relative to DEA registrants under the Controlled Substances Act and DEA rules. Again, in addition to these resources, we understand that multiple commercial firms compile databases and offer services for validation of prescriber identifiers, so an alternative approach would be for sponsors to purchase prescriber identifier

validation services from commercial vendors who already have access to DEA data and are currently providing these services, including whether the provider has authorization to prescribe controlled substances, to pharmacy, health plan, and pharmaceutical manufacturer clients.

Permissible Prescriber Identifiers in 2013: Finally, we are considering proposing a regulatory change that will limit acceptable prescriber identifiers on Part D claims and PDE records in 2013 to only the individual NPI. In other words, a prescription written by an individual prescriber who did not acquire an individual NPI and disclose it to the pharmacy on the prescription or otherwise would not be filled under the Part D program. Since all practitioners who are authorized to prescribe Part D drugs under applicable U.S. state laws can acquire an individual NPI from HHS, we do not believe that this will present a significant barrier to access to Part D drugs for Medicare beneficiaries. Moreover, consistent use of a single validated identifier will enable CMS to provide better oversight over possible fraudulent activities. We received numerous comments recommending CMS restrict Part D prescriptions to U.S.-licensed prescribers, and we are taking this under consideration.

Supplemental Formulary File Submission

The regulation at 42 CFR § 423.272(b)(2) requires that CMS review bids to ensure that the plan designs are not likely to substantially discourage enrollment by certain Part D eligible individuals. Part D sponsors offering partial tier gap coverage, free first fill coverage, home infusion bundling under Part C, coverage of excluded drugs, or coverage of over-the-counter (OTC) drugs under utilization management programs must submit the corresponding required supplemental formulary file(s) as part of their bid submission so that CMS can assess whether or not the plan design meets the non-discrimination requirements as described under 42 CFR § 423.272(b)(2). We are requesting that these supplemental formulary files be submitted no later than June 13, 2011. Given the reduced time frame for review and approval of bids, CMS will not have sufficient information to fully evaluate whether a plan's benefit design meets the non-discrimination requirements if sponsors do not submit these supplemental files in a timely manner. Therefore CMS will assume that if a sponsor does not submit the appropriate supplemental files by the June 13th deadline, then the sponsor does not intend to offer these supplemental benefits and will be asked to revise their bids accordingly. In addition these plans will be subject to a compliance action and will be at risk of having their bids disapproved.

Preventing Part D Payment for Hospice Drugs

Hospice programs, as specified in section 1861(dd) of the Social Security Act and in Federal regulations at Part 418, must provide individuals under hospice care with drugs and biologicals related to the palliation and symptom management of the terminal illness as defined in the hospice plan of care. The only drugs covered by the hospice program are those used primarily for relief of pain and symptom control related to the individual's terminal illness. However,

because hospice care is a Medicare Part A benefit, the drugs provided by the hospice and covered under the Medicare per-diem payment to the hospice program are not covered under Part D.

Our October 23, 2010 memorandum entitled, "Preventing Part D Payment for Hospice Drugs," incorrectly stated that all Part D sponsors currently do not have the ability to identify any Medicare enrollees who have elected hospice. In fact, CMS has been sending beneficiary-level hospice data to all Part D sponsors. These data are currently sent on the transaction reply report (TRR) at the time of the beneficiary's enrollment and subsequently whenever the hospice information changes. As specified in the Plan Communications User Guide, the TRR includes a hospice indicator in position 54 and, in positions 85-96, a hospice start date and, if applicable, hospice termination date. The associated transaction reply codes are 071- Hospice status set and 72- Hospice status terminated. Sponsors need to ensure their claims processor is notified of an enrollee's hospice election and that processes are in place to prevent Part D payment for hospice drugs.

We have received requests for further guidance regarding how sponsors should identify hospice drugs and questioning whether sponsors should establish a point-of-sale prior authorization edit or to pay the claim at point-of-sale and make a retrospective Part A vs. D payment determination. We are currently working with the CMS hospice staff to develop clarifying guidance that will be issued at a later date. In the interim, sponsors need to ensure their claims processor is notified of an enrollee's hospice election. Additionally, we suggest that unless the plan has information available at point-of-sale to determine payment responsibility, sponsors should pay the claims for drugs furnished to members enrolled in a hospice program that may be covered under the hospice benefit and retrospectively determine payment responsibility.

Employer Group Waiver Plans and Application of the Manufacturer Discount

Section 1860D-14A(c)(2) of the Social Security Act specifies that if a Part D sponsor offers supplemental Part D coverage, the manufacturer discount will not be applied until after such supplemental coverage has been applied to the applicable drug. Therefore, CMS announced in a June 2, 2010 HPMS memorandum to all Part D sponsors that the value of supplemental benefits provided as part of a Part D enhanced benefit, including benefits negotiated between EGWP sponsors and employers, must be calculated prior to the application of the Medicare manufacturer coverage gap discount. Until such time CMS can systematically collect supplemental benefits information as part of the EGWP PBP within HPMS, the chief financial officer of the Part D sponsor is required to attest, as part of its contract with CMS, that if the sponsor provides supplemental coverage via any of its enhanced benefit plans, it will apply the manufacturer coverage gap discount only after the plan's supplemental benefits have been applied. Sponsors are also required to attest to the accuracy of the discount amounts submitted

on the prescription drug event (PDE) data and provide documentation, upon request, to CMS's third party administrator (TPA) when required.

CMS will be developing an information collection effort to ensure Part D EGWP sponsors have correctly applied the manufacturer discounts to covered Part D drugs. This information collection effort would require Part D sponsors submit the Part D supplemental benefits negotiated between employers and EGWPs. The information collected by CMS would be available in the event CMS received other indications that an EGWP was not compliant with the administration of the manufacturer discount. More information will be communicated to Part D sponsors regarding the information collection process, including any modifications to existing EGWP waivers, in upcoming memoranda.

Quality Reporting Requirements for Employer/Union-Only Direct Contracts

Currently, Medicare Advantage (MA) contracts are required to collect and report to CMS quality measurement data from the Healthcare Effectiveness Data and Information Set (HEDIS), Medicare Health Outcome Survey (HOS), and Consumer Assessment of Healthcare Providers and Systems (CAHPS). All stand-alone Prescription Drug Plans (PDPs) are required to collect and report CAHPS data to CMS. To date, the Employer/Union Only Direct contracts have been excluded from the quality reporting requirements. Beginning in 2012 all Employer/Union Only Direct contracts will be required to meet the same reporting requirements as MA or PDP contracts. For example, the Employer/Union Only Direct Private Fee-for-Service (PFFS) contracts will be required to collect and report HEDIS, HOS and CAHPS data to CMS. Employer/Union Only Direct MA contracts can see the HPMS memo "2011 HEDIS, HOS and CAHPS Measures for Reporting on Medicare Advantage Organizations" dated November 4, 2010 as an example of the MA reporting requirements for 2011. Employer/Union Only Direct PDPs can view the CAHPS reporting requirements at www.ma-pdpcahps.org.

Improvements to Plan Ratings

CMS is committed to continuing to improve the Part C and D quality performance measurement system to increase focus on improving beneficiary outcomes, beneficiary satisfaction, population health, and efficiency of health care delivery. To that end, CMS has been working on developing a more robust system to measure quality and performance of Part C and D contracts. As new measures are developed and adopted, they will be incorporated into the Plan Ratings published each year on the Medicare Plan Finder website and used to determine star ratings for quality bonus payments.

CMS views the MA quality bonuses also referred to as value-based payments as an important step to revamping how care and services are paid for, moving increasingly toward rewarding better value, outcomes, and innovations. As we add measures to the Plan Ratings over time, we will consider the following principles:

- Public reporting and value-based payment systems should rely on a mix of standards, process, outcomes, and patient experience measures, including measures of care transitions and changes in patient functional status. Across all programs, CMS seeks to move as quickly as possible to the use of primarily outcome and patient experience measures. To the extent practicable and appropriate, outcomes and patient experience measures should be adjusted for risk or other appropriate patient population or provider characteristics.

- To the extent possible and recognizing differences in payment system maturity and statutory authorities, measures should be aligned across Medicare's and Medicaid's public reporting and payment systems. CMS seeks to evolve to a focused core-set of measures appropriate to the specific provider category that reflects the level of care and the most important areas of service and measures for that provider.

- The collection of information should minimize the burden on providers to the extent possible. As part of that effort, CMS will continuously seek to align its measures with the adoption of meaningful use standards for health information technology (HIT), so the collection of performance information is part of care delivery.

- To the extent practicable, measures used by CMS should be nationally endorsed by a multi-stakeholder organization. Measures should be aligned with best practices among other payers and the needs of the end users of the measures. Our strategy is to continue to adopt measures that are nationally endorsed and are in alignment with the private sector as we do today through the use of measures developed by the National Committee for Quality Assurance (NCQA) and the Pharmacy Quality Alliance (PQA), and the use of measures that are endorsed by the National Quality Forum (NQF).

As we modify the calculation approaches for the Plan Ratings, we are incorporating the following principles:

- Plans should be scored on their overall achievement relative to national or other appropriate benchmarks. In addition, scoring methodologies should consider improvement as an independent goal.

- Measures or measurement domains need not be given equal weight, but over time, scoring methodologies should be more weighted towards outcome, patient experience and functional status measures.

- Scoring methodologies should be reliable, as straightforward as possible, and stable over time and enable consumers, providers, and payers to make meaningful distinctions among providers' performance.

Using the principles discussed above, CMS has identified a set of enhancements for the 2012 and 2013 Plan Ratings. For the 2012 Plan Ratings we are considering the following measures to be added to the existing set used in the 2011 Plan Ratings:

- All-Cause Readmission rates. (For more information about this measure, see HEDIS® 2011 Technical Specifications, Volume 2.) These items would be case-mix adjusted.
- Advising Smoker and Tobacco Users to Quit. This information is collected through the CAHPS survey. (For more information about this measure, see HEDIS® 2011 Technical Specifications, Volume 2.). CMS views survey data from beneficiaries as a complement to administrative and clinical data. CAHPS data have been found to display high reliability and acceptable validity at the contract level (Hargraves et al., 2003).
- Body Mass Index. (For more information about this measure, see HEDIS® 2011 Technical Specifications, Volume 2.)
- Special Needs Plan (SNP)-specific measures. This would include three rates included as part of the Care for Older Adults measure that has been collected for the past three years. These would only apply to contracts that have a SNP plan. The three rates being considered are medication review conducted by a prescribing practitioner or clinical pharmacist and the presence of a medication list in the medical record; functional status assessment; and pain screening or pain management plan. (For more information about this measure, see HEDIS® 2011 Technical Specifications, Volume 2.)
- Voluntary Disenrollment Rates. (see 2011 Display Measures – Technical Notes at www.cms.gov/PrescriptionDrugCovGenIn/06_PerformanceData.asp)
- Measures from the Hospital Inpatient Quality Reporting program (formerly known as Reporting Hospital Quality Data for Annual Payment Update). (See http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1138900298473 for a list of measures.) CMS is exploring whether the individual-level hospital data can be associated with individual MA contracts.
- Appropriate implementation of Part D transition processes by plans to ensure continuity of care for beneficiaries. Additional information on this measure will be provided as it becomes available.
- Part D Medication Adherence. This measure would use the proportion of days covered methodology as endorsed by PQA. (Several potential adherence measures are currently posted on the display measures page at http://www.cms.gov/PrescriptionDrugCovGenIn/06_PerformanceData.asp.)

For SNP-specific measures, CMS is examining the feasibility of creating a methodology to incorporate SNP-specific measures into Plan Ratings, including for contracts that have a mix of SNP and non-SNP plans. Additionally, CMS is considering differential weighting to individual measures. Currently all items used in Plan Ratings are given equal weight. A table with the data time frame for each of the measures is now included in the technical notes at www.cms.gov/PrescriptionDrugCovGenIn/06_PerformanceData.asp. CMS is continuing to explore the feasibility of MA and fee for service comparisons.

For all of the measures, CMS will be examining the quality of the data, variation among plans, and the measure's accuracy and validity before making a final determination about inclusion.

For example, for the all-cause readmission rate we will look at the quality of the data reported in June 2011 to make a final decision about whether this measure is incorporated into the 2012 Plan Ratings or the 2013 Plan Ratings. For those measures that are not proven to be reliable and valid, CMS will determine whether such measures may be appropriate "display measures", which would not be used in the plans' star ratings.

CMS is also considering using the same 4-star thresholds that were set for the 2011 Part C and D Plan Ratings. (See http://www.cms.gov/PrescriptionDrugCovGenIn/06_PerformanceData.asp for the current thresholds.) Plans should be aiming to achieve at least the 4-star thresholds which are absolute. Four-star thresholds define expectations about what it takes to be a high-quality contract and drive quality improvement. For the 2011 Plan Ratings, measures that were new or were not part of the Plan Ratings for at least two years did not receive a 4-star threshold. For 2012 and beyond, CMS will be setting 4-star thresholds for measures with at least a two year data history. For example, we will be providing sponsors with the 4-star thresholds (through an HPMS memo) for the following measures: availability of TTY/TDD services and foreign language interpretation and accuracy of information members get when they call the health plan.

Additional enhancements under consideration for the 2012 Part C and D Plan Ratings include:

- Weighting of the measures to provide greater weight to clinical outcomes and lesser weight to process measures such as call center measures,
- Controlling for the concentration of providers in a geographic area, such as Health Professional Shortage Areas (HPSAs),
- Rewarding contracts for quality improvement, and
- Reducing the overall and/or summary Plan Ratings for contracts with serious compliance issues. Serious compliance issues will be defined as situations where CMS curtails enrollment or marketing of new enrollees. A serious compliance sanction in effect as of August 31, 2011 will reduce the 2012 overall and/or summary Plan Ratings published in October 2011. If a contract has a serious compliance issue that occurs between September 1, 2011 and March 31, 2012, the 2012 Plan Ratings will be updated to reflect this issue.

For the 2013 Plan Ratings we are considering adding the following measures:

- Survey measures of care coordination. We are considering adding a set of survey items to the CAHPS survey that will be administered in 2012. We will let sponsors know the set of items through an HPMS memo once they are finalized. We are also working on a Chinese translation of the CAHPS survey instrument.
- Case-mix adjusted mortality rates.
- Preventable hospitalizations.

- Serious Reportable Adverse Events, including Hospital Acquired Conditions. (See the Part C Reporting Requirements posted at www.cms.gov/HealthPlansGenInfo/16_ReportingRequirements.asp.)
- Grievances. (See the Part C Requirements posted at www.cms.gov/HealthPlansGenInfo/16_ReportingRequirements.asp and Part D Reporting Requirements posted at http://www.cms.gov/PrescriptionDrugCovContra/08_RxContracting_ReportingOversight.asp.
- Use of highly rated hospitals by plan members. This will combine information about the use of hospitals by plan members with the total performance score that will be calculated for each hospital as part of Hospital Value-based Purchasing. The total performance score is proposed as part of the Notice of Proposed Rulemaking, "Medicare Program; Hospital Inpatient Value-Based Purchasing Program", published on January 7, 2011.
- Medication therapy management (MTM) measures related to comprehensive medication reviews.
- Evaluation of a contract's Chronic Care Improvement Program (CCIP) and Quality Improvement Project (QIP).

On a regular basis, the Medicare Health Outcomes Survey (HOS) engages in a process of review and refinement to ensure that it is benefiting from the latest advances in survey design, outcomes assessment, psychometrics, and performance measurement. We are currently anticipating the implementation of HOS 3.0 in 2013. As HOS is a HEDIS® Effectiveness of Care Measure, revisions will follow the standard NCQA protocol for HEDIS® measure refinements.

We will provide as much advance notice of these changes to the Plan Ratings as possible, but sponsors are encouraged to take proactive steps to put in place quality assurance efforts in these areas in order to have a head start in effecting improved outcomes. Going forward, we plan to announce potential measures two years in advance. CMS will provide Sponsors the opportunity to comment on proposed changes to the plan rating system later this year.

Section 3 – Improving Beneficiary Protections

I. General

Contracting Organizations with Ratings of Less Than Three Stars in Three Consecutive Years

CMS has previously stated publicly that we consider contracting organizations (i.e., MA organizations and PDP sponsors) with less than an "average" or three-star summary plan rating to be out of compliance with the requirements of the Part C or D programs. For example, in the preamble to our notice of proposed rulemaking published in the Federal Register on October 22, 2009, we stated that, "organizations and sponsors with less than 'good' ratings should expect to

be the subject of our monitoring and compliance actions." We also made a similar statement in the 2009 Call Letter.

CMS cannot continue to contract with organizations whose performance is consistently out of compliance with Medicare requirements. Contracting organizations should interpret a less than "average" (or three-star) summary rating on either their Part C or D performance to be a notice from CMS that they are to take corrective action to come into compliance with program requirements. Also, within the last year, CMS adopted and will continue a policy of issuing formal compliance notices each year to all sponsors that earned low ratings for that year.

CMS considers organizations that fail for three straight years to achieve at least a three-star summary rating on Part C or D to have ignored over a significant period of time their obligation to meet program requirements and to be substantially out of compliance with their Medicare contracts. These organizations should expect CMS to initiate action to terminate their contracts following 1) our publication of the set of annual plan ratings that assigns the organization its third consecutive summary rating of less than three stars and 2) our confirmation that the data used to calculate the star ratings reflect the sponsor's substantial non-compliance with Part C or Part D requirements. CMS would pursue such actions in a manner consistent with our existing statutory and regulatory Part C and D contract termination authority.

Special Election Period for Enrollment in 5-Star MA plans and PDPs

On November 19, 2010, in an HPMS memorandum entitled "Establishing a Special Election Period (SEP) to Enroll in 5-star Medicare Advantage Plans in Plan Year 2012," CMS announced the establishment of an SEP that will allow Medicare beneficiaries eligible for MA plans to enroll in 5-star MA plans at any point during the year. As indicated in the November 19 memorandum, we are providing additional guidance about the new SEP through this call letter.

After consideration of the comments received on the draft call letter, we are making two changes to the scope of the SEP. First, we have expanded the scope of the SEP to include 5-star PDPs, as well as MA plans (including MA-PDs). In addition, we are clarifying that all eligible individuals, including those who are currently in a 5-star MA plan or PDP, may use the SEP to enroll in a new 5-star PDP or MA plan.

Thus, consistent with these changes, the general parameters of the SEP are as follows:

- The SEP is applicable to MA plans and PDPs with an overall plan summary rating of 5 stars regardless of the rating used for purposes of annual quality bonus payments. The summary star rating is provided by CMS prior to the Annual Election Period (AEP) and is effective for the following contract year (January – December).

- The new SEP will apply only for purposes of enrolling in a 5-star MA plan or PDP plan; it cannot be used to enroll in other types of plans (such as section 1876 or 1833 plans). Any individual who meets the applicable MA or PDP eligibility requirements may use the new SEP to enroll in a 5-star PDP or MA plan. However, the SEP does not convey any additional right to select other coverage outside of the normal enrollment periods. Thus, if an individual who is currently enrolled in an MA-PD chooses to instead enroll in a 5-star PDP, that individual must receive his or her health coverage through Original Medicare until the next valid enrollment period. Similarly, if such an individual chooses to instead enroll in a 5-star MA-only plan, that individual could not again elect drug coverage until the next valid enrollment period.
- The annual SEP will be available beginning on December 8, 2011. Enrollment requests made using this SEP will be effective the first of the month following the month the enrollment request is received (January 1 – December 1). Once an individual enrolls in a 5-star MA plan or PDP using this SEP, the individual's SEP ends for that plan year, and the individual will be limited to making changes only during other applicable election periods (e.g., annual enrollment period or another valid SEP). Individuals will be able to enroll in 5-star MA plans and PDPs directly through the plan, or through 1-800-MEDICARE or Medicare.gov.
- Since 5-star ratings are awarded on a calendar year basis, the effective dates of enrollments requested using this SEP are limited to January 1 through December 1 of the calendar year in which the plan has the 5-star rating.
- Plans that have received an overall 5-star rating will be required to accept these SEP requests, similar to any other enrollment request, unless the plan is closed per a CMS-approved capacity limit.
- The SEP is not available to enroll in a plan that does not have an overall 5-star rating, even if the plan receives 5 stars in some rating categories, or if the plan is in the same parent organization.

CMS plans to create a new SEP indicator to be used for plan submitted enrollment transactions and to track the utilization of this SEP. Details on the new indicator will be included in a future CMS system release announcement later in 2011.

II. Part C

Duplicative Plans and Plans with Low Enrollment

The following guidance applies to non-employer MA plans, Chronic Care Special Needs Plans (C-SNPs) and Institutional Special Needs Plans (I-SNPs). Dual-Eligible Special Needs Plans (D-SNPs) remain subject to low enrollment guidance but are excluded from meaningful difference evaluation. Note: We reserve the right to review employer plans for low enrollment and/or meaningful difference in future years.

The large number of MA plan options that have been offered in many areas has made it difficult and confusing for beneficiaries to distinguish between these plans and to choose the best option to meet their needs. MAOs should not submit CY 2012 bids for plans that have insufficient enrollment and/or are not meaningfully different from their other plan offerings in the area.

In 42 CFR § 422.254(a)(5) and 422.256(b)(4)(i), we specify that CMS reviews bids to ensure that an MAO's plans in a given service area are meaningfully different from one another in terms of key benefits or plan characteristics such as cost sharing, benefits offered, or plan type. Using our authority under section 1857(c)(2)(B) of the Act and 42 CFR §422.506(b)(1)(iv), CMS may non-renew plans that do not have sufficient enrollment after a specified length of time. CMS will address low enrollment and duplicative plans for CY 2012 with two separate processes, as described below.

A. Plans With Low Enrollment

During April or May 2011, CMS will send each MAO a list of low enrollment plans that have been in existence for three or more years but, as of April 2011, have fewer than 500 enrollees for non-SNP plans and 100 enrollees for SNP plans. The lists will not include low enrollment plans that CMS determines are located in service areas that do not have a sufficient number of competing options of the same plan type.

Under out authority at 42 CFR §422.506(b)(1)(iv), MAOs must provide a justification for each of the identified low enrollment plans or confirm through return email that the plan will be eliminated or consolidated with another of the organization's plans for CY 2012. If CMS does not find that there is a unique or compelling reason for maintaining a plan with low enrollment, CMS will non-renew the plan. Instructions for how to submit business cases, the timeframe for submissions, and what information is required in those submissions will be included with the list of low enrollment plans sent to the MAO.

CMS recognizes there may be reasonable factors, such as specific populations served and geographic location, which lead to a plan's low enrollment. SNPs, for example, may legitimately have low enrollments because of their focus on a subset of enrollees with certain medical conditions. We will consider all such information when evaluating whether specific plans should be non-renewed based on insufficient enrollment. MAOs are to follow the CY 2012 renewal/non-renewal guidance in this Call Letter to determine whether a low enrollment plan may be consolidated with another plan(s).

B. Duplicative Plan Offerings

MAOs offering more than one plan in a given service area should ensure that beneficiaries can easily identify the differences between the plans and determine which plan provides the highest

value at the lowest cost based on their needs. For CY 2012, CMS will use plan-specific out-of-pocket cost (OOPC) estimates to identify meaningful differences among similar plan types. OOPC estimates are based on a nationally representative cohort of Medicare beneficiaries represented in the Medicare Current Beneficiary Survey data and are used to provide estimated plan cost information to beneficiaries on Medicare Options Compare. Estimated out-of-pocket costs for each plan benefit package are calculated on the basis of utilization patterns for that cohort. The calculation includes Parts A, B, and D services and certain mandatory supplemental benefits, but not optional supplemental benefits. For purposes of evaluating meaningful differences among MA plans, CMS will exclude premiums from the OOPC calculation. Current enrollment and risk scores will not affect the OOPC calculation. A summary of the OOPC estimates is available at: http://www.medicare.gov/MPPF/Include/DataSection/OOPC/OOPCCalculations.asp?language=English.

MAOs have access to CY 2011 OOPC estimates for each of their current plans and can view those OOPC values in HPMS. Part C OOPCs can be viewed in HPMS under: Quality and Performance > Part C Performance Metrics > Part C Out-of-Pocket Costs. On or about April 8, 2011, an OOPC model will be available in SAS software from the CMS website. All documentation and instructions associated with running the OOPC model will be posted on the CMS website on the following page: http://www.cms.gov/PrescriptionDrugCovGenIn/01_Overview.asp#TopOfPage. Organizations can use this information to develop CY 2012 plan bids that comply with CMS requirements.

In response to comments on the February 18, 2011 Advance Notice and Call Letter, CMS will retain for CY 2012 the $20 meaningful difference threshold required in CY 2011. We determined that doing so will help to ensure that plans' initial bids meet the meaningful difference criteria and may help to minimize plans' bid development challenges as they structure plan benefit packages that also satisfy other CMS requirements. Thus, for CY 2012, CMS will evaluate meaningful differences among non-employer plans offered by the same MAO, in the same county, as follows:

1. Non-SNP plan offerings will be separated into five plan-type groups on a county basis: (1) HMO (2) HMOPOS; (3) Local PPO; (4) Regional PPO; and (5) PFFS. SNP plans will be further separated into groups representing the specific target populations served by the SNP. Chronic Care SNPs will be separated by the chronic disease served, and Institutional SNPs will be separated into the following three categories: Institutional (Facility); Institutional Equivalent (Living in the Community); and a combination of Institutional and Institutional Equivalent. D-SNPs are excluded from the meaningful difference evaluation. Please note that using different providers or serving different ethnic populations are not considered meaningfully different characteristics between two plans.

2. Plans within each plan-type group will be further divided into MA-only and MA-PD sub-groups for evaluation. That is, the presence or absence of a Part D benefit is considered a meaningful difference.
3. The combined Part C and Part D OOPC estimate will be calculated for each plan within the plan-type groups and sorted from high to low. There must be a total OOPC difference of at least $20 per member per month between each plan to be considered meaningfully different.

(Note: Employer plans are not included in this evaluation for CY 2012.)

CMS expects MAOs to submit CY 2012 plan bids that meet the meaningful difference requirements but will not prescribe how the MAOs should redesign benefits packages to achieve the differences. Since MAOs have access to the necessary tools to calculate OOPC estimates for each plan prior to bid submission, CMS may not permit revised submissions if a plan's initial bid does not comply with meaningful difference requirements. Ultimately, plan bids that do not meet these requirements will not be approved by CMS. MAOs are to follow the CY 2012 renewal/non-renewal guidance in this Call Letter to determine if their plans may be consolidated with other plans.

CY 2012 Cost Sharing Standards

A. Maximum Out-of-Pocket (MOOP) Limits

CMS strives to ensure that MAOs develop more transparent plan benefit designs so that beneficiaries are better able to predict their out-of-pocket costs and also are protected from excessively high or unexpected cost sharing. As provided at 42 CFR § 422.100(f)(4), all local MA plans (employer and non-employer), including HMOs, HMOPOS, local PPO (LPPO) plans, special needs plans (SNPs) (including Dual-eligible SNPs), and PFFS plans must establish an annual MOOP limit on total enrollee cost sharing liability for Parts A and B services, the dollar amount of which will be set annually by CMS. In addition, as provided at 42 CFR §§ 422.100(f)(5) and 422.101(d)(3) LPPO and RPPO plans, respectively, are required to have a "catastrophic" limit inclusive of both in- and out-of-network cost sharing for all Parts A and B services, the dollar amount of which also will be set annually by CMS. All cost sharing (i.e., deductibles, coinsurance, and copayments) for Parts A and B services must be included in plans' MOOPs. The "catastrophic" maximum out-of-pocket limit is the term used in regulation (§ 422.100(f)(5)) and is synonymous with "combined" maximum out-of-pocket limit used in the PBP and beneficiary marketing materials.

For CY 2012, we do not want to eliminate incentives for organizations to establish lower voluntary MOOP thresholds. Therefore, we will continue to allow MAOs the option of adopting lower, voluntary MOOP limits. MAOs that adopt voluntary MOOP amounts will have more

flexibility in establishing cost-sharing amounts for Parts A and B services than those that do not elect the voluntary MOOP.

Like all other local MA plans, D-SNPs must establish a MOOP limit to provide this enrollee protection even though the State Medicaid program is usually paying those costs on the enrollee's behalf. Enrollees' eligibility for Medicaid may change during the year, leaving the enrollee liable for cost sharing. We strongly encourage D-SNPs to establish MOOP amounts that are greater than $0 to protect the plan from full liability for the cost sharing amounts in the event that an enrollee's Medicaid coverage is discontinued for some period of time. However, adoption of a $0 MOOP is permitted.

Second, although it may be rare that an enrollee of a D-SNP would be responsible for paying any cost sharing because the State Medicaid program is making those payments on his behalf, the PBPs for D-SNPs must reflect the plan's actual out-of-pocket cost sharing charges for covered services as well as a valid MOOP amount. Additionally, the plan must track each enrollee's cost sharing expenditures. The PBP will not be acceptable without entry of a valid MOOP amount.

For purposes of tracking out-of-pocket spending relative to its MOOP limit, a D-SNP must count only the enrollee's actual out-of-pocket spending. Thus, for any D-SNP enrollee, MA plans must count only those amounts the individual enrollee is responsible for paying net of any State responsibility or exemption from cost sharing toward the MOOP limit rather than the cost-sharing amounts for services the plan has established in its plan benefit package. Effectively, this means that D-SNP enrollees who are not responsible for paying the Medicare Parts A and B cost sharing will rarely reach the MOOP limit.

Since implementation of the Medicare Modernization Act of 2003, RPPOs have been required to establish a MOOP for in-network cost sharing and a catastrophic limit inclusive of both in- and out-of-network cost sharing for Parts A and B services, but had the discretion to set those amounts. For CY 2011, we encouraged RPPOs to adopt either the mandatory or voluntary MOOPs established by CMS.

We proposed in our November 22, 2010 Notice of Proposed Rulemaking (75 FR 71233) to require RPPOs to establish MOOP amounts that are consistent with the limits established each year by CMS. If this proposal is finalized RPPOs would be required to establish both in-network and combined in- and out-of-network (catastrophic) MOOP limits like LPPOs for CY 2012 consistent with the voluntary and mandatory MOOP levels established by CMS for all Parts A and B covered services.

The dollar amounts for the **mandatory, voluntary** and **catastrophic** MOOPs will be set annually by CMS.

Mandatory MOOP The amount CMS sets as the highest limit for enrolled beneficiary in-network cost sharing for Parts A and B services for the contract year.

Voluntary MOOP An amount lower than the CMS established mandatory MOOP. Plans may voluntarily adopt this limit or a lower amount in exchange for increased flexibility in establishing cost sharing amounts for Parts A and B services.

Catastrophic MOOP The amount CMS sets as the highest limit charged by LPPOs and if our proposed rule is finalized, beginning CY 2013 by RPPOs, for the combined in-and out-of-network cost sharing for Parts A and B services for the contract year. The catastrophic MOOP amount is calculated as 1.5 times the mandatory or voluntary MOOP amount, as applicable to the plan.

Plans are responsible for tracking enrolled beneficiaries' out-of-pocket spending and to alert them and plan providers when the spending limit is reached. As stated above, D-SNPs also must track enrollee cost sharing but should include only those amounts the enrollee is responsible for paying net of any State responsibility or exemption from cost sharing.

The chart below provides the CY 2012 mandatory MOOP amount that MA plans may not exceed, the maximum voluntary MOOP amount that, if adopted, would result in less scrutiny of individual service category cost sharing, and the catastrophic MOOP amounts applicable to LPPOs and RPPOs.

CY 2012 Voluntary and Mandatory MOOP Amounts By Plan Type

Plan Type	Voluntary	Mandatory
HMO	$3,400	$6,700
HMO POS	$3,400 In-network	$6,700 In-network
Local PPO	$3,400 In-network and $5,100 Catastrophic*	$6,700 In-network and $10,000 Catastrophic*
Regional PPO**	$3,400 In-network and $5,100 Catastrophic*	$6,700 In-network and $10,000 Catastrophic*
PFFS (full network)	$3,400 In- and out-of-network	$6,700 In- and out-of-network
PFFS (partial network)	$3,400 In- and out-of-network	$6,700 In- and out-of-network
PFFS (non-network)	$3,400	$6,700

*Catastrophic MOOP is inclusive of in- and out-of-network Parts A and B services.

** If our proposal to require RPPOs to offer MOOP amounts consistent with those required for LPPOs, the amounts shown apply for CY 2012.

The MA MOOP amounts are based on a beneficiary-level distribution of Parts A and B cost sharing for individuals enrolled in Original Medicare. The mandatory MOOP amount represents approximately the 95th percentile of projected beneficiary out-of-pocket spending for CY 2012. Stated differently, 5 percent of Original Medicare beneficiaries are expected to incur $6,700 or more in Parts A and B deductibles, copayments and coinsurance in CY 2012. The CY 2012 voluntary MOOP amount will be $3,400. This level was established for CY 2012 because, consistent with established methodology, it represents approximately the 85th percentile of projected Original Medicare out-of-pocket costs.

We determined the catastrophic MOOP amounts applicable to LPPOs and proposed for RPPOs, by multiplying the respective MOOP amounts by 1.5 for the relevant year. Thus, the voluntary catastrophic MOOP amount for CY 2012 is calculated as $3,400 x 1.5 = $5,100. Similarly, the mandatory catastrophic MOOP amount for CY 2012 is calculated as $6,700 x 1.5 = $10,000 (with rounding).

For further discussion on MOOP and how it is shown in D-SNPs' Summary of Benefits (SB), please refer to the section entitled "Changes to 2012 Summary of Benefits Regarding Dual Eligible SNP Cost Sharing" on page 135 of this Call Letter.

B. Total Beneficiary Cost (TBC)

CMS will again exercise its authority under section 1854(a)(5)(C)(ii) of the Affordable Care Act to deny bids, on a case by case basis, if it determines that the bid proposes too significant an increase in cost sharing or decrease in benefits from one plan year to the next. We note that we proposed to codify this authority in our November 22, 2010 proposed rule (75 FR 71200-71201) and may provide further guidance following the finalization of that rule.

For CY 2011, CMS established the Total Beneficiary Cost (TBC) metric as a means of evaluating changes in plan benefits from one year to the next, and whether such changes imposed significant increases in cost-sharing or decreases in benefits. TBC is the sum of plan-specific premium and estimated beneficiary out-of-pocket costs. The change in TBC from one year to the next captures the combined financial impact of premium changes and benefit design changes (i.e., cost-sharing changes) on plan enrollees; an increase in TBC is indicative of a reduction in benefits. Note that, for CY 2012, the TBC calculation will include a factor to account for the Part B premium buy-down for those plans that include this additional benefit as part of their benefit package. By limiting excessive increases in the TBC from one year to the next, CMS is able to ensure that beneficiaries who continue enrollment in the same plan are not exposed to significant cost increases from one plan year to the next.

In implementing this approach for CY 2011, we conducted an outlier analysis after bids were submitted, and negotiated with MA organizations about those MA plans that were identified in that analysis as outliers. In the February 18, 2011 Advance Notice and Call letter we solicited comments as to whether we should again analyze the distribution of TBC changes after bid submission and identify outliers, or instead use historical data to identify a TBC change amount in advance and further scrutinize only those bids whose TBC is above the established TBC amount. Under this second approach, we proposed to set the TBC change amount at approximately $36 PMPM (or about a 10% increase) from CY 2011 to CY 2012. We noted that we reserved the ability to adjust this amount following bid submission if the distribution of all bids increase program costs more than anticipated.

We also noted that, under either approach, plans would be required to apply a plan specific adjustment factor to account for geographic and quality bonus payment related changes in each plan's payment rates. This adjustment is needed to return the TBC to the "level playing field" that existed for CY 2011, when plan payment rates were frozen. This adjustment factor would be derived from the projected change in rebate amount from CY 2011 to CY 2012 for a plan's CY 2011 service area, and CMS would provide this factor to each plan shortly after release of the final call letter.

We received many comments, all of which expressed a preference for the second option under which a TBC amount would be provided in advance of the date bids are due, and many asked

that CMS take into consideration the differences in payment rates, the new quality bonus payments, and changes to the rebate percentages by geographic area. Therefore, we plan to implement the second approach for non-employer plans (excluding D-SNPs) as modified in response to these latter comments, and will calculate and provide to each plan an amount that reflects the impact of payment changes and any quality bonus payments for which the plan is eligible. Each plan-specific amount will be an effective TBC limit for that plan. Thus, plans experiencing a net increase in benchmarks/bonus payments will have an effective TBC change amount below the 10% (or $36) amount. Conversely, plans experiencing a net decrease in benchmark and/or bonus payments will have an effective TBC change amount above the 10% (or $36) amount. Based on this analysis, CMS will not deny a bid solely on the grounds that TBC has increased by too much from CY 2011 to CY 2012 if the increase is equal to or less than the plan-specific TBC amount. However, plans whose TBC increases are above their plan-specific amounts would be subject to further scrutiny by CMS, and could be denied. We believe this approach will protect beneficiaries from significant increases in cost sharing or decreases in benefits, while ensuring access to viable and sustainable MA plan offerings. We also note that CMS reserves the right to further examine and to request additional changes to a plan bid, even if its TBC change is within the plan-specific TBC change amount, if we find it is in the best interest of the MA program.

For plans that consolidate multiple CY 2011 plans into a single CY 2012 plan, CMS will use the enrollment-weighted average of the CY 2011 plan values to calculate TBC. Otherwise, these plans will be treated as any other plan for the purpose of enforcing the TBC requirement.

C. Discriminatory Cost Sharing Assessments

For CY 2012, CMS has established three benefit discrimination assessments for all MA plans (employer and non-employer):

1. Per Member Per Month (PMPM) Actuarially Equivalent (AE) Cost Sharing Maximums;
2. Service Category Cost Sharing Standards; and
3. Discriminatory Pattern Analysis.

The PMPM actuarial equivalent cost sharing maximums and service category cost sharing standards described below are provided in advance of the bid submission deadline with the expectation that all CY 2012 plan bids will conform to these standards when submitted on or before June 6, 2011. CMS will perform a discriminatory pattern analysis following bid submission to identify and resolve discriminatory benefit design elements not anticipated by the standards.

Please note that benefit design and cost sharing amounts approved for CY 2011 will not be automatically acceptable for CY 2012 because a separate and distinct review is conducted each contract year.

1. Per Member Per Month (PMPM) Actuarial Equivalent (AE) Cost Sharing Maximums

Total MA cost sharing for Parts A and B services must not exceed cost sharing for those services in Original Medicare on an actuarially equivalent basis. CMS will also apply this requirement separately to the following service categories for CY 2012: Inpatient Facility, Skilled Nursing Facility (SNF), Home Health, Durable Medical Equipment (DME), and Part B drugs.

Whether in the aggregate, or on a service-specific basis, excess cost sharing is identified by comparing two values found in Worksheet 4 of the Bid Pricing Tool (BPT).

Specifically, a plan's PMPM cost sharing for Medicare covered services (BPT Worksheet 4, Section IIA, column l) is compared to Original Medicare actuarially equivalent cost sharing (BPT Worksheet 4, Section IIA, column n). For inpatient facility and SNF services, the AE Original Medicare cost sharing values, unlike plan cost sharing values, do not include Part B cost sharing; therefore, an adjustment factor is applied to these AE Original Medicare values to incorporate Part B cost sharing and to make the comparison valid.

Once the comparison amounts have been determined, excess cost sharing can be identified. Excess cost sharing is the difference (if positive) between the plan cost sharing amount (column #1) and the comparison amount (column #5). The chart below uses illustrative values to demonstrate the mechanics of this determination.

Illustrative Comparison of Service-Level Actuarial Equivalent Costs to Identify Excessive Cost Sharing

	#1	#2	#3	#4	#5	#6	#7
BPT Benefit Category	PMPM Plan Cost Sharing (Parts A&B) *(BPT Col. l)*	Original Medicare Allowed *(BPT Col. m)*	Original Medicare AE Cost sharing (Part A only) *(BPT Col. n)*	Part B Adjustment. Factor to Incorporate Part B Cost Sharing (Based on FFS data)	Comparison Amount *(#3 × #4)*	Excess Cost Sharing (#1 − #5)	Pass/ Fail
Inpatient	$33.49	$331.06	$25.30	1.366	$34.56	$0.00	Pass
SNF	$10.83	$58.19	$9.89	1.073	$10.61	$0.22	Fail
Home Health*	TBD	TBD	TBD	TBD	TBD	TBD	Pass
DME	$3.00	$11.37	$2.65	1.000	$2.65	$0.35	Fail
Part B-Rx	$0.06	$1.42	$0.33	1.000	$0.33	$0.00	Pass

* Home health has no cost sharing under Original Medicare, so the comparison amount (#5) is calculated by multiplying the Medicare allowed amount (#2) by the Part B Adjustment Factor (#4).

2. Service Category Cost Sharing Standards

As provided under 42 CFR § 422.100(f)(6), we may specify service categories for which the cost sharing charged by MA plans may not exceed levels annually determined by CMS to be discriminatory. For purposes of setting cost sharing thresholds for Parts A and B services, CMS reviews the prior year's bid data, as well as actuarial equivalency relative to Original Medicare, in order to identify cost sharing requirements.

Similar to last year, CMS is focusing these standards on those Parts A and B services that are more likely to have a discriminatory impact on sicker beneficiaries. The standards are based on a combination of patient utilization scenarios and Original Medicare. The scenarios reflect factors such as hospital lengths of stay and the number of physician office visits generated by average-to-sicker patients. Some service categories have multiple utilization scenarios in an effort to ensure that plans will consistently distribute cost sharing amounts in a manner that does not discriminate.

We are continuing our current policy of offering MA plans the option to have greater flexibility in establishing Parts A and B cost sharing than is available for plans that adopt the mandatory MOOP by adopting a lower voluntary MOOP limit.

The chart below summarizes the standards and cost sharing amounts by MOOP type (e.g., mandatory or voluntary) for local and regional MA plans. CY 2012 plan bids must reflect enrollee cost sharing for in-network services that is not greater than the amounts displayed below. For LPPOs and RPPOs, these standards will be applied only to in-network services. All standards are inclusive of applicable service category deductibles, copayments and coinsurance, but do not include plan level deductibles.

CY 2012 In-Network Service Category Cost Sharing Requirements

Cost Sharing Limits			
Service Category	**PBP Section B data entry field**	**Voluntary MOOP**	**Mandatory MOOP**
Inpatient - 60 days	1a	N/A	$3,935
Inpatient - 10 days	1a	$2,231	$1,785
Inpatient - 6 days	1a	$2,016	$1,613
Mental Health Inpatient - 60 days	1b	$2,471	$1,977
Mental Health Inpatient - 15 days	1b	$1,796	$1,437
Skilled Nursing Facility – First 20 Days[1]	2a	$100/day	$50/day
Skilled Nursing Facility – Days 21 through 100[1]	2a	$146/day	$146/day
Home Health	6a	TBD	$0
Primary Care Physician	7a	$35 co-pay	$35 co-pay
Chiropractic Care	7b	$20 co-pay	$20 co-pay
Physician Specialist	7d	$50 co-pay	$50 co-pay
Psychiatric Services	7e and 7h	$40 co-pay	$40 co-pay
Therapeutic Radiological Services	8b	20% or $60 co-pay	20% or $60 co-pay
DME-Equipment	11a	N/A	20%
DME-Prosthetics	11b	N/A	20%
DME-Medical Supplies	11b	N/A	20%
DME-Diabetes Monitoring Supplies	11c	N/A	20% or $10 co-pay
DME-Diabetic Shoes or Inserts	11c	N/A	20% or $10 copay
Renal Dialysis	12	20% or $30 co-pay	20% or $30 co-pay
Part B Drugs-Chemotherapy[2]	15	20% or $75 co-pay	20% or $75 co-pay
Part B Drugs-Other	15	20% or $50 co-pay	20% or $50 co-pay

1. MA plans may have cost sharing for the first 20 days of a SNF stay, consistent with cost sharing guidance. The per-day cost sharing for days 21 through 100 must not be greater than the Original Medicare SNF amount. Total cost sharing for the overall SNF benefit must be actuarially equivalent with Original Medicare.
2. Home health cost sharing policy for CY 2012 will be determined in the current notice and comment rulemaking process (75 FR 71190)
3. Chemotherapy includes administration services. Chemotherapy drugs and administration services in an inpatient setting are covered under the MA plan's inpatient benefit coverage.

3. Discriminatory Pattern Analysis

Following CY 2012 plan bid submissions, CMS will ensure that MA plans conform to the cost sharing requirements. In addition, CMS will analyze bids to ensure that discriminatory benefit designs are identified and corrected. This could include bids that meet standards but have cost

sharing amounts that are distributed in a manner that may discriminate against sicker, higher-cost patients. This analysis may also evaluate the impact of benefit design on patient health status and/or certain disease states. CMS will contact plans to discuss and correct any issues that are identified as a result these analyses.

Other Cost Sharing Policy Issues

A. Multi-Year Benefits

In the February 18, 2011 Advance Notice and Call Letter we shared our concern that allowing MA plans and section 1876 cost contract plans to offer benefits and cost sharing that span multiple contract years, multi-year benefits, is inconsistent with its goal to provide beneficiaries with plan choices that are easy to understand. We expressed our beliefs that a benefit that spans multiple contract years is confusing to many enrolled beneficiaries because it requires them to keep track of which services have been received and which are unused, across years and that multi-year benefits complicate the comparison of plans by beneficiaries during the open enrollment periods. We proposed to make no change to policy for CY 2012 but we encouraged plans to limit CY 2012 benefit offerings to one contract year in order to minimize the potential for beneficiary confusion.

We received many comments on this topic expressing both support for discontinuation of multi-year benefit offerings and opposition to such a policy. Many of the commenters stated that some benefits are more appropriately offered over a multi-year period and that plans would be unable to afford to offer some benefits at all (e.g., denture and eyewear coverage) if they are not permitted to offer the benefit over more than one year. The commenters who were in favor of limiting plans' benefit offerings to one contract year stated that they shared CMS' concerns about beneficiaries being able to compare plans when some offer multi-year benefits and enrollees being able to keep track of their benefits while in the plan. These commenters also stated their belief that having benefits that span contract years can act as a disincentive for beneficiaries to actively compare plans annually and make choices that meet their needs.

We understand that some benefits are appropriately offered over multiple years, but continue to encourage plans to limit offerings to one contract year where possible.

B. Copayment and Coinsurance for the Same Service

We have found that, as is allowed for PBP data entry, a small number of plans enter both coinsurance and copayment amounts for the same service categories, presumably to capture variation in the plan's contracting agreements. We want to enable plans to accurately reflect their benefit packages in the PBP but also are committed to ensuring that plan benefits and cost sharing are easily understood by beneficiaries and that an enrollee is not charged both a

coinsurance and a copayment for the same service. In our work to revise the PBP for CY 2012, we performed analyses to see how often plans were entering both coinsurance and copayment amounts for the same service categories. We were pleased to find that very few plans entered both types of cost sharing values for any service category in the CY 2011 bids and determined that we would be interested in simplifying the PBP by enabling plans to enter only one type of cost sharing for each of the service categories.

We received many comments on this topic both from commenters who share CMS' concerns about permitting both types of cost sharing for the same service category and from those that assert that there is a legitimate need to maintain that capability in the PBP. They explained that the PBP needs to accept both types of cost sharing in some service categories because, as plans contract with various providers, they must have the flexibility to agree to copayment arrangements with some and coinsurance arrangements with others.

Therefore, for CY 2012, we continue to discourage plans from entering both types of cost sharing for any service category, but will not disallow those entries because we understand that, as reflected in the comments, to offer enrollees the most effective network of providers, plans need the flexibility to contract with different service settings (for example, freestanding imaging center, hospital outpatient department) to furnish services within a service category and they may require varying cost sharing arrangements. Plans must make those differences in cost sharing transparent to beneficiaries through the ANOC, EOC, SB sentences and marketing materials and ensure that enrollees are not charged twice for the same service.

C. PBP Notes

CMS' longstanding policy requires that the Notes sections in the PBP may be used to provide additional information about the benefit that is being offered. The information in the note must not contain any cost sharing for the benefit/service that is not reflected in the PBP data entry field for the benefit/service. Any information in a note must be consistent with the benefit/service as it is reflected in the PBP data entry fields. The Notes must not be used to enter additional benefits, conditions for coverage or cost sharing charges because that information is not captured to generate summary of benefits (SB) sentences that would make it available to beneficiaries. All cost sharing must be transparent and readily accessible to beneficiaries as they make plan comparisons. Plans may request hard copy SB changes that can be used to relay to beneficiaries more detailed, additional information about the benefit offered.

We received a number of comments on this topic urging CMS to make the PBP more flexible to enable entry of more complex cost sharing arrangements. The commenters stated that plans are currently unable to enter all of their cost sharing arrangements in the PBP and sometimes must use the notes to reflect required cost sharing, especially for out-of-network services.

We thank the commenters for sharing their opinions with us. We have already completed the revisions to the PBP for the upcoming CY 2012 bid submissions and can make no further revisions at this time, but, as we move forward with revisions to the PBP for CY 2013, we will make every effort to ensure that it accommodates plans' entries for any acceptable cost sharing strategies.

D. Supplemental Benefits for Section 1876 Cost Plans

Although cost contracts are prohibited from offering mandatory supplemental benefits, CMS has permitted cost contracts to include collections of optional supplemental benefits in addition to their basic Parts A and B benefits as separate plan benefit package (PBPs) in order to indicate to potential enrollees in Medicare Plan Finder and Medicare & You that optional supplemental benefits are available. CMS does not, however, consider such collections of optional supplemental benefits as separate plan benefit packages, and cost contracts cannot require that potential enrollees choose one of the collections of supplemental benefits in order to enroll. If a cost contract wishes to discontinue a package of optional supplemental benefits for a subsequent contract year, CMS does not consider this a termination of a PBP. Any cost optional supplemental package marked as "terminated" for Contract Year (CY) 2012 will be required to be crosswalked via the plan crosswalk to another supplemental package offered by the cost contract. Cost contracts in this situation must transition enrollees to the cost contract's basic Parts A and B package – with or without Part D depending on the enrollee's original election – via the HPMS Plan Crosswalk. Additional detail on this issue is provided in the renewal/non-renewal guidance in this Call Letter.

Changes to 2012 Summary of Benefits Regarding Dual Eligible SNP Cost Sharing

CMS is changing the structure of the Summary of Benefits (SB) to address an issue related to how the Maximum Out-of-Pocket (MOOP) limit is reflected for D-SNP enrollees. For contract year 2010, CMS added a new requirement in the bid submission, whereby plans were required to have a MOOP limit in their bids, resulting in a MOOP value appearing in the SB (in column 3 under the plan benefit information).

For contract year 2011, CMS provided a temporary solution by allowing plans to submit a hard copy change to add qualifying language via an asterisk, indicating that the amount beneficiaries may have to pay is based on their level of state Medicaid assistance.

For contract year 2012, CMS is making programming changes to the SB sentences to ensure that cost sharing amounts are displayed accurately.

Renewal Material Timelines Given AEP Changes

Due to the statutory changes to the Annual Enrollment Period (AEP), the CY 2012 standardized, combined Annual Notice of Change (ANOC)/Evidence of Coverage (EOC) documents are due to current members of all MA plans, MA-PD plans, PDPs, and cost-based plans offering Part D by September 30, 2011. Organizations are not required to mail the Summary of Benefits (SB) to existing members when using the combined, standardized ANOC/EOC; however the SB must be available upon request.

In addition to the ANOC/EOC documents, organizations must provide the LIS rider and formulary, if applicable, to enrollees for receipt by September 30, 2011. Plan sponsors should note that no other materials regarding 2011 plan offerings may be sent prior to the beginning of marketing activities on October 1, 2011.

CMS received numerous comments on the short timeframes available for plans to meet the September 30 mailing date of the ANOC/EOC and LIS rider as well as requests to move up the marketing start date to September 1 instead of October 1. We believe that the new schedule – with marketing beginning on October 1, and the AEP beginning 15 days later – actually reduces confusion for beneficiaries and plans, and are therefore retaining the October 1 start date. In prior years, plans were able to begin marketing well in advance of the AEP, but beneficiaries could not submit enrollment requests until the AEP began on November 15. Beneficiaries were often confused by this discrepancy and submitted enrollment forms in advance of the AEP, which the organization then had to "hold" until November 15. While we realize that plans will have less time to market prior to the start of the AEP, they will be able to continue marketing throughout the AEP, and beneficiaries will receive information from CMS (via the Medicare Handbook, by contacting 1-800-MEDICARE) throughout that time, and will be able to obtain the information they need to make an informed choice by the time the AEP ends on December 7.

III. Part D

Generic Samples Paid for Through Part D Sponsors' Administrative Costs

As described in section 60.2 of Chapter 7 of the Prescription Drug Benefit Manual, CMS allows Part D sponsors the option to provide OTCs as part of their administrative cost structure when a component of a cost-effective drug utilization management program and without any cost sharing on the part of the beneficiary at the point-of-sale. We have been asked whether the provision of generic samples in physician offices could be similarly treated under Part D and are now providing this guidance, effective immediately. Sponsors may incur expenses related to distribution of and reporting on generic drug samples, provided to members within a physician's office setting, under the plan's administrative cost structure if doing so is consistent with a cost effective drug utilization management program. Any provision of generic samples must be conducted consistent with the requirements of the Prescription Drug Marketing Act, 21 USC

§353 and the Food and Drug Administration's implementing regulations at 21 CFR Part 203. A drug sample, as defined by 21 CFR §203.3(i), means a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug. To clarify, for purposes of this analysis, a generic drug sample is a "unit of a prescription drug, limited to a drug subject to an application approved under section 505(j) of the Federal Food, Drug, and Cosmetic Act, which is not intended to be sold and is intended to promote the sale of the drug." A brand drug sample is "a unit of a prescription drug, limited to a drug subject to an application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act, which is not intended to be sold and is intended to promote the sale of the drug." Drug samples do not meet the definition of a covered Part D drug under 42 CFR §423.100 because they are not dispensed at a network pharmacy nor are they consistent with our out-of-network pharmacy coverage requirements stated at 42 CFR § 423.124. In other words, drug samples do not meet the emergency definition (42 CFR §124 (a)(1)) and do not represent Part D drugs, unlike vaccines, which are appropriately dispensed and administered by physicians (42 CFR §124 (a)(2)).

Given that generic samples do not meet the definition of a Part D drug, Part D sponsors cannot include the provision of samples as part of their benefit structure. Thus, such samples would not be placed on formulary tiers, and like similarly treated OTC products, such samples must be provided to enrollees without cost sharing requirements. However, in contrast to our related policy on the use of OTC products as part of a utilization management program (See Prescription Drug Manual, Chapter 7, Section 60.2), generic samples may not be incorporated into step-therapy protocols because all enrollees would not have equal access to such samples. More broadly, Part D sponsors may not require beneficiaries to use generic samples under any conditions. CMS recognizes that generic drug samples may be an effective utilization management tool used to promote compliance with a new drug therapy. By facilitating access to trial supplies of less costly generic versions of Part D drugs, plan sponsors can enhance their enrollees' experience in Part D by reducing their current and future cost sharing expenses. In the case of low income subsidy entitled beneficiaries, facilitating medication starts on generic versions of drugs also helps to limit federal low income cost sharing subsidy reimbursements and overall program costs to the Trust Fund. Therefore, we believe that Part D sponsors may contract with vendors to provide access to and reporting on generic drug samples as part of their drug utilization management program as an incentive to reduce drug costs by promoting the use of lower cost generic medications (We expect that Part D sponsors will have the appropriate business associate agreements with the vendors providing generic sample to Part D beneficiaries. The business associate agreement should require that a beneficiary's protected health information only be used for transactions directly related to providing a generic sample to the Part D beneficiary and reporting the beneficiary's receipt of a generic sample to the Part D sponsor).

If desirable, Part D sponsors should account for such costs when developing their 2012 bids, but may also contract for such services in 2011 if they determine that doing so under their utilization

management programs would be an offset to their prescription drug costs. CMS currently has no plans to require reporting on generic samples provided to Part D beneficiaries through PDE reporting, or otherwise.

In making this clarification, we specifically distinguish generic samples from brand samples. We believe that the provision of brand name drug samples would not be an appropriate use of administrative costs and would not be consistent with the requirements relating to drug utilization management at 42 CFR §423.153(b), which direct Part D sponsors to establish a drug utilization management program that includes incentives to reduce costs when medically appropriate.

Applying Best Available Evidence Policy to Beneficiaries of Home and Community Based Waiver Services

Section 3309 of the Affordable Care Act (the ACA) eliminates Part D cost sharing for full-benefit dual-eligible individuals who would be institutionalized individuals, if they were not receiving home- and community-based services (HCBS) under Title XIX of the Act.

The elimination of Part D cost sharing applies to all full-benefit dual-eligible individuals receiving HCBS under an HCBS waiver authorized for a State under section 1115 of the Act, subsections (c) or (d) of section 1915 of the Act, under a State plan amendment under subsection (i) of such section, or services provided through enrollment in a Medicaid managed care organization with a contract under section 1903(m) or section 1932 of the Act. HCBS eligibility is not based on where an individual resides. In other words, sponsors cannot assume that all beneficiaries residing in assisted living facilities receive HCBS and therefore qualify for the $0 cost sharing. Thus, in order to receive the waiver under Section 3309, a plan sponsor must determine or a beneficiary must demonstrate that s/he is a full-benefit dual-eligible Individual receiving HCBS under Title XIX. This provision will be implemented effective January 1, 2012.

Section 70.5 of Chapter 13 in the Medicare Managed Care manual already includes a list of acceptable documents that may be used to demonstrate Medicaid eligibility, if a beneficiary is not already in CMS' data systems as a full-benefit dual-eligible. We will be updating Chapter 13 to also include a list of acceptable documents that may be used as best available evidence (BAE) for demonstrating receipt of HCBS, such as:

a) A copy of a State-issued Notice of Action, Notice of Determination, or Notice of Enrollment that includes the beneficiary's name and HCBS eligibility date during a month after June of the previous calendar year;
b) A copy of a State-approved HCBS Service Plan that includes the beneficiary's name and effective date beginning during a month after June of the previous calendar year;

c) A copy of a State-issued prior authorization approval letter for HCBS that includes the beneficiary's name and effective date beginning during a month after June of the previous calendar year; or
d) Other documentation provided by the State showing HCBS eligibility status during a month after June of the previous calendar year.

We are committed to working closely with states to clarify the contents of the state file submissions and the BAE policy for HCBS. The data that CMS receives from the states identifying full-benefit dual-eligible individuals receiving HCBS will generate copay level 3 ($0) for these individuals, effective January 1, 2012. Plan sponsors must use this information to update their own systems as necessary to reflect $0 Part D cost sharing for their qualified Part D enrollees.

Monitoring the Implementation of Transition Policy

In CY 2011 CMS required Part D sponsors to complete transition attestations in HPMS and submit a transition policy and implementation statements through the CMS Part D transition mailbox. The CY 2011 review revealed many polices were deficient and did not adequately address all attestations. CMS spent a significant amount of time reviewing updated policies and providing technical assistance and guidance to Part D sponsors to bring the policies into compliance with the regulatory requirements. Despite CMS' efforts to work with plans to achieve approvable transition policies, subsequent audits revealed that Part D sponsors were not implementing the transition policies appropriately in their claims adjudication systems. Therefore, beneficiaries were not receiving their required transition supplies, which is a basic protection of the Part D program to ensure continuity of care. On August 27, 2010, CMS issued an HPMS memo to provide additional clarification to Part D sponsors on the transition benefit.

As a result of the audit findings, CMS remains concerned with whether Part D sponsors are appropriately implementing the transition policy. CMS is exploring several methods to determine if Part D sponsors are implementing their transition policy consistent with CMS' guidance and applicable regulations. CMS will require that Part D sponsors provide documentation that their transition policy is correctly implemented in their claims system and that beneficiaries are receiving their required transition supplies. This documentation may require the sponsor to submit any or all of the following: (1) up to one quarter's worth of denied claims for 2012; (2) test claims for new beneficiaries; (3) identification of new beneficiaries and documentation of paid claims for transition supplies; or (4) evidence of transition supplies provided across contract years.

Medication Therapy Management (MTM) Services and Racial Disparities

In August 2010, Health Services Research (HSR), an organization that publishes findings from investigations in the field of health care to help improve the health of individuals and communities, published findings from a research study under the title "Disparity Implications of Medicare Eligibility Criteria for Medication Therapy Management Services." (Wang et al. 2010. "Disparity Implications of Medicare Eligibility Criteria for Medication Therapy Management Services." *Health Services Research 45 (4*): 1061-1082.) The objective of the research study was to determine if there were racial and ethnic disparities in meeting eligibility criteria for MTM services provided for Medicare Part D beneficiaries. The report findings suggest that Hispanic and African American beneficiaries could have a lower likelihood of meeting the MTM eligibility criteria when compared to whites based on the original MTM eligibility thresholds in 2006 and the new thresholds beginning in 2010. The study also found that there was disparity among beneficiaries with severe health problems. There are important implications for the Part D program considering these findings are consistent with other literature which suggests that minorities have lower utilization of drugs and health services in general, and the MTM eligibility criteria are based on utilization. The Part D benefit requires prescription drug sponsors to establish a MTM program to optimize therapeutic outcomes for targeted beneficiaries who meet high risk criteria, but currently a potentially vulnerable segment of the population may not be targeted accurately to receive MTM services.

CMS is conducting an analysis to verify the report's findings. As a first step of the analysis, CMS is replicating the analysis conducted in the HSR study using a larger sample of beneficiaries and will also investigate potential racial disparities using the plan-reported MTM data which reflects actual experience. If the report findings are validated, CMS may consider changes to the MTM eligibility thresholds in future rulemaking. Sponsors have had flexibility to determine the first two elements that make up the definition of MTM targeted beneficiaries, and CMS has put in place additional restrictions to define these elements beginning in 2010. CMS appreciates the comments sponsors made to the draft Call letter regarding the MTM eligibility criteria that could be used to target individuals who would otherwise receive a disparate level of care. We strongly encourage sponsors to continue to examine their defined MTM targeting criteria and implement or pilot any changes to the criteria as needed to minimize racial disparities in MTM eligibility. We look forward to additional sponsor input as we further evaluate and develop this area of our MTM policies.

Reassignment Policy for 2012

In the fall of 2011, CMS will again reassign auto-enrolled low income subsidy (LIS) beneficiaries who are in a PDP that has a premium at or below the LIS benchmark in 2011, but above the LIS benchmark in 2012, as well as all LIS beneficiaries whose PDP is terminating for 2012. CMS will also reassign beneficiaries who remain LIS-eligible as of January 1, 2012, and

are in Medicare Advantage plans that are terminating in 2012. Consistent with section 3303 of the Affordable Care Act (ACA), PDPs that volunteer to waive a de minimis amount of the premium will no longer lose LIS beneficiaries to reassignment based on the fact that their monthly premium exceeds the low-income benchmark; however, such PDPs will not receive reassignments and auto-enrollments. We anticipate establishing the de minimis amount in August 2011. Details of the reassignment process may be found in section 40.1.5 of the PDP Eligibility, Enrollment, and Disenrollment Guidance, available on our website at: http://www.cms.gov/MedicarePresDrugEligEnrol/Downloads/FINALPDPEnrollmentandDisenrollmentGuidanceUpdateforCY2011.pdf.

Consistent with section 40.1.5 of the enrollment guidance, CMS will first reassign beneficiaries within the same organization if the organization offers another qualified PDP in the same region, either under the same contract number, or if that is not available, under a different contract number sponsored by the same parent organization. If the organization does not offer another qualifying PDP, CMS will randomly reassign affected beneficiaries to other PDP sponsors that have at least one qualifying PDP in that region. CMS will follow the two-step process used for auto-enrollment, i.e., random distribution first at the organization level, then randomly among qualifying PDPs within the organization (see section 40.1.4.C).

Note that organizations under an enrollment sanction will not receive reassignments, either from within their organization or through the random reassignment process. Thus, if a sanctioned organization offers a PDP with a 2011 premium below the low-income benchmark amount and that PDP's premium will be above this threshold for 2012—resulting in premium liability for LIS beneficiaries—affected enrollees in that PDP will be randomly reassigned to other PDPs in the region with a premium at or below the LIS benchmark amount.

Benefit Design

Low Enrollment Plans (Stand-alone PDPs only)

CMS has the authority under to 42 CFR §423.507(b)(1)(iii) to non-renew plans (at the benefit package level) that do not have sufficient number of enrollees to establish that they are viable plan options. Consistent with that authority, we will again be scrutinizing low-enrollment plans during the bid review period and will expect that sponsors will have withdrawn or consolidated low-enrollment plans prior to submitting bids for CY 2012. This guidance applies to non-employer stand-alone Part D plans since CMS previously granted a waiver of 42 CFR §423.512(a) (minimum enrollment requirements) for sponsors of employer group plans. We reserve the right to reconsider this waiver in the future.

CMS intends to notify Part D sponsors in writing in April 2011, concerning the plans the agency considers to be low enrollment plans that may need to be withdrawn or consolidated . We expect

to particularly examine plans that constitute the lowest quintile (20%) per region of 2011 plans ranked by enrollment. As of February 2011, the lowest quintile was comprised of 173 plans, with an average of 5 plans per each of the 34 PDP regions. These plans had a total enrollment of 79,953 beneficiaries, with an average of 462 enrollees and a median enrollment of 273 per plan. The actual plan enrollments ranged from a low of 4 to a high of 2,490 beneficiaries. While we are particularly concerned about the smallest plans, we urge sponsors to consider withdrawing or consolidating any stand-alone plan with less than 1,000 enrollees. Sponsors are strongly encouraged to view data on plan enrollment count at: www.cms.hhs.gov/MCRAdvPartDenrolData/ to determine if any of their plans fall into the lowest quintile.

Before CMS would take any action to non-renew a plan pursuant to 42 CFR §423.507(b)(1)(iii), CMS would take into account all relevant factors, including, but not limited to: (1) whether the plan is a basic plan offered to meet the regulatory requirement in 42 CFR § 423.104(f)(2) that a PDP sponsor may not offer enhanced alternative coverage in a service area unless the sponsor also offers a basic drug plan in the area, in which case CMS would renew the basic plan;(2) whether the plan was a new plan and if it has been in existence for three or more years; (3) whether the plan is offered nationally; (4) the total number of plan offerings in the applicable region; and (5) if the plan's premium currently falls at or below the low income benchmark premium amount.

Meaningful Differences in Part D Coverage

As part of the bid negotiation process, CMS seeks to ensure a proper balance between affording beneficiaries a wide range of plan choices and avoiding undue beneficiary confusion in making coverage selections. Part D regulations require that plan offerings by sponsors represent meaningful differences to beneficiaries with respect to benefit packages and plan cost structures. Pursuant to § 423.272(b)(3)(i), CMS will only approve a bid submitted by a Part D sponsor if its plan benefit package or plan cost structure is substantially different from those of other plan offerings by the sponsor in the service area with respect to key characteristics such as premiums, cost-sharing, formulary structure, or benefits offered. Section 423.265(b)(2) also requires that Part D sponsors' bid submissions in the same service area reflect differences in benefit packages or plan costs that we determine to represent substantial differences from each other.

Again for 2012, CMS will be waiving the meaningful differences requirements of sections 42 CFR 423.272(b)(3)(i) and 423.265(b)(2) to allow sponsors of employer group plans (800 series and direct contract plans) to submit, and seek approval of, employer plan benefit packages that do not meet the meaningful differences requirements. We reserve the right to reconsider this waiver in the future.

As noted last year in the 2011 Part D Plan Benefit Package (PBP) Submission and Review Instructions, CMS does not believe that sponsors can demonstrate meaningful differences based on expected Cost-Sharing Out-of-Pocket Costs (OOPCs) between two stand-alone basic Part D benefit designs and maintain both the statutory actuarial equivalence requirements and fulfill the requirement in §423.153(b) to maintain cost-effective drug utilization review programs. Therefore, sponsors again for the 2012 contract year should submit only 1 basic offering (where basic offering includes defined standard, actuarial equivalent and basic alternative drug benefit types) for a stand-alone prescription drug plan (PDP) in a service area. As in prior years, CMS will negotiate with Part D sponsors to offer no more than 3 stand-alone prescription drug plan offerings in a service area, resulting in a mix of 1 basic and at most, 2 enhanced plans—subject to the following qualifications.

A. Cost-Sharing OOPC Differential Thresholds (Stand-Alone PDPs Only)

To determine if cost sharing and formulary and benefit differences result in meaningful differences for the 2012 Contract Year, CMS expects the Cost-Sharing OOPC differential (exclusive of premium amounts) between a basic benefit offering and an enhanced offering of the same Part D sponsor in the same service area to be at least $22 monthly ($264 annually). In other words, the expected Cost-Sharing OOPCs of the basic plan should be higher by at least $22 monthly than the enhanced offering. This amount has not changed from last year.

CMS will also continue its expectation that where 2 enhanced stand-alone drug plans are offered within the same service area, the second enhanced plan will have a higher value than the first and include coverage of at least some brand drugs in the gap (where "some" is defined as ≥ 10% - 65% of formulary drug entities labeled as brands). In addition, CMS expects that the Cost-Sharing OOPC differential between the two enhanced offerings will be at least $16. In other words, the expected Cost-Sharing OOPCs of the first enhanced offering will be at least $16 higher than the second enhanced offering. Assigning a value to the Cost-Sharing OOPC differential between two enhanced offerings is new this year.

B. Cost-Sharing OOPC Differential Analysis (Stand-Alone PDPs Only)

For the CY 2011 bid submission, CMS used the cost-sharing OOPC amounts in establishing differences between basic and enhanced plans and between low and high value enhanced. Since then, CMS has received questions about our Cost-Sharing OOPC differential analysis. We employ this analysis to establish meaningful differences among basic and enhanced plans across the Part D program, not just between contract offerings. The purpose of the analysis and the setting of the target differential dollar amounts is to ensure that beneficiaries will receive a minimum additional value over basic coverage, and between enhanced coverage offerings, when they select and pay premiums for any enhanced plan. The analysis is not used to evaluate relative levels of all out-of-pocket costs that a beneficiary may incur, but rather, to establish the

difference in cost-sharing incurred among plans as a measure of additional benefits available to the average consumer. For this reason, the analysis is not intended to take plan-level enrollee utilization into account. Similarly, premiums are not included in the calculation because in the case of enhanced plans (as opposed to basic plans), any additional premium exactly offsets the additional benefits, by law. Thus, supplemental premiums cancel out the additional value of the enhanced benefits and do not leave a comparable amount to be compared to the value of basic benefits.

In order to set a value for meaningful differences, CMS must be able to evaluate plan benefit packages (PBPs) on the same yardstick. This is accomplished by running the identical Medicare Current Beneficiary Survey (MCBS) data through each PBP. More specifically, CMS established the targets for differentiation by evaluating expected Cost-Sharing OOPC amounts under each 2011 plan offering by the same sponsor in a service area. For this relative analysis, CMS utilized a uniform market basket of drugs from a representative population of Medicare beneficiaries run through each plan's benefit design. Cost-sharing OOPC estimates were originally calculated using PBP and formulary data available during the 2011 bid review period, but were reevaluated using more recent PBP, formulary, and MCBS data (2005/6) as well as more precise calculations related to additional gap coverage for a subset of drugs on a particular tier or tiers (i.e., partial tier additional gap coverage). The latter calculation includes the MCBS data that will be used for the 2012 OOPC estimates. The chart below depicts a summary of the results of our analysis based on CY 2011 data:

2011 Cost-Sharing OOPC Differential Analysis

August Bid/Formulary Data, 2004/5 MCBS Data						
Plan Comparison	**# of Plans**	**Mean**	**25th**	**50th**	**75th**	**95th**
1st Enhanced Plan vs. Basic Plan	886	-$23.55	-$23.48	-$22.58	-$22.16	-$20.88
2nd Enhanced Plan vs. 1st Enhanced Plan	146	-$15.41	-$16.17	-$16.17	-$13.68	-$13.35
December Bid/Formulary Data, 2005/6 MCBS Data						
Plan Comparison	**# of Plans**	**Mean**	**25th**	**50th**	**75th**	**95th**
1st Enhanced Plan vs. Basic Plan	886	-$27.96	-$32.36	-$28.14	-$25.63	-$17.60
2nd Enhanced Plan vs. 1st Enhanced Plan	146	-$12.29	-$16.25	-$15.93	-$5.78	-$5.78

Using the updated OOPC model with the most current formulary, PBP and MCBS data and a more precise calculation for partial gap coverage, the median monthly difference between basic and enhanced plan offerings increased to nearly $28. However, to maintain consistency in this meaningful differences test while sponsors continue to gain experience calculating OOPC estimates, the minimum monthly threshold value between basic and enhanced plan offerings will remain at $22 for CY 2012. Because the 2011 OOPCs considered partial gap coverage to be the same as full gap, the impact on the partial gap plans was greater as the OOPC differentials decreased further away from the median. This was especially evident in the comparison between enhanced plan offerings (with adjusted OOPC differentials) that were not meaningfully different for these plans. Therefore, for CY 2012, CMS is also finalizing the requirement to use the median monthly cost-sharing OOPC difference of $16 between 2 enhanced plans in the same service area.

C. Cost-Sharing Out-of-Pocket (OOPC) Software

For CY 2012, CMS will make the Cost-Sharing Out-of-Pocket Cost model (Cost-Sharing OOPC model) available in SAS via the CMS website which will allow plans to calculate Cost-Sharing OOPC estimates for each of their benefit offerings to prepare for meaningful difference negotiations with CMS (see below). Standalone Prescription Drug Plans (PDP), and Medicare Advantage Plans with Prescription Drug coverage (MA-PD) will be encouraged to run their plan benefit structures through the SAS Cost-Sharing OOPC model to ensure meaningful differences between their plan offerings as required by CMS regulations (see 42 CFR §§ 423.272(b)(3)(i) and 423.265(b)(2)). The SAS Cost-Sharing OOPC model will be available no later than Friday, April 8, 2011. Instructions for downloading the model and a User Guide will also be published via the CMS website.

CMS expects PDPs and MA-PDs to prepare CY 2012 plan bids that meet the meaningful difference requirements with their initial submissions, since there will be access to the necessary tools to consistently calculate Cost-Sharing OOPC estimates for each plan prior to bid submission. CMS might not permit revised submissions if a plan's initial bid does not comply with meaningful difference requirements. Ultimately, plan bids that do not meet these requirements will not be approved by CMS. Thus, plans should complete this analysis prior to submitting their bids for the 2012 contract year.

Co-pay Thresholds for Cost Shares

According to 1860D-11(e) of the Social Security Act, the Secretary can only approve a plan if the design of the plan and its benefits are not likely to substantially discourage enrollment by certain Part D eligible individuals. Pursuant to 42 CFR 423.104(d)(2)(iii), tiered cost sharing for non-defined standard benefit designs may not exceed levels annually determined by CMS to be discriminatory.

To implement these requirements, CMS will examine PDP and MA-PD bid (benefit package) data for 2012 to determine acceptable cost sharing thresholds. While EGWPs are not part of the benefit package analysis, sponsors should take into consideration these thresholds when designing their tiered benefits to ensure they are not discriminating and discouraging certain beneficiaries from enrolling in the EGWP.

Consistent with prior years' review, we plan to conduct an analysis to identify drug tier cost-sharing outliers relative to other sponsors' competing benefit packages submitted using the 30-day retail in-network pharmacy copay cost-sharing associated with the 95th percentile across all initially submitted bids consisting of three or more tiers. CMS believes that cost-sharing at the 95th percentile would reflect the level at which a beneficiary could easily identify outliers they would consider to be discriminatory based on other plan offerings. As part of this analysis, we will also take into consideration plan type (basic versus enhanced), the number of drug tiers within a PBP, cost structure (copayment versus coinsurance), tier content and differences between MA-PDs (including cost plans) as well as differences between MA-PDs and PDPs. The table below shows the results of the threshold analysis for the initial 2011 bid submissions.

Copay Cost-Sharing Distribution for 2011 Bid Submissions with Three or More Tiers

2011 Copay Distribution (Percentiles)					
Tier ID	**Plan Count**	**20th**	**50th**	**70th**	**95th**
1	2846	$2	$5	$6	$10
2	2696	$15	$35	$40	$45
3	2570	$40	$70	$80	$95

Assuming similar benefit designs are submitted for 2012 as they were for 2011, sponsors can expect that CMS will establish 2012 thresholds that are reasonably consistent with the prior year's experience. Therefore, in constructing 2012 PBPs, Part D sponsors should consider the following thresholds that were used as part of the 2011 discrimination review for drug plans with three or more tiers:

Tier 1 over $10
Tier 2 over $45
Tier 3 over $95

Based on the most common tier designs submitted by plans, tier 1 represents preferred generic cost-sharing, tier 2 represents preferred brand cost-sharing and tier 3 represents non-preferred brand cost-sharing. As in 2011, the established threshold for preferred generic, preferred brand and non-preferred brand cost-sharing still apply when the tier level for these categories are shifted based on variations in tier design. For instance, if a sponsor had a 4 tier formulary with

tier 3 as the preferred brand tier (instead of tier 2), the $45 dollar threshold would apply to tier 3. It is important to note that in identifying drug tier outliers, CMS will consider specific benefit design aspects that could justify an exception for the purpose of our discrimination review. For instance, we may allow cost-sharing thresholds for plan benefit designs in which a particular tier represents the specialty tier such that if a plan has a 3 tier formulary which includes a specialty tier, the specialty tier will be held to the specialty tier thresholds, not the thresholds established by the 95th percentile. Atypical tiering structures, such as a two-tier formulary, will also be considered. Because of the additional standardization in tier design required for 2012, the benefits offered will have a distribution that is unique to each tier structure. Therefore, CMS will be able to refine the target cost-sharing thresholds and expects to establish cost-sharing threshold levels for all 2012 PBP tiers based on the standardized models described in the next section.

During 2011, CMS will increase scrutiny of the expected cost-sharing amounts incurred by beneficiaries under coinsurance tiers, in order to more consistently compare copay and coinsurance cost-sharing impacts. We expect to derive average expected cost sharing amounts for a sponsor's 2012 coinsurance tiers using 2010 PDE drug cost data mapped to 2012 formulary tiers. If a sponsor submits coinsurance values (instead of copayment values) for its non-specialty formulary tiers that are greater than the standard benefit of 25% for non-specialty tiers, CMS may also request documentation from the sponsor on the average expected price for medications on the coinsurance tier(s) in order to better translate the coinsurance value into an average cost-sharing amount for the purpose of our discrimination review.

Consistent with the meaningful difference review, CMS will notify plan sponsors whose benefit structures include drug tiers that exceed our discriminatory cost-sharing threshold limits and conduct negotiation calls as applicable prior to bid approval. Sponsors not meeting our targets will be asked to amend or withdraw their PBPs.

Tier Labeling and Hierarchy

Over the last few years CMS has heard from various beneficiary and advocacy stakeholders and Part D sponsors that a large number of drug tiers, non-standardized labeling of those tiers and formularies using duplicative tier names or tier names that include multiple drug types in the label (e.g., Brand and Generic Drugs) are confusing to beneficiaries especially when trying to compare plans. In order to improve the clarity and consistency of tier designs, CMS revised the PBP and formulary upload software in 2011 to accept a maximum of six drug tiers and established a uniform set of tier label description options based upon the most common tier names used by Part D sponsors. However, CMS believes that additional standardization of the tier structure and number could further improve the comparability of plan offerings by beneficiaries and will simplify the discriminatory cost-sharing analysis performed by CMS.

First, in order to keep drug benefits meaningful to beneficiaries while allowing sponsors adequate flexibility in the Part D benefit design, the 2012 PBP and formulary upload will continue to accept 6 formulary tiers. CMS continues to observe that the vast majority of Part D plan benefit packages reflect benefit designs using five tiers or less, and those plans with six tier designs are similar to those submitted by five tier plans, but typically include an extra non-preferred cost-sharing tier that does not provide a clear additional value to the beneficiary. Therefore, CMS will only allow a 6th tier if it is an excluded-drug-only tier or a tier that provides a meaningful benefit offering such as a $0 vaccine-only tier, a low or $0 cost-sharing tier for special needs plans (SNP) targeting one or more specific conditions (e.g., $0 tier for drugs related to diabetes and/or smoking cessation), or an injectable drug tier with cost-sharing that is at or below the cost-sharing for specialty tier drugs in the other five tiers. Plans offering supplemental benefits for excluded drug coverage are not required to have an optional excluded-drug-only tier and may continue to offer excluded drugs on tiers that are shared by Part D covered drugs.

Second, CMS is establishing tier labels and hierarchy to reflect standards established by industry and assist in our analysis of discriminatory benefit practices. CMS updated its regulations at §423.104(d)(2) by adding paragraph (iii) to specify that tiered cost-sharing for non-defined standard benefit designs may not exceed levels (or cost-sharing thresholds) annually determined by CMS to be discriminatory. In order to accurately evaluate whether tiered cost-sharing is discriminatory, there needs to be a consistency between the tier names adopted by the plan sponsors and the cost-sharing thresholds CMS established as part of its discriminatory analyses. Some of the variation in tier labeling that currently exists in Part D presents challenges for the discriminatory cost-sharing analyses, and does not lend itself to a common understanding of how competing plans compare in terms of tier offerings. As a result, beginning with the 2012 bid submissions, CMS expects sponsors to utilize certain tier labels and tiering hierarchy consistent with the industry standards already established in the market place. These standard tier names and hierarchy reflect the common tier patterns utilized by the majority of sponsors in 2011 and will provide for a more comprehensible description of the overall tier offering as it relates to the drug content and assigned cost-sharing. In addition, the 2012 tier labeling convention parallels the anticipated tier name options in the formulary submission module, in that only a single description can be selected as the tier name. The new tier label standards do not preclude sponsors from continuing to include brands and generics on the same tier as long as the drugs placed on the tier are associated with the same cost-sharing level.

Below is a chart depicting the tier labels and hierarchy as observed currently in the industry. Although the 2012 PBP tool will allow plans' to select tier names and hierarchies that are not consistent with the options described below, CMS expects plans to only submit PBPs that reflect the 2012 models. CMS will have difficulty determining whether a plan's tier cost-sharing structure is discriminatory if Part D sponsors submit plan benefit packages that do not reflect these industry standards. CMS will require Part D sponsors to provide justification that the

PBP's cost-sharing tier structure is not discriminatory for any PBP that differs from the expected models. In addition because of the ACA provision that moved the annual enrollment period from November to October, CMS will have a shortened time frame for review and approval of 2012 Part D bids and may not have enough time to approve bids that are incomplete or otherwise challenging to evaluate. CMS strongly encourages Part D sponsors to ensure that their initial submissions due on June 7, 2011 are complete and consistent with CMS policy and guidance, to avoid the risk of being denied participation in the program. In addition, sponsors must ensure that the formularies submitted in advance of the bids only include a 6th tier that provides a meaningful offering. We further note that the tier names submitted on the formularies should match those names submitted in the PBP, with the exception of free text field names in the formulary submission module that are not available in the PBP. These free text field names on the formulary submission should be limited to describing the $0 vaccine-only tier, the targeted chronic disease SNP tier with low or $0 cost-sharing, or other 6th tier meaningful benefit that cannot be adequately described by the existing 2012 PBP tier label options. As in previous years, excluded-drug-only tiers will not be reflected on formulary submissions.

Because the 2012 PBP tier label options are unchanged from 2011, plan sponsors will be permitted to customize the tier label for the 6th tier via the summary of benefits (SB) hard copy change process for 2012, as long as it reflects the meaningful benefit being offered on that tier. SB hard copy changes for 2012 should not be submitted by the sponsor for injectable drugs and excluded-drug-only tiers since they already have specific tier labels included in the PBP. CMS will also permit sponsors to enter a Part D PBP note describing 6th tier offerings for which they will be requesting an SB hard copy tier name change. CMS will revise the PBP for 2013 to allow customization of the 6th tier label.

2012 Tier Labels and Hierarchy

		2012 Tier Label					
2012 Tier Structure	**2012 Option**	**Tier 1**	**Tier 2**	**Tier 3**	**Tier 4**	**Tier 5**	**Optional Tier 6***
2 Tier	A	Generic or Preferred Generic	Brand or Preferred Brand	---	---	---	---
3 Tier	A	Generic or Preferred Generic	Brand or Preferred Brand	Specialty Tier	---	---	---
	B	Generic or Preferred Generic	Preferred Brand	Non-Preferred Brand	---	---	---
4 Tier	A	Generic or Preferred Generic	Preferred Brand	Non-Preferred Brand	Specialty Tier	---	---
	B	Preferred Generic	Non-Preferred Generic	Preferred Brand	Non-Preferred Brand	---	---
5 Tier	A	Preferred Generic	Non-Preferred Generic	Preferred Brand	Non-Preferred Brand	Specialty Tier	optional
	B	Preferred Generic	Non-Preferred Generic	Preferred Brand	Non-Preferred Brand	Injectable Drugs	optional
	C	Preferred Generic	Non-Preferred Generic	Preferred Brand	Injectable Drugs	Specialty Tier	optional
	D	Generic or Preferred Generic	Preferred Brand	Non-Preferred Brand	Injectable Drugs	Specialty Tier	optional

*The optional 6th tier can be used as an excluded-drug-only tier or for other meaningful offerings such as a $0 vaccine-only tier.

Gap Coverage

Consistent with our bid submission requirements provided at 42 CFR 423.265, a Part D sponsor's bid submission must reflect differences in benefit packages or plan costs that CMS determines to represent substantial differences relative to a sponsors other bid submissions. This being the case, CMS expects that the additional gap coverage of generic (non-applicable) drugs offered by plans to reflect meaningful enhancements over the standard prescription drug benefit, which provides 14% generic drug cost coverage in the gap for CY 2012.

To determine how much additional coverage in the coverage gap over the basic benefit would be recognized as substantially different, CMS considered the amount of additional coverage provided by the Part D sponsors in their plan benefit packages for CY 2011. CMS found that the majority of plans offering coverage in the gap had cost-sharing levels for generics equal to 50%

coinsurance or less, and brand cost-sharing at 60% coinsurance or less. Since the majority of plans reflect additional coverage of at least 50% in the gap for generics and 40% coverage of brands in the gap, CMS intends to scrutinize any 2012 plans that provide gap coverage at or below 30% of the cost of generic or brand drugs - in other words, the plan's benefit has beneficiary cost-sharing during the coverage gap that is equal to or more than 70% coinsurance. For example, if a plan submits a basic benefit package which reflects the defined-standard benefit structure of 86% coinsurance for generics during the coverage gap and submits another enhanced plan that reflects more than 70% coinsurance for generics during the coverage gap, CMS will evaluate whether the enhanced plan is substantially different from what is offered under the sponsor's basic plan in accordance with our meaningfully different policies.

Plan Corrections

The plan correction module will be available in HPMS for 2012 PBPs for a limited period, from mid-September until October 1, 2011. Organizations may request a plan correction only after their contract has been approved. This limited timeframe will ensure that correct bid information will be available for review on the Medicare Prescription Drug Plan Finder in time for the open enrollment start date. Only changes to the PBP that are supported by the BPT are allowed during the plan correction period.

CMS expects that sponsors' requests for plan corrections will be very rare. A request for a plan correction indicates the presence of inaccuracies and/or the incompleteness of a bid and calls into question an organization's ability to submit correct bids and the validity of the final actuarial certification and bid attestation. Please be advised that an organization requesting a plan correction will receive a compliance notice.

CMS did not receive any comments on the plan corrections guidance provided in the draft call letter; however we did receive public comments requesting a shorter and streamlined review period and that we release the SB Hard Copy Change Request Module on June 6 in order to allow plans to submit SB requests sooner. We appreciate the comments provided; however, CMS will not shorten the review period for the SB standardized document, which is currently a 10-day review. We believe that the current review process is sufficient and will work with plans to ensure timely approval. For CY2012, CMS will not change the date that the HPMS Summary of Benefits Hard Copy Change Request Module will be available; however, we will consider this for the next calendar year, if possible.

Specialty Tier Threshold

For contract year 2012, we will maintain the $600 threshold for drugs on the specialty tier. Thus, only Part D drugs with negotiated prices that exceed $600 per month may be placed in the specialty tier, and the specialty tiers will be evaluated and approved in accordance with section

30.2.4 of Chapter 6 of the Medicare Prescription Drug Benefit Manual. In addition to cost calculations, CMS considers claims history in reviewing the placement of drugs on Part D sponsors' specialty tiers. Except for newly approved drugs for which Part D sponsors would have little or no claims data, CMS will approve specialty tiers that only include drugs on specialty tiers when their claims data demonstrates that the majority of fills exceed the specialty tier cost criteria. Part D sponsors should be prepared to provide CMS the applicable claims data during the formulary review process.

Appendix A-1 – Contract Year 2012 Guidance for Medicare Advantage, Medicare Advantage Prescription Drug, and Section 1876 Cost Contract Plan Renewals

I. MA PBP Renewal and Non-Renewal Guidance

Each renewal/non-renewal option available to MAOs for CY 2012 is outlined in Appendix A-2 and summarized below. Some of these actions can be effectuated by MAOs in the HPMS Plan Crosswalk, while others require explicit prior approval from CMS. Note that CMS will not permit plan renewals across product types. For example, we will not permit MA-only plans to renew as, or consolidate into, MA-PD plans (and vice versa), Health Maintenance Organization (HMO) plans to renew as, or consolidate into, Preferred Provider Organization (PPO) plans (and vice versa); HMO plans or PPO plans to renew as, or consolidate into, Private-Fee-for-Service (PFFS) plans (and vice versa); Special Needs Plans (SNPs) to renew as, or consolidate into, non-SNP MA plans (and vice versa); and section 1876 cost contract plans to renew as, or consolidate into, MA plans (and vice versa). With limited exceptions (outlined below) CMS will not permit consolidation of PBPs, regardless of plan type, across contracts. Furthermore, CMS will not permit a non-segmented plan to convert to a segmented plan and to request that current enrollees be transitioned to plan segments.

1. ***New Plan Added***

An MAO may create a new PBP for the following contract year with no link to a PBP it offers in the current contract year in the HPMS Plan Crosswalk. In this situation, beneficiaries electing to enroll in the new PBP must complete enrollment requests, and the MAO offering the MA plan must submit enrollment transactions to MARx.

2. ***Renewal Plan***

An MAO may continue to offer a current PBP that retains all of the same service area for the following year. The renewing plan must retain the same PBP ID number as in the previous contract year in the HPMS Plan Crosswalk. Current enrollees are not required to make an enrollment election to remain enrolled in the renewal PBP, and the MAO will not submit enrollment transactions to MARx for current enrollees. New enrollees must complete enrollment requests, and the MAO will submit enrollment transactions to MARx for those new enrollees. Current enrollees of a renewed PBP must receive a standard Annual Notice of Change (ANOC) notifying them of any changes to the renewing plan.

3. ***Consolidated Renewal Plan***

MAOs are permitted to combine two or more entire PBPs offered in the current contract year into a single renewal plan in the HPMS Plan Crosswalk so that all enrollees in the combined plans are under one PBP with the same benefits in the following contract year. However, an

MAO may not split a current PBP among more than one PBP for the following contract year. An MAO consolidating one or more entire PBPs with another PBP must designate which of the renewal PBP IDs will be retained following the consolidation. The renewal PBP ID will be used to transition current enrollees of the plans being consolidated into the designated renewal plan. This is particularly important with respect to minimizing beneficiary confusion when a plan consolidation affects a large number of enrollees.

Current enrollees of a plan or plans being consolidated into a single renewal plan will not be required to take any enrollment action, and the organization will not submit enrollment transactions to MARx for those current members. However, the MAO may need to submit updated 4Rx data to CMS for the current enrollees affected by the consolidation. New enrollees must complete enrollment requests, and the MAO will submit enrollment transactions to MARx for those new enrollees. Current enrollees of a consolidated renewal plan must receive a standard ANOC.

4. ***Renewal Plan with a Service Area Expansion (SAE)***

An MAO may continue to offer the same local MA PBP but add one or more new service areas (i.e., counties) to the plan's service area in the following contract year. This is known as a service area expansion, or SAE. Organizations that include any new service area additions to a PBP should have submitted an SAE application to CMS for review and approval. An MAO renewing a plan with a SAE in the HPMS Plan Crosswalk must retain the renewed PBP's ID number in order for all current enrollees to remain enrolled in the same plan in the following contract year.

Current enrollees of a PBP that is renewed with a SAE will not be required to take any enrollment action, and the MAO will not submit enrollment transactions to MARx for those current enrollees. New enrollees must complete enrollment requests, and the MAO will submit enrollment transactions to MARx for those new enrollees. Current enrollees of a renewed PBP with a SAE must receive a standard ANOC notifying them of any changes to the renewing plan.

5a. ***Renewal Plan with a Service Area Reduction (SAR) and No Other MA Options Available***

An MAO offering a local MA plan may reduce the service area of a current contract year's PBP. This is known as a service area reduction, or SAR. An MAO renewing a plan with a SAR must retain the renewed PBP's ID number in the HPMS Plan Crosswalk so that current enrollees in the renewal portion of the service area remain enrolled in the same plan in the following contract year. Current enrollees in the renewal portion of the service area will not be required to take any enrollment action, and the MAO will not submit enrollment transactions in MARx for these current members. Current enrollees in the renewal portion of the service area must receive a standard ANOC notifying them of any changes to the renewing plan.

For the CY 2012 contract year, current plan enrollees in reduced service areas will be disenrolled at the end of 2011. These individuals affected by the SAR will need to elect another plan. The MAO will submit disenrollment transactions pursuant to instructions that CMS will release later this year.

The MAO will send a termination notice to enrollees in the reduced portion of the service area that includes notification of special election period (SEP) and Medigap guaranteed issue rights. Only when there are no other MA options in the reduced service area, the MAO may offer current enrollees in the reduced portion of the service area the option of remaining enrolled in the renewal plan consistent with CMS continuation area policy as provided under 42 CFR 422.74(b)(3)(ii). If an MAO elects to offer current enrollees in the reduced service area the option of remaining enrolled in the renewal plan, the MAO may provide additional information, in addition to the termination notice, about the option to remain enrolled in the plan for CY 2012. However no specific CY 2012 plan information can be shared with any beneficiaries prior to October 1, 2011. Any current enrollees in the reduced portion of the service area who wish to continue their enrollment must complete an enrollment request, and the organization must submit enrollment transactions to MARx for those members.

5b. ***Renewal Plan with a Service Area Reduction (SAR) When the MAO Will Offer Another PBP in the Reduced Portion of the Service Area***

An MAO offering a local MA plan may elect to reduce the service area of a current contract year's PBP and make the reduced area part of a new or renewal MA PBP service area in the following contract year. An MAO renewing a plan with a SAR must retain the renewed PBP's ID number in the HPMS Plan Crosswalk so that current enrollees in the renewal portion of the service area remain enrolled in the same plan in the following contract year. Current enrollees in the renewal portion of the service area will not be required to take any enrollment action, and the MAO will not submit enrollment transactions to MARx for these current members. These individuals must receive a standard ANOC notifying them of any changes to the renewing plan.

Current enrollees in the reduced portion of the service area must be disenrolled, and the MAO must submit disenrollment transactions to MARx for these individuals, pursuant to instructions that CMS will release later this year. The MAO will send a termination notice to current enrollees in the reduced portion of the service area that includes notification of special election period (SEP) and Medigap guaranteed issue rights. If the MAO offers one or more MA plans in the reduced portion of the service area, it may offer current enrollees in the reduced portion of the service area the option of enrolling in that plan (or those plans). However, no specific CY 2012 plan information can be shared with any beneficiaries prior to October 1, 2011. Any current enrollees in the reduced portion of the service area who wish to enroll in another MA plan offered by the same organization in the reduced service area must complete an enrollment request, and the organization must submit enrollment transactions to MARx for those members.

6. ***Terminated Plan (Non-Renewal)***

An MAO may elect to terminate a current PBP for the following contract year and must notify CMS in writing (by sending an email to MA_Applications@cms.hhs.gov) by the first Monday in June,[6] pursuant to 42 CFR 422.506(a)(2)(i). However, even absent written notification to CMS, an MAO's failure to submit a timely bid to CMS constitutes a voluntary non-renewal by the sponsor. In this situation, the MAO will not submit disenrollment transactions to MARx for affected enrollees. CMS will disenroll these individuals from the MA plan at the end of the current contract year. These individuals must make a new election for their Medicare coverage for the following contract year. Regardless of whether these individuals elect to enroll in another plan offered by the same or another MAO, or to revert to Original Medicare and enroll in a PDP, they must complete an enrollment request, and the enrolling organization or sponsor must submit enrollment transactions to MARx. If these individuals do not make a new MA plan election prior to the beginning of the following contracting year, they will have Original Medicare coverage as of January 1st of the following contract year.

Enrollees in terminated PBPs will be sent a termination notice by the terminating plan that includes notification of a special election period and Medigap guaranteed issue rights, as well as information about alternative options. For more information about non-renewal processes and beneficiary notification requirements, refer to our forthcoming HPMS memorandum providing non-renewal and service area reduction guidance and model notices, to be released this summer.

7a, 7b, 8a, 8b, 9a, and 9c. ***Non-Network and Partial Network PFFS Plans Transitioning to Partial or Full Network PFFS Plans***

As provided under 42 CFR 422.114(a)(3), PFFS plans in certain counties ("network counties" with two network plans available) must operate with networks. We have historically required organizations to establish separate contracts for PFFS non-network, partial network, and network plans. CMS has not typically allowed plans to move members from one contract to another, and contract-to-contract moves are currently not possible in the HPMS Plan Crosswalk. However, CMS created an exception to this rule for CYs 2010 and 2011, which we will continue for CY 2012, in anticipation of a large number of transitions from non- or partial network PFFS plans to partial or full network PFFS plans due to the PFFS network requirements. The permissible PFFS transitions are outlined below. We note that some of these scenarios involve consolidations of whole PFFS PBPs and others involve transitions of some, but not all, counties of current non-network and partial network PFFS PBPs.

MAOs must complete the outlined PFFS renewal options by submitting a crosswalk exception request through HPMS. CMS will provide detailed technical instructions for completing a crosswalk exception request through HPMS in forthcoming guidance. Requests will be reviewed

[6] CY 2012 bids are due no later than June 6, 2011.

and, if approved, the action will be on behalf of the requesting MAO. In addition, for those transitions that will involve some, but not all, counties of current non-network and partial network PFFS PBPs, MAOs must submit enrollment transactions to MARx for individuals residing in consolidating counties (i.e., where the contract and PBP number will be different in 2012) following the instructions that CMS will release later this year.

7a. ***Non-Network PFFS Plan Transitioning to a Partial Network PFFS Plan***

An MAO with a PFFS non-network contract may consolidate one or more current non-network PFFS PBPs into a new or renewal partial network PFFS PBP under a separate contract held by the same legal entity. HPMS will record the consolidation of one or more PBPs following the submission and approval of an exceptions request (per the instructions outlined above).

Current enrollees of a PFFS non-network plan or plans being consolidated into a new or renewal PFFS partial network plan will not be required to take any enrollment action, and the organization will not submit enrollment transactions to MARx for those current members, although it may need to submit updated 4Rx data to CMS for the current enrollees affected by the consolidation. New enrollees must complete enrollment requests, and the MAO will submit enrollment transactions to MARx for those new enrollees. Current enrollees of the consolidated PFFS partial network plan must receive a standard ANOC.

7b. ***Some Counties of a Non-Network PFFS Plan Transitioning to a Partial Network PFFS Plan***

An MAO with a PFFS non-network contract may consolidate some counties in the service area of a current non-network PFFS PBP into a single new or renewal partial network PFFS PBP under a separate contract held by the same legal entity. Current enrollees in the remaining counties in the non-network PFFS PBP may remain in that non-network PBP in the following contract year provided the MAO follows the rules for a renewal plan with a SAR described elsewhere in this guidance.

Following the submission of an exceptions request (per the instructions outlined above) and its approval, the MAO must submit enrollment transactions to MARx for current enrollees in the counties affected by the SAR who will be transitioned to a new or renewing partial network PBP under a separate contract held by the same legal entity. CMS will provide specific instructions for the submission of these transactions later in the year. New enrollees must complete enrollment requests, and the MAO will submit enrollment transactions to MARx for those new enrollees as usual. Current enrollees transitioned to the PFFS partial network plan must receive a standard ANOC.

8a. ***Non-Network PFFS Plan Transitioning to a Full Network PFFS Plan***

An MAO with a PFFS non-network contract may consolidate one or more current entire non-network PFFS PBPs into a new or renewal full network PFFS PBP under a separate contract held by the same legal entity. HPMS will record the consolidation of one or more PBPs following the submission and approval of an exceptions request (per the instructions outlined above).

Current enrollees of a PFFS non-network plan or plans being consolidated into a new or renewal PFFS full network plan will not be required to take any enrollment action, and the organization will not submit enrollment transactions to MARx for those current members, although it may need to submit updated 4Rx data to CMS for the current enrollees affected by the consolidation. New enrollees must complete enrollment requests, and the MAO will submit enrollment transactions to MARx for those new enrollees. Current enrollees of the consolidated PFFS full network plan must receive a standard ANOC.

8b. ***Some Counties of a Non-Network PFFS Plan Transitioning to a Full Network PFFS Plan***

An MAO with a PFFS non-network contract may consolidate some counties in the service area of a current non-network PFFS PBP into a single new or renewal full network PFFS PBP under a separate contract held by the same legal entity. Current enrollees in the remaining counties in the non-network PFFS PBP may remain in that non-network PBP in the following contract year provided the MAO follows the rules for a renewal plan with a SAR described elsewhere in this guidance.

Following the submission of an exceptions request (per the instructions outlined above) and its approval, the MAO must submit enrollment transactions to MARx for current enrollees in the counties affected by the SAR who will be transitioned to a new or renewing full network PBP under a separate contract held by the same legal entity. CMS will provide specific instructions for the submission of these transactions later in the year. New enrollees must complete enrollment requests, and the MAO will submit enrollment transactions to MARx for those new enrollees. Current enrollees transitioned to the PFFS full network plan must receive a standard ANOC.

9a. ***Partial Network PFFS Plan Transitioning to a Full Network PFFS Plan***

An MAO with a PFFS partial network contract may consolidate one or more current partial network PFFS PBPs into a new or renewal full network PFFS PBP under a separate contract held by the same legal entity. HPMS will record the consolidation of one or more PBPs following the submission and approval of an exceptions request (per the instructions outlined above).

Current enrollees of a PFFS partial network plan or plans being consolidated into a new or renewal PFFS full network plan will not be required to take any enrollment action, and the organization will not submit enrollment transactions to MARx for those current members. New

enrollees must complete enrollment requests, and the MAO will submit enrollment transactions to MARx for those new enrollees. Current enrollees of the consolidated PFFS full network plan must receive a standard ANOC.

9b. ***Some Counties of a Partial Network PFFS Plan Transitioning to a Full Network PFFS Plan***

An MAO with a PFFS partial network contract may consolidate some counties in the service area of a current partial network PFFS PBP into a single new or renewal full network PFFS PBP under a separate contract held by the same legal entity. Current enrollees in the remaining counties in the partial network PFFS PBP may remain in that partial network PBP in the following contract year provided the MAO follows the rules for a renewal plan with a SAR described elsewhere in this guidance.

Following the submission of an exceptions request (per the instructions outlined above) and its approval, the MAO must submit enrollment transactions to MARx for current enrollees in the counties affected by the SAR who will be transitioned to a new or renewing full network PBP under a separate contract held by the same legal entity. CMS will provide specific instructions for the submission of these transactions later in the year. New enrollees must complete enrollment requests, and the MAO will submit enrollment transactions to MARx for those new enrollees. Current enrollees transitioned to the PFFS full network plan must receive a standard ANOC.

10. ***Consolidation of a Renewal Dual Eligible SNP (D-SNP) with a D-SNP with a State Contract***

An MAO currently offering one or more D-SNP PBPs with no State contracts may consolidate those PBPs into a single renewal PBP that is a D-SNP with a State contract (offered by the same MAO under the same contract and containing the applicable service area of all consolidating PBPs). The organization must retain one of the current year plan IDs as the renewal plan ID for the following contract year.

Current eligible enrollees are not required to make an enrollment election to remain enrolled in the consolidated renewal PBP, and the MAO will not submit enrollment transactions to MARx for those current eligible enrollees. However, the MAO must submit disenrollment transactions for current enrollees who are no longer eligible for the renewing D-SNP's designation, pursuant to instructions CMS will release later this year.

Current eligible enrollees of the consolidated PBP (including newly transitioned enrollees) must receive an ANOC. Current enrollees whose enrollment is terminated because they are no longer eligible for the new State contracted D-SNP's designation must be sent a disenrollment notice that includes information about other plan options, as well as additional details about Medigap

rights and/or SEP rights, as applicable. A CMS model for this special disenrollment notice will be provided in forthcoming guidance.

11. MAO with a Renewing D-SNP that Also Creates a New Medicaid Subset D-SNP and Transitions Eligible Enrollees into the New Medicaid Subset D-SNP

An MAO that renews a current D-SNP that retains the same service area for CY 2012 and also creates a new Medicaid subset D-SNP PBP for the following contract year may transition the subset of current enrollees who are eligible for the new Medicaid subset into the new Medicaid subset D-SNP PBP and may retain current enrollees who are not eligible for the new Medicaid subset D-SNP in the renewing D-SNP. The renewing plan must retain the same PBP ID number as in the previous contract year. MAOs that meet the criteria for this renewal option must complete and submit a request through HPMS. CMS will provide detailed technical instructions for completing a crosswalk exception request through HPMS in forthcoming guidance. Requests will be reviewed and, if approved, the MAO will be permitted to submit enrollment transactions to transition eligible current enrollees into the new Medicaid subset D-SNP. Current enrollees not eligible for the new Medicaid subset D-SNP are not required to make an enrollment election to remain enrolled in the renewal PBP, and the MAO will not submit enrollment transactions to MARx for these current enrollees not eligible for the new Medicaid subset D-SNP. The MAO must submit enrollment transactions for current enrollees eligible for the new Medicaid subset D-SNP in order to enroll them in the new Medicaid subset D-SNP pursuant to instructions that CMS will release later this year. New enrollees in either the renewing or new Medicaid subset D-SNP must complete enrollment requests, and the MAO will submit enrollment transactions to MARx for those new enrollees.

Current enrollees not eligible for the new Medicaid subset D-SNP and who remain in the renewal D-SNP PBP must receive a standard ANOC. Current enrollees transitioned to the new Medicaid subset D-SNP must also receive a standard ANOC.

12. Renewing D-SNP in a Multi-State Service Area with a SAR to Accommodate State Contracting Efforts in Portions of that Service Area

As MAOs make efforts to comply with State contracting requirements for CY 2013, we are aware that the nature of negotiations with States may particularly impact MAOs with D-SNPs that operate across State lines. CMS will therefore allow a narrow renewal exception described below.

An MAO that renews a current D-SNP PBP operating in a multi-State service area (a service area that covers counties in more than one state) may reduce the service area of the current contract year's PBP to accommodate State contracting in portions of the service area. The MAO may then transition enrollees in the reduced area, who are thus no longer eligible for the renewed D-SNP PBP, into a new or renewal SNP service area in the following contract year.

The renewing plan must retain the same PBP ID number as in the previous contract year so that current enrollees in the renewal portion of the service area remain enrolled in the same plan in the following contract year. MAOs must complete this renewal option by submitting a crosswalk exception request through HPMS. CMS will provide detailed technical instructions for completing a crosswalk exception request through HPMS in forthcoming guidance. Requests will be reviewed and, if approved, the MAO will be permitted to submit enrollment transactions to transition eligible current enrollees into a new or renewal D-SNP. Current enrollees who remain eligible for the renewing D-SNP PBP are not required to make an enrollment election to remain enrolled in the renewal PBP, and the MAO will not submit enrollment transactions to MARx for these current enrollees. The MAO must submit enrollment transactions for current enrollees being transitioned to a new or renewal D-SNP in order to enroll them in the new or renewal SNP pursuant to instructions that CMS will release later this year. New enrollees in any of the plans affected by this transition must complete enrollment requests, and the MAO will submit enrollment transactions to MARx for those new enrollees.

Current enrollees who remain in the renewal D-SNP PBP must receive a standard ANOC. Current enrollees transitioned to a new or renewal D-SNP must also receive a standard ANOC.

13a. ***D-SNP that Transitions Current Enrollees to a New D-SNP with a Different Designation and Less Restrictive Eligibility Requirements***

An MAO currently offering a D-SNP PBP that has requested conversion to a different D-SNP type under the same MAO contract may transition current eligible enrollees into its newly created D-SNP PBP of the new SNP type. If the new D-SNP type has less restrictive eligibility requirements than the original D-SNP, the MAO may retain current eligible enrollees in the newly designated D-SNP PBP because all current enrollees will remain eligible for the new D-SNP with the new designation.

MAOs must complete this renewal option by submitting a crosswalk exception request through HPMS. CMS will provide detailed technical instructions for completing a crosswalk exception request through HPMS in forthcoming guidance. Requests will then be reviewed and, if approved, CMS will complete the transition on behalf of the organization.

Current enrollees of the newly designated D-SNP with expanded eligibility criteria are not required to make an enrollment election to be transitioned to the newly created D-SNP PBP, and the MAO will not submit enrollment transactions to MARx for these current enrollees. New enrollees must complete enrollment requests, and the MAO will submit enrollment transactions to MARx for those new enrollees. Current eligible enrollees remaining in the D-SNP must receive an ANOC.

13b. ***D-SNP that Transitions Some Current Enrollees to a New D-SNP with a Different Designation and More Restrictive Eligibility Requirements Consistent with the New D-SNP's State Contract***

An MAO currently offering a D-SNP PBP that has requested conversion to a different D-SNP type under the same MAO contract may transition current eligible enrollees into its newly created D-SNP PBP of the new SNP type. If the new D-SNP type has more restrictive eligibility requirements than the original D-SNP (for example, because the MAO is contracting with a State and a condition of this contract is that the plan enroll a Medicaid subset), the MAO may retain current eligible enrollees in the new D-SNP with the new designation.

MAOs must complete this renewal option by submitting a crosswalk exception request through HPMS. CMS will provide detailed technical instructions for completing a crosswalk exception request through HPMS in forthcoming guidance. Requests will then be reviewed and, if approved, CMS will complete the transition on behalf of the organization.

Current enrollees who are eligible for the new D-SNP with the more restrictive designation are not required to make an enrollment election to be transitioned to the newly created D-SNP PBP, and the MAO will not submit enrollment transactions to MARx for these current eligible enrollees. New enrollees must complete enrollment requests, and the MAO will submit enrollment transactions to MARx for those new enrollees. Current eligible enrollees remaining in the D-SNP must receive an ANOC.

Current enrollees whose enrollment is terminated because they are no longer eligible for the new D-SNP's designation must be sent a disenrollment notice that includes information about other plan options, as well as additional details about Medigap rights and/or SEP rights, as applicable. A CMS model for this special disenrollment notice will be provided in forthcoming guidance.

14. ***Renewing SNP with Ineligible or "Disproportionate Share" Members***

As provided under MIPPA and section 3205(c) of the Affordable Care Act, SNPs may only enroll individuals who meet the plan's specific eligibility criteria; they may no longer enroll and serve a "disproportionate share" of individuals who do not meet the targeted criteria or condition. Also pursuant to MIPPA, chronic care SNPs (C-SNPs) may only enroll and serve individuals with certain chronic conditions, as specified by CMS.

Many SNPs currently include members: (1) who enrolled prior to January 1, 2010 under the "disproportionate share" policy (i.e., the members did not meet the special needs criteria at the time of enrollment); or (2) who were enrolled in a C-SNP as of January 1, 2010, but no longer met the special needs criteria as of that date. In both of these circumstances, rather than require the MAO offering these SNPs to involuntarily disenroll these members as of December 31, 2010 because they no longer met the SNP's targeted criteria, CMS required the MAOs to allow these individuals to continue to be enrolled through CY 2011. However, effective CY 2012, SNPs that

include members who enrolled under the two circumstances described above will be required to disenroll those individuals if they do not request enrollment in a different plan prior to January 1, 2012. MAOs will not be permitted to transition these current enrollees into other MA plans offered by the organization. However, MAOs must retain any of these enrollees whose circumstances change and who regain special needs status prior to January 1, 2012.

The process for disenrollment of ineligible members by January 1, 2012, will be as follows:

- No later than June 30, 2011, MAOs offering SNPs must provide their account managers with the total number of non-special needs individuals who continued to be enrolled in these SNPs as of January 1, 2011.
- By no later than July 29, 2011, CMS will issue an HPMS memorandum that will provide further details about the disenrollment process, and will include model notices to be sent to affected enrollees. We anticipate that the model notices will incorporate information about other plan options, as well as additional details about Medigap rights and/or SEP rights, as applicable.
- MAOs must then notify each affected enrollee no later than September 30, 2011, that s/he will be disenrolled effective January 1, 2012, and will need to enroll in another plan prior to that date if he/she wants MA coverage for CY 2012. This notice must include information about other plan options, as well as additional details about Medigap rights and/or SEP rights as applicable.
- By December 31, 2011, the MAO must submit disenrollment transactions to MARx for those individuals who do not meet the plan's specific eligibility criteria, pursuant to instructions that CMS will release this year.

Please refer to the renewal plan guidance provided in this Call Letter for the notification requirements for current SNP enrollees other than those described above. Enrollees who will need to be disenrolled because they lose their special needs status in 2011 must be sent a disenrollment notice that includes information about other plan options, as well as additional details about Medigap rights and/or SEP rights, as applicable.[7] MAOs must retain any of these enrollees whose circumstances change and who regain their special needs status during their period of deemed continued eligibility, as described in section 50.2.5 of the MA Enrollment and Disenrollment Guidance.

MAOs must retain any of these enrollees through their period of deemed continued eligibility, and also retain enrollees whose circumstances change and who regain their special needs status

[7] Plans should note that the notification policy in this paragraph applies to those SNP enrollees who lost special needs status in 2011 *not* to disproportionate share enrollees who were not eligible for the SNP as of January 1, 2010.

during such period, as described in section 50.2.5 of the MA Enrollment and Disenrollment Guidance.

Section 1876 Cost Contract Renewal and Non-Renewal Guidance

In general, the MA renewal and non-renewal guidance above applies to section 1876 cost contracts that submit PBPs.

A section 1876 cost contract may not, like MA plans, offer separate PBPs. Instead, a cost contract may offer supplemental benefits as separate collections of benefits under its contract for purposes of Medicare Plan Finder and Medicare & You. Because such benefit collections are not considered separate PBPs, a cost contract, unlike an MA plan, is not considered to have terminated a PBP. In the HPMS plan crosswalk, cost contracts are required to consolidate any collection of benefits that have been marked as "terminated" with another collection of benefits. Thus, instead of disenrolling the individual as in the transactions identified in the MA renewal and non-renewal guidance above, the cost contract must send an ANOC to enrollees specifying the benefit changes and notifying the beneficiary that he or she will remain enrolled in the cost contract's A and B-only package (with or without Part D depending on the individual's original election), or, if the enrollee so chooses, may receive one of the cost contract's other benefit packages.

Appendix A-2 – Contract Year 2012 Guidance for Medicare Advantage and Medicare Advantage Prescription Drug Plan Renewals

	Activity	Guidelines	Renewal Effectuation Method	Systems Enrollment Activities	Enrollment Procedures	Beneficiary Notifications
1	New Plan (PBP) Added	An MAO creates a new plan benefit package (PBP).	**HPMS Plan Crosswalk Definition:** A new plan added for 2012 that is not linked to a 2011 plan. **HPMS Plan Crosswalk Designation:** New Plan	The MAO **must submit enrollment transactions** for 2012.	New enrollees must complete an enrollment request.	None
2	Renewal Plan	An MAO continues to offer a CY 2011 MA PBP in CY 2012 and retains all of the same service area. **The same PBP ID number must be retained** in order for all current enrollees to remain in the same MA PBP in CY 2012.	**HPMS Plan Crosswalk Definition:** A 2012 plan that links to a 2011 plan and retains all of its plan service area from 2011. The 2012 plan must retain the same plan ID as the 2011 plan **HPMS Plan Crosswalk Designation:** Renewal Plan	**The renewal PBP ID must remain the same** so that current enrollees will remain in the same PBP ID. The MAO **does not submit enrollment transactions** for current enrollees.	No enrollment request is required for current enrollees to remain enrolled in the renewal PBP in 2012. New enrollees must complete enrollment requests.	Current enrollees are sent a standard ANOC.

Appendix A-2

	Activity	Guidelines	Renewal Effectuation Method	Systems Enrollment Activities	Enrollment Procedures	Beneficiary Notifications
3	Consolidated Renewal Plan	An MAO ***combines one or more whole MA PBPs*** of the same type offered in CY 2011 into a single renewal PBP so that all current enrollees in combined PBP are offered the same benefits in CY 2012. The MAO must designate which of the renewal PBP IDs will be retained in CY 2012 after consolidation. CMS will not allow for consolidations across contracts (with limited exceptions for some renewal options, as described elsewhere in this guidance). Only whole PBPs may be consolidated; a CY 2011 PBP may not be split among different PBPs in CY 2012. **Note:** If an MAO reduces a service area when consolidating PBP, it must follow the rules for a renewal plan with SAR described elsewhere in this guidance.	**HPMS Plan Crosswalk Definition:** One or more 2011 plans that consolidate into one 2012 plan. The 2012 plan ID must be the same as one of the consolidating 2011 plan IDs. **HPMS Plan Crosswalk Designation:** Consolidated Renewal Plan	**The MAO's designated renewal PBP ID must remain the same** so that CMS can consolidate enrollees into the designated renewal PBP ID in CMS systems. The MAO **does not submit enrollment transactions** for current enrollees. The MAO may have to submit 4Rx data for individuals whose PBP number changed.	No enrollment request is required for current enrollees to remain enrolled in the renewal PBP in 2012. New enrollees must complete enrollment request.	Current enrollees are sent a standard ANOC.

Appendix A-2

	Activity	Guidelines	Renewal Effectuation Method	Systems Enrollment Activities	Enrollment Procedures	Beneficiary Notifications
4	Renewal Plan with an SAE	**This option is available to local MA plans only.** An MAO continues to offer a CY 2011 local MA PBP in CY 2012 and retains all of the same PBP service area, but also adds one or more new service areas. **The same PBP ID number must be retained** in order for all current enrollees to remain in the same MA PBP in CY 2012.	**HPMS Plan Crosswalk Definition:** A 2012 plan that links to a 2011 plan and retains all of its plan service area from 2011, but also adds one or more new counties. The 2012 plan must retain the same plan ID as the 2011 plan. **HPMS Plan Crosswalk Designation:** Renewal Plan with an SAE **Note**: If the 2012 plan has both an SAE and a SAR, the plan must be renewed as a renewal plan with a SAR.	**The renewal PBP ID must remain the same** so that current enrollees in the remaining in the service area will remain in the same PBP ID. The MAO **does not submit enrollment transactions** for current 2011 enrollees. The MAO submits enrollment transactions for new enrollees.	No enrollment request is required for current enrollees to remain enrolled in the renewal PBP in 2012. New enrollees must complete enrollment request.	Current enrollees are sent a standard ANOC.

Appendix A-2

	Activity	Guidelines	Renewal Effectuation Method	Systems Enrollment Activities	Enrollment Procedures	Beneficiary Notifications
5a	Renewal Plan with a SAR and no other MA options available	**This option is available to local MA plans only.** An MAO reduces the service area of a CY 2011 MA PBP and the reduced service area is not contained in another MA PBP offered by the same organization or any other MAO. The MAO **may offer** the option to individuals in the reduced portion of the service area for CY 2012 to enroll in its remaining PBP if no other MA plans are available (see 42 CFR 422.74(b)(3)(ii)). **Note:** One renewal plan with a SAR may have counties that should follow the guidance provided in 5a, and other counties in the SAR that should follow the guidance provided under 5b (i.e., the guidance provided in 5a and 5b may both apply to a single plan).	**HPMS Plan Crosswalk Definition:** A 2012 plan that links to a 2011 plan and only retains a portion of its plan service area. The 2012 plan must retain the same plan ID as the 2011 plan. **HPMS Plan Crosswalk Designation:** Renewal Plan with a SAR **Note**: If the 2012 plan has both an SAE and a SAR, the plan must be renewed as a renewal plan with a SAR	The MAO **must submit disenrollment transactions** for individuals residing in the reduced portion of the service area for whom it does not collect an enrollment request. The MAO **does not submit enrollment transactions** for current enrollees in the renewal portion of the service area.	Enrollees impacted by the SAR need to complete an enrollment request if the MAO offers the option of continued enrollment (see 42 CFR 422.74(b) (3) (ii)).	The MAO sends a termination notice to current enrollees in the reduced service area that includes notification of SEP and guaranteed issue Medigap rights. The MAO may also provide affected enrollees additional information, in addition to the termination notice, about the option to remain enrolled in the plan if the MAO elects to offer enrollment to enrollees in the reduced portion of the service area. Current enrollees in the renewal portion of the service area receive the standard ANOC.

Appendix A-2

	Activity	Guidelines	Renewal Effectuation Method	Systems Enrollment Activities	Enrollment Procedures	Beneficiary Notifications
5b	Renewal Plan with a SAR when the MAO will offer another PBP in the reduced portion of the service area	**This option is available to local MA plans only.** An MAO reduces the service area of a CY 2011 MA PBP and the reduced service area is part of a new or renewal PBP offered by that MAO in 2012. The MAO **may market** to enrollees in the reduced service area any other PBP offered in the reduced service area for CY 2012. Affected enrollees who elect to enroll in another MA plan offered in the reduced service area must submit an enrollment request. **Note:** One renewal plan with a SAR may have counties that should follow the guidance provided in 5a and other counties in the SAR that should follow the guidance provided under 5b (i.e., the guidance provided in 5a and 5b may both apply to a single plan**).**	**HPMS Plan Crosswalk Definition:** A 2012 plan that links to a 2011 plan and only retains a portion of its plan service area. The 2012 plan must retain the same plan ID as the 2011 plan. **HPMS Plan Crosswalk Designation:** Renewal Plan with a SAR **Note**: If the 2012 plan has both an SAE and a SAR, the plan must be renewed as a renewal plan with a SAR.	The MAO **must submit transactions to disenroll individuals** residing in the reduced portion of the service area. The MAO **submits enrollment transactions** to enroll beneficiaries who have requested enrollment in other PBP offered in the reduced service area.	Enrollees impacted by the SAR **need to complete enrollment requests** if they elect to enroll in another PBP (plan) in the same organization or a different MA plan.	The MAO sends a termination notice to current enrollees in the reduced portion of the service area that includes notification of SEP and guaranteed issue Medigap rights. The MAO may also provide additional information, in addition to the termination notice, including instructions on how to complete an enrollment request to switch to another PBP offered by the same organization. Current enrollees in the renewal portion of the service area receive the standard ANOC.

Appendix A-2

	Activity	Guidelines	Renewal Effectuation Method	Systems Enrollment Activities	Enrollment Procedures	Beneficiary Notifications
6	Terminated Plan (Non-Renewal)	An MAO terminates the offering of a CY 2011 PBP.	**HPMS Plan Crosswalk Definition:** A 2011 plan that is no longer offered in 2012. **HPMS Plan Crosswalk Designation:** Terminated Plan.	The MAO **does not submit disenrollment transactions**. If the terminated enrollee elects to enroll in another MA plan with the same or any other MAO, that organization **must submit enrollment transactions** to enroll the beneficiary.	Terminated enrollees must complete an enrollment request if they choose to enroll in another PBP, even in the same organization.	Terminated enrollees are sent a termination notice that includes notification of SEP and guaranteed issue Medigap rights.
7a	Non-network PFFS plan transitioning to a partial network PFFS plan.	**For PFFS only:** An MAO **consolidates** one or more CY 2011 non-network PFFS PBPs into a single new or renewing CY 2012 partial PFFS PBP under a separate contract held by the same legal entity. Only consolidation of whole PBPs is allowed under this option; PBPs may not be split.	**Exceptions Renewal Request:** Organizations must submit an exceptions request via HPMS and CMS staff will complete the transition on behalf of the organization. **HPMS Plan Crosswalk Designation:** The non-network plan being transitioned must be marked as a terminated plan in the HPMS Plan Crosswalk. The 2012 partial network plan must be active and contain the applicable service area from the terminated plan being renewed.	HPMS will record the consolidation of one or more whole PBPs. The MAO **does not** submit enrollment transactions for current enrollees. MAOs may need to submit updated 4RX data for enrollees affected by the consolidation.	No enrollment request is required for current enrollees to remain enrolled in the renewal PBP in 2012. New enrollees must complete enrollment request.	Current enrollees are sent a standard ANOC.

Appendix A-2

	Activity	Guidelines	Renewal Effectuation Method	Systems Enrollment Activities	Enrollment Procedures	Beneficiary Notifications
7b.	Some counties of a non-network PFFS plan transitioning to a partial network PFFS plan.	**For PFFS only:** For the counties in the 2011 non-network PFFS PBP that will remain non-network, the MAO must follow the rules for a renewal plan with SAR described elsewhere in this guidance. For current enrollees residing in the counties in the 2011 non-network PFFS PBP that will be consolidated into a single new or renewing partial network PBP under a separate contract held by the same legal entity, the MAO must submit enrollment transactions.	**Exceptions Crosswalk Request:** Organizations cannot complete the transition of current enrollees to the partial network PFFS plan via the HPMS Plan Crosswalk. Organizations must submit an exceptions request via HPMS . If approved, the MAO will be permitted to submit enrollment transactions. **HPMS Plan Crosswalk Definition:** A 2012 non-network plan that links to a 2011 non-network plan and only retains the available non-network counties in its plan service area. The 2012 plan must retain the same plan ID as the 2011 plan. **HPMS Plan Crosswalk Designation:** Renewal Plan with a SAR.	The MAO **must submit enrollment transactions** to transition current enrollees to the new or renewing partial network PBP under a separate contract held by the same legal entity. For current enrollees that remain in the renewed non-network PFFS plan, the MAO does not submit enrollment transactions.	No enrollment request is required for current enrollees. New enrollees must complete enrollment requests.	Current enrollees are sent a standard ANOC.
8a.	Non-network PFFS plan transitioning to a full network PFFS plan.	**For PFFS only:** An MAO consolidates one or more whole CY 2011 non-network PFFS PBPs into a single new or renewing CY 2012 full network PFFS PBP under a separate contract held by the same legal entity. Under this option, only consolidation of whole PBPs is allowed; PBPs may not be split.	**Exceptions Crosswalk Request:** Organizations must submit an exceptions request via HPMS and CMS staff will complete the transition on behalf of the organization. **HPMS Plan Crosswalk Designation:** The non-network plan being transitioned must be marked as a terminated plan in the HPMS Plan Crosswalk. The 2012 full network plan must be active and contain the applicable service area from the terminated plan being transitioned.	HPMS will record the consolidation of one or more whole PBPs. The MAO **does not submit enrollment transactions** for current enrollees. MAOs may need to submit updated 4RX data for enrollees affected by the consolidation.	No enrollment request is required for current enrollees to remain enrolled in the renewal PBP in 2012. New enrollees must complete enrollment requests.	Current enrollees are sent a standard ANOC.

Appendix A-2

	Activity	Guidelines	Renewal Effectuation Method	Systems Enrollment Activities	Enrollment Procedures	Beneficiary Notifications
8b.	Some counties of a non-network PFFS plan transitioning to a full network PFFS plan.	**For PFFS only:** For the counties in the 2011 non-network PFFS PBP that will remain non-network, the MAO must follow the rules for a renewal plan with SAR described elsewhere in this guidance. For current enrollees residing in the counties in the 2011 non-network PFFS PBP that will be consolidated into a single new or renewing full network PBP under a separate contract held by the same legal entity, the MAO must submit enrollment transactions.	**Exceptions Crosswalk Request:** Organizations cannot complete the transition of current enrollees to the full network PFFS plan via the HPMS Plan Crosswalk. Organizations must submit an exceptions request via HPMS. If approved, the MAO will be permitted to submit enrollment transactions. **HPMS Plan Crosswalk Definition:** A 2012 non-network plan that links to a 2011 non-network plan and only retains the available non-network counties in its plan service area. The 2012 plan must retain the same plan ID as the 2011 plan. **HPMS Plan Crosswalk Designation:** Renewal Plan with a SAR	The MAO **must submit enrollment transactions** to transition current enrollees to the new or renewing full network PBP under a separate contract held by the same legal entity. For current enrollees that remain in the renewed non-network PFFS plan the MAO **does not submit enrollment transactions.**	No enrollment request is required for current enrollees. New enrollees must complete enrollment requests.	Current enrollees are sent a standard ANOC.
9a	Partial network PFFS plan transitioning to a full network PFFS plan.	**For PFFS only:** An MAO consolidates one or more CY 2011 partial network PFFS PBPs into a single new or renewing CY 2012 full network PFFS PBP under a separate contract held by the same legal entity. Only consolidation of whole PBPs is allowed; PBPs may not be split.	**Exceptions Crosswalk Request:** Organizations must submit an exceptions request via HPMS and CMS staff will complete the transition on behalf of the organization. **HPMS Plan Crosswalk Designation:** The partial network plan being transitioned must be marked as a terminated plan in the HPMS Plan Crosswalk. The 2012 full network plan must be active and contain the applicable service area from the terminated plan being transitioned.	HPMS will record the consolidation of one or more whole PBPs. The MAO **does not submit enrollment transactions** for current enrollees. MAOs may need to submit updated 4RX data for enrollees affected by the consolidation, as applicable.	No enrollment request is required for current enrollees to remain enrolled in the renewal PBP in 2012. New enrollees must complete enrollment requests.	Current enrollees are sent a standard ANOC.

Appendix A-2

	Activity	Guidelines	Renewal Effectuation Method	Systems Enrollment Activities	Enrollment Procedures	Beneficiary Notifications
9b.	Some counties of a partial PFFS plan transitioning to a full network PFFS plan.	**For PFFS only:** For the counties in the 2011 partial network PFFS PBP that will remain partial, the MAO must follow the rules for a renewal plan with SAR described elsewhere in this guidance. For current enrollees residing in the counties in the 2011 partial network PFFS PBP that will be consolidated into a single new or renewing full network PBP under a separate contract held by the same legal entity, the MAO must submit enrollment transactions.	**Exceptions Crosswalk Request:** Organizations cannot complete the transition of current enrollees to the full network PFFS plan via the HPMS Plan Crosswalk. Organizations must submit an exceptions request via HPMS. If approved, the MAO will be permitted to submit enrollment transactions. **HPMS Plan Crosswalk Definition:** A 2012 partial network plan that links to a 2011 partial network plan and only retains the available partial network counties in its plan service area. The 2012 plan must retain the same plan ID as the 2011 plan. **HPMS Plan Crosswalk Designation:** Renewal Plan with a SAR.	The MAO **must submit enrollment transactions** to transition current enrollees to the new or renewing full network PBP under a separate contract held by the same legal entity. For current enrollees that remain in the renewed partial-network PFFS plan the MAO **does not submit enrollment transactions.**	No enrollment request is required for current enrollees. New enrollees must complete enrollment requests.	Current enrollees are sent a standard ANOC.

Appendix A-2

	Activity	Guidelines	Renewal Effectuation Method	Systems Enrollment Activities	Enrollment Procedures	Beneficiary Notifications
10.	D-SNP with no State contract consolidating with a D-SNP with a State contract, so that, effectively, an entire D-SNP is transferred into another D-SNP with a state contract and the D-SNP without a State contract no longer exists	**For D-SNPs only**: An MAO offering a CY 2011 D-SNP PBP with no State contract may consolidate with a CY 2012 D-SNP, offered under the same contract, which has a contract with the State.	**HPMS Plan Crosswalk Definition:** Two or more whole 2011 D-SNP plans (PBPs) that consolidate into one 2012 plan. The 2012 plan ID must be D-SNP with the state contract. **HPMS Plan Crosswalk Designation:** Consolidated Renewal Plan	The MAO **does not send enrollment transactions** for current enrollees who will remain enrolled in the 2012 PBP. The MAO **must submit disenrollment transactions** for current enrollees who are ineligible for the renewal PBP.	No enrollment request is required for current eligible enrollees to remain enrolled in the renewal PBP in 2012. New enrollees must complete enrollment requests.	Current enrollees eligible to remain enrolled in the renewal plan receive a standard ANOC. The MAO sends a CMS model disenrollment notice to ineligible current enrollees who are to be disenrolled, which will convey information about other plan options, as well as additional details about Medigap rights and/or SEP rights, as applicable.

Appendix A-2

	Activity	Guidelines	Renewal Effectuation Method	Systems Enrollment Activities	Enrollment Procedures	Beneficiary Notifications
11.	Renewing D-SNPs that also creates new Medicaid subset D-SNP and transitions eligible enrollees into the new Medicaid subset D-SNP	**For D-SNPs only**: An MAO renewing a D-SNP plan for 2012 and also creating a new Medicaid subset D-SNP for 2012. A subset of current enrollees under the renewing D-SNP is eligible to be enrolled in the new Medicaid subset D-SNP. The organization must submit enrollment transactions to move the eligible D-SNP enrollees into the new Medicaid subset D-SNP.	**Exceptions Crosswalk Request:** Organizations cannot complete the transition of current eligible enrollees to the new Medicaid subset D-SNP via the HPMS Plan Crosswalk. Organizations must submit an exceptions request via HPMS. If approved, the MAO will be permitted to submit enrollment transactions. **HPMS Plan Crosswalk Definition:** A 2012 D-SNP that links to a 2011 D-SNP and retains all of its plan service area from 2011. The 2012 plan must retain the same plan ID as the 2011 plan. In addition, a new Medicaid subset plan is added for 2012 that is not linked to a 2011 plan. **HPMS Plan Crosswalk Designation:** Renewal Plan (renewing D-SNP designation) AND New Plan (new Medicaid subset D-SNP designation)	**The renewal PBP ID must remain the same** so that the HPMS Plan Crosswalk will indicate that beneficiaries remain in the same PBP ID. The MAO **must submit enrollment transactions** to transition eligible current enrollees into the new Medicaid subset D-SNP. Individual enrollees not transitioned by the submission of enrollment transactions will remain enrolled in the renewing PBP.	No enrollment request is required for current enrollees to remain enrolled in the renewal PBP in 2012. New enrollees must complete enrollment request.	Current enrollees transitioned to the renewal plan receive a standard ANOC. Current enrollees who are transitioned to the new Medicaid subset PBP receive a standard ANOC.

Appendix A-2

	Activity	Guidelines	Renewal Effectuation Method	Systems Enrollment Activities	Enrollment Procedures	Beneficiary Notifications
12.	Renewing D-SNP in a multi-state service area with a SAR to accommodate State contracting efforts in portions of that service area	**For D-SNPs only:** An MAO reduces the service area of a CY 2011 D-SNP PBP to accommodate State contracting efforts in a multi-State service area. Current enrollees in the reduced portion of the service area are transitioned to one or more new or renewing CY 2012 D-SNP PBPs. The organization must submit enrollment transactions to move current enrollees in the reduced portion of the CY 2011 D-SNP PBP into the new or renewing CY 2012 D-SNP PBPs.	**Exceptions Crosswalk Request:** Organizations cannot complete the transition of current enrollees to one or more new or renewing CY 2012 D-SNP PBPs via the HPMS Plan Crosswalk. Organizations must submit an exceptions request via HPMS. If approved, the MAO will be permitted to submit enrollment transactions. **HPMS Plan Crosswalk Definition:** A 2012 plan that links to a 2011 plan and only retains a portion of its plan service area. The 2012 plan must retain the same plan ID as the 2011 plan. In addition, a new plan(s) is added for 2012 that is not linked to a 2011 plan(s), or a 2011 plan is renewed in 2012. **HPMS Plan Crosswalk Designation:** Renewal Plan with a SAR AND/OR New Plan AND/OR Renewal Plan	**The renewal PBP ID must remain the same** so that the HPMS Plan Crosswalk will indicate that beneficiaries remain in the same PBP ID The MAO **must submit enrollment transactions** to transition current enrollees in the reduced portion of the service area into a new or renewing D-SNP. Individual enrollees not transitioned by the submission of enrollment transactions will remain enrolled in the renewing PBP.	No enrollment request is required for current enrollees in the remaining portion of the service area to remain enrolled in the renewal PBP in CY 2012. New enrollees must complete enrollment request.	Current enrollees in the renewal portion of the service area receive the standard ANOC. Current enrollees in the reduced portion of the service area who are transitioned to a new or renewal D-SNP PBP receive the standard ANOC.

Appendix A-2

	Activity	Guidelines	Renewal Effectuation Method	Systems Enrollment Activities	Enrollment Procedures	Beneficiary Notifications
13a.	D-SNP that transitions current enrollees to a new D-SNP with a different designation and less restrictive eligibility requirements.	**For D-SNPs only**: An MAO offering a CY 2011 D-SNP PBP that requests conversion to a different D-SNP type for CY 2012. The new D-SNP has less restrictive eligibility and all current enrollees remain eligible for the new D-SNP with the new designation.	**Exceptions Crosswalk Request:** Organizations **must** submit an exceptions request via HPMS and CMS staff will complete the transition on behalf of the organization. **HPMS Plan Crosswalk Definition:** The 2011 D-SNP must be marked as a terminated plan in the HPMS Plan Crosswalk. The new 2012D-SNP must be active and contain the applicable service area from the terminated plan being transitioned.	The MAO **does not submit enrollment transactions** for current enrollees.	No enrollment request is required for current enrollees to remain enrolled in the renewal PBP in 2012. New enrollees must complete enrollment requests.	Current enrollees are sent a standard ANOC.
13b.	D-SNP that transitions some current enrollees to a new D-SNP with a different designation and more restrictive eligibility requirements consistent with the new D-SNP's State contract.	**For D-SNPs only**: An MAO offering a CY 2011 D-SNP PBP that requests conversion to a different D-SNP type for CY 2012. The new D-SNP has more restrictive eligibility criteria. A subset of current enrollees is eligible to remain enrolled in the new 2012 D-SNP.	**Exceptions Crosswalk Request:** Organizations **must** submit an exceptions request via HPMS and CMS staff will complete the transition on behalf of the organization. **HPMS Plan Crosswalk Definition:** The 2011 D-SNP must be marked as a terminated plan in the HPMS Plan Crosswalk. The new 2012 D-SNP must be active and contain the applicable service area from the terminated plan being transitioned.	The MAO **does not submit enrollment transactions** for current enrollees who will be transitioned to the new D-SNP. The MAO **submits disenrollment transactions** for current enrollees who are ineligible for the new D-SNP..	No enrollment request is required for current enrollees to remain enrolled in the new PBP in 2012. New enrollees must complete enrollment requests.	Current enrollees who remain eligible for the renewing plan receive a standard ANOC. The MAO sends a CMS model disenrollment notice to ineligible current enrollees who are to be disenrolled, which will convey information about other plan options, as well as additional details about Medigap rights and/or SEP rights, as applicable.

Appendix A-2

	Activity	Guidelines	Renewal Effectuation Method	Systems Enrollment Activities	Enrollment Procedures	Beneficiary Notifications
14.	Renewing SNP with ineligible, or "disproportionate share," enrollees.	An MAO renewing a SNP that includes a subset of current enrollees who do not meet the eligibility criteria for enrollment in the SNP ("disproportionate share" enrollees or enrollees affected by change in scope of C-SNP).	**HPMS Plan Crosswalk Definition:** A 2012 plan that links to a 2011 plan and retains all of its plan service area from 2011. The 2012 plan must retain the same plan ID as the 2011 plan **HPMS Plan Crosswalk Designation:** Renewal Plan	The MAO **does not submit enrollment transactions** for current enrollees who meet the SNP eligibility criteria for enrollment and will remain enrolled in the 2012 PBP. Plans must submit disenrollment transactions for current enrollees who were enrolled as of January 1, 2010 and continue to not meet the eligibility criteria for enrollment in the SNP.	No enrollment request is required for enrollees eligible to remain enrolled in the renewal PBP in 2012. New enrollees must complete enrollment requests.	Enrollees who remain eligible for the renewing plan receive a standard ANOC. The MAO sends a CMS model disenrollment notice to ineligible current enrollees who are to be disenrolled, which will convey information about other plan options, as well as additional details about Medigap rights and/or SEP rights, as applicable

Appendix B-1 – CY 2012 PDP PBP Renewal and Non-Renewal Guidance

PDP regions are defined by CMS and consist of one or more entire states (refer to Appendix 3, Chapter 5, of the Prescription Drug Benefit Manual for a map of the 34 PDP regions). Each PDP sponsor's PBPs must be offered in at least one entire region and a PDP sponsor's PBP cannot be offered in only part of a region. Please note that PDP bidding rules require PDP sponsors to submit separate bids for each region to be covered. HPMS only accepts a PDP sponsor's PBPs to cover one region at a time for individual market plans (e.g., a PDP sponsor offering a "national" PDP must submit 34 separate PBP bids in order to cover all PDP regions).

A PDP sponsor may expand the service area of its offerings by submitting additional bids in the PDP regions the sponsor expects to enter in the following contract year, provided the sponsor submits a PDP Service Area Expansion (SAE) application and CMS approves that application and then approves the sponsor's submitted bids for the new region or regions. For more information about the application process, refer to: http://www.cms.hhs.gov/PrescriptionDrugCovContra/04_RxContracting_ApplicationGuidance.asp#TopOfPage.

Conversely, a PDP sponsor may reduce its service area by electing not to submit bids for those regions from which it expects to withdraw. A PDP sponsor must notify CMS in writing (by sending an email to drugbenefitimpl@cms.hhs.gov) of its intent to non-renew one or more plans under a contract by the first Monday in June[8] pursuant to 42 CFR §423.507(a)(2)(i). The same procedure applies to PDPs converting contracts from offering both individual and employer products to employer-only products. However, even absent written notification to CMS, a PDP sponsor's failure to submit a timely bid to CMS constitutes a voluntary non-renewal by the sponsor. (Note that PDP sponsors reducing their service areas must provide notice of their action to affected beneficiaries consistent with regulatory requirements, CMS' PDP Eligibility, Enrollment, and Disenrollment Guidance, Chapter 3 of the Prescription Drug Benefit Manual and CMS non-renewal and service area reduction guidance.)

Each renewal/non-renewal option available to PDP sponsors for CY 2012 is outlined in Appendix B-2 and summarized below. All but one of these actions can be effectuated by PDP sponsors in the HPMS Plan Crosswalk.

1. New Plan Added

A PDP sponsor may create a new PBP for the following contract year with no link to a PBP it offers in the current contract year in the HPMS Plan Crosswalk. In this situation, beneficiaries electing to enroll in the new PBP must complete enrollment requests, and the PDP sponsor offering the PBP must submit enrollment transactions to MARx. No beneficiary notice is required in this case beyond receipt of the Evidence of Coverage (EOC), and other documents as required by current CMS guidance, following enrollment.

[8] CY 2012 bids are due no later than June 6, 2011

2. Renewal Plan

A PDP sponsor may continue to offer a current PBP that retains all of the same service area for the following year. The renewing plan must retain the same PBP ID number as in the previous contract year in the HPMS Plan Crosswalk. Current enrollees are not required to make an enrollment election to remain enrolled in the renewal PBP, and the sponsor will not submit enrollment transactions to MARx for current enrollees. New enrollees must complete enrollment requests, and the sponsor will submit enrollment transactions to MARx for those new enrollees. Current enrollees of a renewed PBP must receive a standard Annual Notice of Change (ANOC) notifying them of any changes to the renewing plan.

3. Consolidated Renewal Plan

PDP sponsors are permitted to combine two or more entire PBPs offered in the current contract year into a single renewal plan in the HPMS Plan Crosswalk. A PDP sponsor may not split a current PBP among more than one PBP for the following contract year. A PDP sponsor consolidating one or more entire PBPs must designate which of the renewal PBP IDs will be retained following the consolidation; the organization's designated renewal plan ID must remain the same in order for CMS to consolidate the beneficiary's election by moving him or her into the designated renewal plan ID. This is particularly important with respect to minimizing beneficiary confusion when a plan consolidation affects a large number of enrollees. When consolidating two existing PBPs into a single renewal PBP, it is permissible for the single renewal PBP to result in a change from:

(1) A basic benefit design (meaning either defined standard, actuarially equivalent standard, or basic alternative benefit designs) to another basic benefit design;

(2) An enhanced alternative benefit design to a basic benefit design; or

(3) An enhanced alternative benefit design to another enhanced alternative benefit design.

We will not, however, permit consolidation of two existing PBPs into a single renewal PBP through the HPMS Plan Crosswalk when it involves a change from a basic benefit design to an enhanced alternative benefit design, since enrollees previously not subject to a supplemental premium under a basic benefit design will have to pay a combined basic and supplemental premium under an enhanced alternative benefit design that may be higher than a basic premium.

Current enrollees of a plan or plans being consolidated into a single renewal plan will not be required to take any enrollment action, and the sponsor will not submit enrollment transactions to MARx for those current members, although it may need to submit updated 4Rx data to CMS for the current enrollees affected by the consolidation. New enrollees must complete enrollment requests, and the sponsor will submit enrollment transactions to MARx for those new enrollees. Current enrollees of a consolidated renewal plan must receive a standard ANOC.

4. Renewal Plan with a Service Area Expansion ("800 Series" EGWPs only)

A PDP sponsor offering an 800 series EGWP PBP in the current contract year may expand its EGWP service area to include additional PDP regions for the following contract year through the Part D application process. In order for currently enrolled beneficiaries to remain in the renewed PBP, the sponsor must retain the same PBP identification number for the following contract year.

Current enrollees will not be required to take any enrollment action, and the sponsor will not submit enrollment transactions to MARx for those current enrollees. New enrollees must complete enrollment requests, and the sponsor will submit enrollment transactions to MARx for those new enrollees. Current enrollees of a renewed PBP with a SAE must receive a standard ANOC notifying them of any changes to the renewing plan.

5. Terminated Plan (Non-Renewal)

A PDP sponsor may elect to terminate a current PBP for the following contract year and must notify CMS in writing (by sending an email to drugbenefitimpl@cms.hhs.gov) by the first Monday in June[9] pursuant to 42 CFR §423.507(a)(2)(i). In this situation, the sponsor will not submit disenrollment transactions to MARx for affected enrollees. When a sponsor terminates a PBP, plan enrollees must make a new election for their Medicare coverage in the following contract year. To the extent that a current enrollee of a terminated PBP elects to enroll in another plan offered by the current or another PDP sponsor – or, alternatively, elects to enroll in an MA plan – he/she must complete an enrollment request, and the enrolling organization or sponsor must submit enrollment transactions to MARx so that those individuals are enrolled. Enrollees of terminated PBPs will be sent a model termination notice that includes notification of a special election period, as well as information about alternative options. For more information about non-renewal processes and beneficiary notification requirements, refer to our forthcoming HPMS memorandum providing non-renewal and service area reduction guidance and model notices, to be released this summer.

6. Consolidated Plans under a Parent Organization

For purposes of ensuring compliance with transition requirements following an acquisition or merger under our significant differences policy, or to make plan transitions following a novation, CMS may elect to combine two or more entire PBPs offered under different contracts (the contracts may be offered by the same legal entity or represent different legal entities). PDP sponsors must complete this renewal option by submitting a crosswalk exception request through HPMS. CMS will provide detailed technical instructions for completing a crosswalk exception request through HPMS in forthcoming guidance. Requests will be reviewed and, if approved, the action will be completed on behalf of the requesting PDP. Current enrollees of a plan or plans being consolidated across contracts in this manner will not be required to take any

[9] CY 2012 bids are due no later than June 6, 2011

enrollment action, and the sponsor will not submit enrollment transactions to MARx for those current members, although it may need to submit updated 4Rx data to CMS for the current enrollees affected by the consolidation. New enrollees must complete enrollment requests, and the sponsor will submit enrollment transactions to MARx for those new enrollees.

Current enrollees of a consolidated renewal plan must receive a special notice along with a standard ANOC. Plan sponsors should use the CMS model for this special notice provided in Appendix C of this Call Letter.

Appendix B-2 – Contract Year 2012 Guidance for Prescription Drug Plan Renewals

	Activity	Guidelines	HPMS Plan Crosswalk	Systems Enrollment Activities	Enrollment Procedures	Beneficiary Notifications
1	New Plan (PBP) Added	PDP sponsor creates a new PBP.	**HPMS Plan Crosswalk Definition:** A new plan added for 2012 that is not linked to a 2011 plan. **HPMS Plan Crosswalk Designation:** New Plan	The PDP sponsor must submit enrollment transactions.	New enrollees must complete an enrollment request.	None.
2	Renewal Plan	A PDP sponsor continues to offer a CY 2011 PBP in CY 2012. **The same PBP ID number must be retained** in order for all current enrollees to remain in the same PBP in CY 2012.	**HPMS Plan Crosswalk Definition:** A 2012 plan that links to a 2011 plan and retains all of its plan service area from 2011. The 2012 plan must retain the same plan ID as the 2011 plan. **HPMS Plan Crosswalk Designation:** Renewal Plan	**The renewal PBP ID must remain the same** so that current enrollees will remain in the same PBP ID. The PBP sponsor **does not** submit enrollment transactions for current enrollees.	No enrollment request for current enrollees to remain enrolled in the renewal PBP in 2012. New enrollees must complete enrollment request.	Current enrollees are sent a standard ANOC.

Appendix B-2

	Activity	Guidelines	HPMS Plan Crosswalk	Systems Enrollment Activities	Enrollment Procedures	Beneficiary Notifications
3	Consolidated Renewal Plan	A PDP sponsor combines two or more PBPs offered in CY 2011 into a single renewal PBP for CY 2012. The PDP sponsor must designate which of the renewal PBP IDs will be retained in CY 2012 after consolidation. When a PDP sponsor combines an enhanced PBP with a basic PBP, the HPMS crosswalk only allows a crosswalk to a consolidated PBP that offers a basic benefit design.	**HPMS Plan Crosswalk Definition:** Two or more 2011 plans that consolidate into one 2012 plan. The 2012 plan ID must be the same as one of the consolidating 2011 plan IDs. **HPMS Plan Crosswalk Designation:** Consolidated Renewal Plan	**The PDP sponsor's designated renewal PBP ID must remain the same** so that CMS can consolidate current enrollees into the designated renewal PBP ID. The PDP sponsor **does not** submit enrollment transactions for current enrollees. Sponsors may need to submit updated 4RX data for enrollees affected by the consolidation.	No enrollment request for current enrollees to remain enrolled in the renewal PBP in 2012.	Current enrollees are sent a standard ANOC.
4	Renewal Plan with an SAE (**applicable only to employer/union group waiver plans**)	A PDP sponsor continues to offer an 800 series CY 2011 prescription drug PBP in CY 2012 and expands it s EGWP service area to include additional regions. **The PDP sponsor must retain the same PBP ID number** in order for all current enrollees to remain in the same PBP in CY 2012.	**HPMS Plan Crosswalk Definition:** A 2012 800-series plan that links to a 2011 800-series plan and retains all of its plan service area from 2011, but also adds one or more new regions. The 2012 plan must retain the same plan ID as the 2011 plan. **HPMS Plan Crosswalk Designation:** Renewal Plan with an SAE	**The renewal PBP ID must remain the same** so that current enrollees in the current service area will remain in the same PBP ID. The PDP sponsor does not submit enrollment transactions for current enrollees.	No enrollment request for current enrollees to remain enrolled in the renewal PBP in 2012. New enrollees must complete enrollment request.	Current enrollees are sent a standard ANOC.

Appendix B-2

	Activity	Guidelines	HPMS Plan Crosswalk	Systems Enrollment Activities	Enrollment Procedures	Beneficiary Notifications
5	Terminated Plan (Non-Renewal)	A PDP sponsor terminated the offering of a 2011 PBP.	**HPMS Plan Crosswalk Definition:** A 2011 plan that is no longer offered in 2012. **HPMS Plan Crosswalk Designation:** Terminated Plan	The PDP sponsor does not submit disenrollment transactions. If the terminated enrollee elects to enroll in another PBP with the same or another PDP sponsor or MAO, the enrolling PDP sponsor or organization **must submit enrollment transactions** to enroll the terminated enrollees.	Terminated enrollees must complete an enrollment request if they choose to enroll in another PBP, even a PBP offered by the same PDP sponsor.	Terminated enrollees are sent a CMS model termination notice including SEP information and receive a written description of options for obtaining prescription drug coverage in the service area.
6	Consolidated Plans across Contracts under the Same Parent Organization	A parent organization combines two or more whole PBPs under different contracts (the contracts may be the same legal entity or represent different legal entities) as a result of a merger, acquisition, or novation. A PDP sponsor cannot complete this renewal option in the HPMS Plan Crosswalk.	**Exceptions Crosswalk Request:** Organizations must submit an exceptions request via HPMS and CMS staff will complete the transition on behalf of the organization. **HPMS Plan Crosswalk Designation:** The plan being crosswalked must be marked as a terminated plan in the HPMS crosswalk. The remaining 2012 plan must be active and contain the applicable service area from the terminated plan being crosswalked.	PDP sponsors cannot complete this renewal option in the HPMS Plan Crosswalk. CMS will effectuate this renewal option and HPMS will record the consolidation of one or more whole PBPs. The PDP sponsor **does not** submit enrollment transactions for current enrollees. Sponsors may need to submit updated 4RX data for enrollees affected by the consolidation.	No enrollment election for current enrollees to remain enrolled in the renewal PBP in 2012. New enrollees must complete enrollment request.	Current enrollees are sent a special notice (based on the CMS model in Appendix C) along with a standard ANOC.

Appendix C – CMS Model Notice

Contract Year 2012 Guidance for PDP PBP Renewal Option 6 Special Disenrollment Notice

<Insert Date>

IMPORTANT NOTICE: Your Medicare Prescription Drug Coverage Is Changing

Dear <member name>,

<Organization name> will no longer offer <terminating plan name> after December 31, 2011. To make sure you continue to have the same level of Medicare Prescription Drug coverage, **you'll be enrolled in our <receiving plan name> starting < January 1, 2012>.**

Your new plan coverage starts January 1
<Organization name> has approval from Medicare to transfer your enrollment into our <receiving plan name> for 2012. Medicare approved this transfer because the prescription drug benefits in <receiving plan name> are similar to the prescription drug benefits you've been getting in <terminating plan name>. See the attached information about this new plan.

Here's what to do next
If you do nothing, you'll be a member of <receiving plan name> starting <January 1, 2012>. After reviewing your ANOC/EOC, if you have questions about your prescription drug benefits or how this new plan works, including what your costs will be or which pharmacies you can use call <receiving plan name> at <receiving plan phone number>. You should use this letter as proof of coverage under <receiving plan name> until you get your membership card.

You should look carefully at the prescription drug benefits of <receiving plan name> to see if they meet your needs. Although the prescription drug benefits are similar to the prescription drug benefits you have now, they may be different in ways that are important to you.

What if you don't want to be in this plan?
If you don't want to be in <receiving plan name> in 2012, you have the right to choose another Medicare Prescription Drug Plan **anytime between <xxxxx date> and <xxxxx date>.** Your new coverage will start on January 1, 2012.

Here are your options for Medicare Prescription Drug coverage:
Option 1: If you do nothing, you'll get prescription drug coverage from <receiving plan> starting <January 1, 2012>.

Option 2: You can join another Medicare Prescription Drug Plan. Joining a new plan will automatically disenroll you from <receiving plan name>. You should compare the plans available in your area. You can call the plans to get more information about their rules and coverage and find a plan that best meets your needs.

Option 3: You may be able to join a Medicare Advantage plan.
Other information you need to know:
If you qualify for Extra Help (the low-income subsidy) for 2012, you have the right to change plans at any time.

If you have an employer or union group health plan, VA benefits, or TRICARE for Life, call your insurer or benefits administrator to find out how joining a new plan**.**
If you get help from the Medicaid program, contact <State Medicaid Agency and phone number> to learn how joining a new plan affects your Medicaid coverage.

Get help and more information about your options
If you need more information about your changing coverage, please call us at <Phone Number> <Days & Hours>. TTY users should call <insert number >. Tell the customer service representative you got this notice.

To join another Medicare Prescription Drug Plan, you should compare available plans and join one that meets your needs. You should find out which plans cover the prescriptions you take. For help comparing plans and joining a plan that works for you, visit www.medicare.gov, or call 1-800-MEDICARE (1-800-633-4227). TTY users should call 1-877-486-2048. You can also call your State Health Insurance Assistance Program for free personalized counseling at <SHIP phone number>.

To see if your state has a program for people with limited income and resources, call your State Medical Assistance Office at <State Medical Assistance Office Number>. You may be able to get help paying Medicare premiums, deductibles and coinsurance. TTY users should call <State Medical Assistance Office> at <TTY Number>.

Sincerely,
<CEO or other official of PDP organization>

[Insert Federal contracting statement.]

[Insert Material ID number][insert **CMS Approved** *followed by mm/dd/yyyy]*

[“Model Beneficiary Notice for CMS Approved Crosswalk Situations”- (material submission code # 2054).]

Federal Register

Thursday,
April 15, 2010

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 417, 422, 423, and 480

Medicare Program; Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 417, 422, 423, and 480

[CMS–4085–F]

RIN 0938–AP77

Medicare Program; Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule makes revisions to the regulations governing the Medicare Advantage (MA) program (Part C) and prescription drug benefit program (Part D) based on our continued experience in the administration of the Part C and D programs. The revisions strengthen various program participation and exit requirements; strengthen beneficiary protections; ensure that plan offerings to beneficiaries include meaningful differences; improve plan payment rules and processes; improve data collection for oversight and quality assessment, implement new policies and clarify existing program policy.

DATES: *Effective Date:* These regulations are effective on June 7, 2010. However, we note that because health and drug plans under the Part C and D programs operate under contracts with CMS that are applicable on a calendar year basis, the provisions will not be applicable prior to contract year January 1, 2011, except where otherwise noted.

FOR FURTHER INFORMATION CONTACT:
Alissa Deboy, (410) 786–6041, General information and Part D issues.
Sabrina Ahmed, (410) 786–7499, Part C issues.
Terry Lied, (410) 786–8973, Collection of information requirements and regulatory impact analysis issues.
Kristy Nishimoto, (410) 786–8517, Part C and D enrollment and appeals issues.
Jennifer Smith, (410) 786–2987, Part C and D compliance and sanction issues.
Frank Szeflinski, (303) 844–7119, Part C payment issues.

SUPPLEMENTARY INFORMATION:

Table of Contents

Acronyms

AO Accrediting Organization
ADS Dispensing System
AEP Annual Enrollment Period
AHFS American Hospital Formulary Service
AHFS–DI American Hospital Formulary Service—Drug Information
AHRQ Agency for Health Care Research and Quality
ALJ Administrative Law Judge
BBA Balanced Budget Act of 1997 (Pub. L. 105–33)
BBRA [Medicare, Medicaid and State Child Health Insurance Program] Balanced Budget Refinement Act of 1999 (Pub. L. 106–113)
BIPA Medicare, Medicaid, and SCHIP Benefits Improvement Protection Act of 2000 (Pub. L. 106–554)
CAHPS Consumer Assessment Health Providers Survey
CAP Corrective Action Plan
CCIP Chronic Care Improvement Program
CCS Certified Coding Specialist
CMR Comprehensive Medical Review
CMP Civil Money Penalties

CMR Comprehensive Medical Review
CMS Centers for Medicare & Medicaid Services
CMS–HCC CMS Hierarchal Condition Category
CTM Complaints Tracking Module
COB Coordination of Benefits
CORF Comprehensive Outpatient Rehabilitation Facility
CPC Certified Professional Coder
CY Calendar year
DOL U.S. Department of Labor
DRA Deficit Reduction Act of 2005 (Pub. L. 109–171)
EGWP Employer Group/Union-Sponsored Waiver Plan
EOB Explanation of Benefits
ESRD End-stage renal disease
FACA Federal Advisory Committee Act
FDA Food and Drug Administration (HHS)
FEHBP Federal Employees Health Benefits Plan
FFS Fee-For-Service
FY Fiscal year
GAO General Accounting Office
HCPP Health Care Prepayment Plans
HEDIS HealthCare Effectiveness Data and Information Set
HHS [U.S. Department of] Health and Human Services
HIPAA Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104–191)
HMO Health Maintenance Organization
HOS Health Outcome Survey
HPMS Health Plan Management System
ICD–9–CM Internal Classification of Disease, 9th, Clinical Modification Guidelines
ICEP Initial Coverage Enrollment Period
ICL Initial Coverage Limit
ICR Information Collection Requirement
IVC Initial Validation Contractor
LEP Late Enrollment Penalty
LIS Low Income Subsidy
LTC Long Term Care
LTCF Long Term Care Facility
MA Medicare Advantage
MAAA American Academy of Actuaries
MAO Medicare Advantage Operations
MA–PD Medicare Advantage-Prescription Drug Plans
M+C Medicare+Choice program
MPDPF Medicare Prescription Drug Plan Finder
MIPPA Medicare Improvements for Patients and Providers Act of 2008
MMA Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173)
MSA Metropolitan statistical area
MSAs Medical Savings Accounts
MSP Medicare Secondary Payer
MTM Medication Therapy Management
MTMP Medication Therapy Management Programs
NAIC National Association Insurance Commissioners
NCPDP National Council for Prescription Drug Programs
NGC National Guideline Clearinghouse
NIH National Institutes of Health
NOMNC Notice of Medicare Non-coverage
OEP Open Enrollment Period
OIG Office of Inspector General
OMB Office of Management and Budget
OPM Office of Personnel Management
OTC Over the Counter
PART C Medicare Advantage
PART D Medicare Prescription Drug Benefit Programs
PPACA Patient Protection and Affordable Care Act (Pub. L. 111–148)
PBM Pharmacy Benefit Manager
PDE Prescription Drug Event
PDP Prescription drug plan
PFFS Private Fee For Service Plan
POS Point of service
PPO Preferred Provider Organization
PPS Prospective Payment System
P&T Pharmacy & Therapeutics
QIO Quality Improvement Organization
QRS Quality Review Study
PACE Programs of All Inclusive Care for the Elderly
RADV Risk Adjustment Data Validation
RAPS Risk Adjustment Payment System
RHIA Registered Health Information Administrator
RHIT Registered Health Information Technician
SCHIP State Children's Health Insurance Programs
SEP Special Enrollment Periods
SHIP State Health Insurance Assistance Programs
SNF Skilled Nursing Facility
SNP Special Needs Plan
SPAP State Pharmaceutical Assistance Programs
SSI Supplemental Security Income
TrOOP True Out Of Pocket
U&C Usual and Customary
USP U.S. Pharmacopoeia

SUPPLEMENTARY INFORMATION:

I. Background

A. Overview of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) was enacted on December 8, 2003. The MMA established the Part D program and made revisions to the provisions in Part C of the Medicare statute governing the Medicare Advantage (MA) program. The MMA directed that important aspects of the new Medicare prescription drug benefit program under Part D be similar to and coordinated with regulations for the MA program.

Generally, the provisions enacted in the MMA took effect January 1, 2006. The final rules for the MA and Part D prescription drug programs appeared in the **Federal Register** on January 28, 2005 (70 FR 4588–4741 and 70 FR 4194–4585, respectively). While the provisions of the final rule did not govern plan payment or benefits until January 1, 2006, given the fact that provisions relating to applications, marketing, contracts, and the new bidding process for the MA and Part D programs, many provisions in these final rules became effective on March 22, 2005, 60 days after publication of the rule.

As we have gained experience with the MA program and the prescription drug benefit program, we periodically have revised the Part C and D regulations to continue to improve or clarify existing policies and/or codify current guidance for both programs. For example, in December 2007, we published a final rule with comment on contract determinations involving Medicare Advantage (MA) organizations and Medicare Part D prescription drug plan sponsors (72 FR 68700). In April 2008, we published a final rule to address policy and technical changes to the Part D program (73 FR 20486). In September 2008 and January 2009, we finalized revisions to both the Medicare Advantage and prescription drug benefit programs (73 FR 54226 and 74 FR 1494, respectively) to implement provisions in the Medicare Improvement for Patients and Providers Act (MIPPA) (Pub. L. 110–275), which contained provisions impacting both the Medicare Part C and D programs, and make other policy clarifications based on experience with both programs (73 FR 54208, 73 FR 54226, and 74 FR 2881).

B. History and Overview

The Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33) established a new "Part C" in the Medicare statute (sections 1851 through 1859 of the Social Security Act (the Act) which provided for what was then called the Medicare+Choice (M+C) program. Under section 1851(a)(1) of the Act, every individual entitled to Medicare Part A and enrolled under Medicare Part B, except for most individuals with end-stage renal disease (ESRD), could elect to receive benefits either through the original Medicare program or an M+C plan, if one was offered where he or she lived. The primary goal of the M+C program was to provide Medicare beneficiaries with a wider range of health plan choices. The M+C provisions in Part C were amended by the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–111), and further amended by the Medicare, Medicaid, and State Children's Health Insurance Program SCHIP) Benefits Improvement Act of 2000 (BIPA) (Pub. L. 106–554).

As discussed above, the MMA, enacted on December 8, 2003, added a new "Part D" to the Medicare statute (sections 1860D–1 through 42 of the Act) creating the Medicare Prescription Drug Benefit Program, and made significant changes to the M+C program.

Also as noted above, MIPPA, enacted on July 15, 2008, addressed a number of provisions impacting the Part C and D programs, including provisions impacting marketing under both programs which were implemented in regulations published in the **Federal Register** on September 18, 2008 (73 FR 54208), a final rule effective October 1, 2008, that paralleled provisions in MIPPA, and in the same issue of the **Federal Register** (73 FR 54226), a separate interim final rule that addressed the other provisions of MIPPA affecting the MA and Part D programs. We also clarified the MIPPA marketing provisions in a November 2008 interim final rule (73 FR 67407 and issued a separate interim final rule in January 2009 to address MIPPA provisions related to Part D plan formularies (74 FR 2881).

In October 22, 2009 **Federal Register** (74 FR 54634), we published a proposed rule (file code CMS–4085–P), hereinafter referred to as the October 22, 2009 proposed rule) addressing additional policy clarifications under the Part C and D programs. As noted when issuing this proposed rule, we believe that additional programmatic and operational changes are needed in order to further improve our oversight and management of the Part C and D programs and to further improve beneficiary experience under MA or Part D plans.

Indeed, one of the primary reasons set forth in the preamble for issuing the October 22, 2009 proposed rule was to address beneficiary concerns associated with the annual task of selecting one plan from so many options. We noted that while it is clear that the Medicare Part D program has improved access to drug coverage for elderly and offered beneficiaries a wide range of plans from which to choose, some have suggested that a significant numbers of beneficiaries are confused by the array of choices and find it difficult to make enrollment decisions that are best for them. Moreover, experience has shown that organizations submitting bids under Part C and D to offer multiple plans have not consistently submitted plan benefit designs that were significantly different from each other, which can add to beneficiary confusion. In this rule, we finalize a number of proposals to the way we administer the Part C and D programs to promote beneficiaries making the best plan choice that suits their needs. Although we believe these provisions will go a long way to further that goal, we are committed to additional explorations of ways to structure choices for seniors to aid them in making better plan choices, and will continue to evaluate program changes in this area.

We also proposed additional provisions aimed at strengthening existing beneficiary protections, improving payment rules and processes, enhancing our ability to pursue data collection for oversight and quality assessment, strengthening formulary policy, and finalizing a number of clarifications and technical corrections to existing policy. Except as noted or otherwise modified, we finalize these requirements in this rule.

Section 902 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) amended section 1871(a) of the Act and requires the Secretary, in consultation with the Director of the Office of Management and Budget, to establish and publish timelines for the publication of Medicare final regulations based on the previous publication of a Medicare proposed or interim final regulation. Section 902 of the MMA also states that the timelines for these regulations may vary but shall not exceed 3 years after publication of the preceding proposed or interim final regulation except under exceptional circumstances.

This final rule has been published within the 3-year time limit imposed by section 902 of the MMA, and thus is in accordance with the Congress' intent to ensure timely publication of final regulations.

On March 23, 2010, the Patient Protection and Affordable Care Act (Pub. L. 111–148) was enacted. Several provisions of this public law affect the Part C and D programs. In sections II.B. and II.F. of this final rule, we provide a discussion of the effects of two of these provisions on our proposed policies regarding MA cost sharing and "protected classes" of drugs under Part D, respectively.

II. Provisions of the Proposed Rule and Analysis and Responses to Public Comments

We received approximately 114 items of timely correspondence containing comments on the October 22, 2009 proposed rule. Commenters included health and drug plan organizations, insurance industry trade groups, pharmacy associations, pharmaceutical benefit manager (PBM) organizations, provider associations, representatives of hospital and long term care institutions, drug manufacturers, mental health and disease specific advocacy groups, beneficiary advocacy groups, researchers, and others.

In this final rule, we address all timely comments and concerns on the policies included in the proposed rule. We note that there were several comments submitted that were outside the scope of the proposals set forth in the proposed rule and, as such, we do not address them within this final rule. Generally, the commenters supported our efforts to improve plan offerings by the same sponsor that are meaningfully different from each other in order to support improved beneficiary decision making and our efforts to clarify and codify existing policy through rulemaking.

A. Changes to Strengthen Our Ability To Distinguish for Approval Strong Applicants for Part C and D Program Participation and To Remove Consistently Poor Performers

This section finalizes a number of proposed revisions designed to strengthen our ability to approve strong applicants and remove poor performers in the Part C and D programs. Since the implementation of revisions to the MA and initial implementation of the prescription drug programs in January 2006, we have steadily enhanced our ability to measure MAO and PDP sponsor performance through efforts such as the analysis of data provided routinely by sponsors and by our contractors, regular review of beneficiary complaints, marketing surveillance activities, and routine audits. This information, combined with feedback we have received from beneficiary satisfaction surveys, HEDIS data, and information from MAOs and PDP sponsors themselves, has enabled us to develop a clearer sense of what constitutes a successful Medicare organization capable of providing quality Part C and D services to beneficiaries. Additionally, this information has also allowed us to identify and take appropriate action against organizations that are not meeting program requirements and not meeting the needs of beneficiaries.

As set forth below, we are finalizing changes and clarifications to our regulations to make certain that all current and potential MAOs and PDP sponsors clearly understand and can reasonably anticipate how we measure sponsor performance, determine when there is noncompliance, and when enforcement actions are warranted.

These provisions are described in detail in Table 1.

TABLE 1—PROVISIONS STRENGTHENING OUR ABILITY TO DISTINGUISH FOR APPROVAL STRONG APPLICANTS AND TO REMOVE CONSISTENTLY POOR PERFORMERS

Provision	Part 422		Part 423	
	Subpart	Section	Subpart	Section
Notice of Intent to Apply	Subpart K ...	§ 422.501	Subpart K ...	§ 423.502.
Application Standards	Subpart K ...	§ 422.502	Subpart K ...	§ 423.503.
Compliance Measures/Analysis	Subpart K ...	§ 422.502	Subpart K ...	§ 423.503.
Compliance Programs	Subpart K ...	§ 422.503(b)(4)(vi)	Subpart K ...	§ 423.504(b)(4)(vi).
Network Adequacy of Coordinated Care and Network-Based Private-Fee-For-Service plans under Part C.	Subpart C ..	§ 422.112	N/A	N/A.
Clarify programmatic elements that are "deemable"	Subpart D ..	§ 422.156(b)(7), § 422.156(f).	Subpart D ..	§ 423.165(b), § 423.165(f).
Procedures for termination and Nonrenewals: Part C and D	Subpart K ...	§ 422.510(c)(1), § 422.506(b)(3).	Subpart K ...	§ 423.509(c)(1), § 423.507(b)(3).
Intermediate Sanctions: procedures for imposing civil and money penalties.	Subpart O ..	§ 422.756	Subpart O ..	§ 423.756.
Contract Termination	Subpart K ...	§ 422.510(a)	Subpart K ...	§ 423.509(a).
Proper request for hearings	Subpart N ..	§ 422.662	Subpart N ..	§ 423.651.
Burden of Proof, Standard of Proof, Standard of Review and Conduct of Hearing.	Subpart N ..	§ 422.660, § 422.676(d).	Subpart N ..	§ 423.650, § 423.658(d).
Postponement of effective date of determination when a request is being filed.	Subpart N ..	§ 422.664	Subpart N ..	§ 423.652.
Extending timeframe for contract determination hearings	Subpart N ..	§ 422.670	Subpart N ..	§ 423.655.
Appeal times: require each party provide witness list and documents 5 calendar days before hearing.	Subpart N ..	§ 422.682	Subpart N ..	§ 423.661.
Appeal times: require request for a review by the administrator must be received with 15 days after receipt of hearing decision.	Subpart N .. § 422.692(a)	§ 422.692(a)	Subpart N ..	§ 423.666(a).
Contract redeterminations and reopening	Subpart N ..	§ 422.696	Subpart N ..	§ 423.668.
Mutual termination of contract	Subpart K ...	§ 422.503(b)(6)	Subpart K ...	§ 423.504(b)(6).

1. Require Notice of Intent To Apply Under Part C and D Within the Application Requirements (§ 422.501 and § 423.502)

Under the authority of section 1871(a)(1) of the Act, which authorizes us to prescribe such regulations as may be necessary to carry out the administration of the Medicare program, we proposed an administrative requirement in the October 22, 2009 proposed rule for both the Part C and D programs related to the application submission to qualify as MA and PDP sponsor contractors. We specifically proposed in § 422.501 and § 423.502 to codify our existing guidance that initial applicants and existing contractors seeking to expand complete a nonbinding Notice of Intent to Apply.

We noted that as a result of the fully electronic submission process and restrictions on access to the CMS Health Plan Management System (HPMS), every applicant must complete a Notice of Intent to Apply as described in the HPMS memo dated October 10, 2008. This includes both initial applicants and current contractors seeking to expand their organizations' service area and current contractors adding a Special Needs Plan (SNP) or an Employer Group/Union-Sponsored Waiver Plan (EGWP) to their existing contract.

We also noted that submitting a Notice of Intent to Apply does not bind that organization to submit an application for the following year. However, without a pending contract number and completed CMS User ID connectivity, an organization will not be able to access the appropriate modules in HPMS to complete the application materials.

In this final rule, we address comments received and finalize this provision with modification. As explained below, we modified § 422.503(b)(2) and § 423.502 (b)(2) to clearly indicate that the decision not to submit an application after submission of a notice of intent will not result in any compliance consequences.

Comment: Several commenters supported this provision.

Response: We appreciate the commenters support of our proposal.

Comment: Some commenters were concerned about the due date of the Notice of Intent to Apply and wanted exceptions to allow CMS the flexibility to accept notice of intent after the due date. Some commenters were particularly concerned about special need plans offered in conjunction with Medicaid. Commenters also urged CMS to provide organizations adequate time to make the decision whether to apply and stated that some organizations may not consider submitting an application at the time notices are due.

Response: As stated in the proposed regulation at § 422.503(b)(2) and § 423.503(b)(2), the Notice of Intent to Apply does not bind the organization to submit an application. For this reason, we do not believe it is necessary to be flexible with the due date of the notice of intent. Organizations are free to submit a Notice of Intent to Apply and then consider whether or not to submit an application without risking any negative consequences from CMS. We also believe that the notice of intent requirement will benefit applicants as it will serve as a 3-month advance reminder to begin preparation for their submission. We anticipate that the additional lead time will result in more successful applications.

Comment: One commenter questioned whether the three month lead time is necessary, particularly for existing sponsors, to ensure timely connectivity to CMS systems.

Response: Our preparation for the receipt of applications is a process that can take up to 3 months. We encourage interested parties to see the October 2, 2009 HPMS memo for an example of the timeline from submission of the Notice of Intent to Apply to the application submission.

Comment: One commenter wanted CMS to add language indicating that for those notices of intent that do not result in the submission of an application, lack of submission would not be considered as part of any punitive evaluation.

Response: As we stated in the October 2009 proposed rule, the Notice of Intent

to Apply does not bind the organization to submit an application. We want to make clear that the submission of a notice of intent without a subsequent application submission would present no risk of reprimand or sanction by us. For this reason, we are modifying § 422.503(b) and § 423.502 (b) to clearly indicate that the decision not to submit an application after submission of a notice of intent will not result in any compliance consequences.

2. Application Requirements (§ 422.501 (c) and § 423.502 (c)) and Evaluation and Determination Procedures for Determining Whether Applicants Are Qualified for a Contract Under Parts C and D (§ 422.502 and § 423.503)

In the October 2009 proposed rule, we proposed a single clarification that applies to both MA organizations and Part D sponsors related to our application evaluation procedures and appeals of our determinations regarding applications. At § 422.502 and § 423.503, we specifically proposed to make explicit that we will approve only those applications that demonstrate that they meet all (not substantially all) Part C and D program requirements.

We noted that the application process under Part C and D requires an applicant to submit for our review a combination of attestations that it will comply with stated program requirements, as well as submit contracts with organizations the applicant has contracted with to perform key Part C or D functions, evidence of the applicant's risk-bearing licenses, and data documenting that the applicant can provide its members access to Part C and D services consistent with the programs' requirements. We proposed at § 422.501(c)(1) and (2), § 422.502(a)(2), § 423.502(c)(1) and (2), and § 423.503(a)(2) to require that applicants demonstrate that they meet all requirements outlined in the MA organization and Part D sponsor applications.

We simplified the application evaluation process under § 422.502(a)(1) and § 423.503(a)(1) by limiting the evaluation of an entity's application to information contained in the application and any additional information that we obtain through onsite visits. As we noted in the proposed rule, limiting our review to this information ensures that we will afford all applicants (numbering in the hundreds each of the last 4 years) a fair and consistent review of their qualifications. Organizations can be assured that we will not consider additional sources of information regarding one applicant's qualifications that we do not consider for others.

We also proposed to clarify our authority to decline to consider application materials submitted after the expiration of the 10-day period following our issuance of a notice of intent to deny an organization's contract qualification application. We clarified § 422.502(c)(2) and § 423.503(c)(2) by proposing to add a new paragraph (iii) to establish that if we do not receive a revised application within 10 days from the date of the intent to deny notice, or if after timely submission of a revised application the applicant still appears unqualified to contract as an MA organization or Part D sponsor or has not provided enough information to allow us to evaluate the application, we will deny the application.

Further, we noted that consistent with the revisions to § 422.650(b)(2) and § 423.660(b)(2), which are discussed elsewhere in this final rule, the applicant would not be permitted to submit additional revised application material to the Hearing Officer for review should the applicant elect to appeal the denial of its application. Allowing for such a submission and review of such information as part of the hearing would, in effect, extend the deadline for submitting an approvable application. In this final rule, we adopt these provisions as proposed. *Comment:* A number of commenters expressed support for all areas of this provision.

Response: We appreciate the commenters support of our proposal.

Comment: Many commenters urged CMS to be flexible and allow for unique circumstances. Several commenters noted that SNPs have only limited ability to influence the terms and timelines that State Medicaid agencies follow in executing the SNP agreements.

Response: We design our solicitations to ensure that all organizations have a fair opportunity to demonstrate their qualifications for an MA or PDP contract. As noted in the preamble to the October 2009 proposed rule, allowing exceptions to requirements to address unique circumstances would undermine the need for a uniform application process applied fairly to all applicants. With respect to Medicaid agency contracts, we may require that organizations submit those documents as part of an application to qualify to offer a SNP plan. When we include that requirement in a particular year's SNP application, we have determined that organizations can reasonably be expected to obtain the executed agreements in time for us to determine that it is qualified to operate a SNP during the coming contract year. We do not anticipate the need to provide any flexibility on this particular matter.

Comment: One commenter stated that the "all" standard is not practical given that there is not a narrative of requirements in the applications, but a series of attestations and tables (with detailed requirements stated in regulations and CMS subregulatory guidance).

Response: We believe the "all" standard is practical. Applicants receive enough information to successfully apply and are given two opportunities with instructions to cure deficiencies. While we advise that applicants should be familiar with Part C and D program regulations and guidance, in most instances they are not required to describe how their organization will meet a requirement; rather they simply attest that they will meet the requirement. Therefore, an explanation of all the program requirements in the application is not necessary for organizations to submit successful Part C or D applications to us.

Comment: Several commenters stated that CMS has been unclear in its previous deficiency responses to applicants and that it has been difficult to obtain guidance from CMS. Commenters urged CMS to provide clear rules and be consistent. In light of the inconsistencies with which applications are reviewed, one commenter recommended using a standard that emphasizes the materiality of the requirements that sponsors must meet.

Response: We agree that in order for applicants to have a consistent understanding of the expectations on which we base our contract approval and denials, we must ensure the clarity and transparency of the program requirements and review criteria. Applicants receive up to three communications which explain our application requirements and provide clear instructions on how to be a successful applicant. Organizations that fail to completely and accurately apply receive a courtesy e-mail explaining the deficiencies and are given an opportunity to cure. Organizations that are still deficient after the initial opportunity to cure receive a notice of intent to deny and are given another opportunity to cure. All application communications include contact information for CMS subject matter specialists. We are always willing to work with applicants to ensure a complete understanding of program and contracting requirements.

Comment: One commenter stated that the applicants that have disagreed with CMS' network adequacy determinations have been reluctant to seek re-

evaluation of their network adequacy in specific counties because of the possibility that CMS will confirm its original finding and deny the entire application. A denial of one county in one state could result in the denial of an entire application. To address this problem, the commenter recommended that CMS revise its policy to provide that an applicant for a network-based plan or service area expansion (SAE) may drop a county or portion of its service area that has been identified in the intent to deny notice after receiving CMS' final decision based upon the additional information submitted by the organization.

Response: We afford sponsors multiple opportunities during the application review process for applicants to modify their proposed service area. However, when we conduct our final review of an application prior to the issuance of a notice of intent to deny, we must make the reasonable assumption, for the sake of consistency, that the applicant seeks approval for its entire proposed service area, not some portion that the applicant will identify at a later date. Therefore, we will not allow applicants to modify their service areas after they have received a final notice of denial of their application from us.

Comment: One commenter recommended that CMS explicitly provide in the regulation for a process to permit applicants to cure deficiencies identified by CMS subsequent to the issuance of the notice of intent to deny; and that if such an opportunity is not provided, CMS should base any denial notice only on issues raised in the notice of intent to deny and not on deficiencies that are identified later in the application review process.

Response: When we have discovered a deficiency after we have issued a notice of intent to deny, we have not disapproved that application based on the failure to correct the new deficiency. Rather, we approve the application (assuming all corrections have been made based on deficiencies identified in the Notice of Intent to Deny), but communicate to the applicant that the newly identified deficiency must be corrected prior to executing a Medicare contract. If the issue is not so corrected, it immediately becomes the subject of a CMS contract compliance action.

Comment: One commenter requested that we clarify the type of information gained via the onsite visits and how this information will be used in evaluation of applications.

Response: We clarify, that we limit our application reviews (with the exception of the past performance analysis) to the materials organizations submit in response to the annual solicitations. We would also make clear that we retain our authority to conduct site visits to conduct compliance and monitoring activities.

Comment: One commenter noted that it would be beneficial to sponsors if CMS provided a tool that allows sponsors to self-determine network adequacy. The commenter stated that the CMS network adequacy standards are subject to reviewer discretion and stated that this ambiguity is unfair when the sponsor must identify, negotiate, and complete contract terms, sometimes with multiple entities, within a 10-day period.

Response: We have developed standardized network criteria and an automated review process that we will use, starting with the contract year 2011 application cycle, to review network adequacy. Applicants may request exceptions where they do not meet the standardized criteria for individual provider types in individual counties under limited, defined circumstances. We believe these changes will increase the consistency and transparency of network reviews.

3. Deny Contract Qualification Applications Based on Past Contract Performance (§ 422.750 and § 423.750)

As described in the existing provisions at § 422.502(b) and § 423.503(b), we may deny an application based on the applicant's failure to comply with the terms of a prior contract with CMS even if the applicant currently meets all of the application requirements. In the October 22, 2009 proposed rule, we proposed to modify these provisions at § 422.502(b) and § 423.503(b) to clarify that we will review past performance across any and all of the contracts held by the applicant, by specifically revising the language to refer to "any current or prior contract" held by the organization, instead of the current language referring to a "previous year's contract." We also clarified that the period that will be examined for past performance problems will be limited to those identified by us during the 14 months prior to the date by which organizations must submit contract qualification applications to CMS. Fourteen months covers the time period from the start of the previous contract year through the time that applications are received for the next contract year.

In making these proposed changes, we noted that indicia of performance deficiencies that might lead us to conclude that an organization has failed to comply with a current or prior contract include, but are not limited to, poor performance ratings as displayed on the Medicare Options Compare and MPDPF Web sites; receipt of requests for corrective action plans (CAPs) unrelated to an audit (as these types of CAPs generally involve direct beneficiary harm); and receipt of one or more other types of noncompliance notices from CMS (for example, notices of noncompliance or warning letters).

Additionally, consistent with the proposed changes to § 422.503(b), § 422.508(c), § 423.504(b), and § 423.508(e), we indicated that the withdrawal of Part C or D operations from some or all of an organization's newly contracted service area prior to the start of a benefit year (through mutual termination or otherwise) is an indication of poor performance. Such a situation can arise when, for example, an organization, after it has signed its Medicare contract for the upcoming program year, loses a contract with a significant number or type of providers, jeopardizing its ability to provide its members adequate access to services. Also, an organization may suddenly face financial difficulties that threaten its ability to offer the benefit packages approved by us throughout the upcoming contract year. In such instances, we noted that we could simply leave the contract in place and take enforcement actions against the organization. However, under such an approach, we would knowingly be permitting beneficiaries to remain enrolled with an organization that cannot effectively deliver the benefit. Instead, we indicated our preference to act in the best interests of the beneficiaries by agreeing with the organization to terminate its contract and work with the organization to make certain that beneficiaries receive uninterrupted access to Medicare services through another MA organization, PDP sponsor, or original Medicare. We are adopting these proposed changes without further modification in this final rule.

Comment: Several commenters expressed their support for our use of the past performance review authority to ensure that underperforming sponsors are not permitted to expand their participation in the Part C and D programs.

Response: We appreciate the commenters' support.

Comment: Several commenters requested that CMS more clearly articulate the methodology it will apply to past performance reviews conducted under this regulatory provision. For example, commenters were interested in knowing the relative weights CMS will

be assigning to different types of compliance actions (such as, corrective action plan requests, warning letters) and whether we will afford organizations the opportunity to correct deficiencies before CMS makes past performance determinations.

Response: We expect to make past performance methodology available through publication in our manuals. We believe that the manuals provide us and sponsors with the best available avenue for providing such detailed information and making updates to it as we continue to gain more experience with conducting past performance analysis. Given that, we note that the information on which we will base our past performance analysis has already been made available to organizations. For example, at any time an organization can review its own record of compliance correspondence received from us to get a sense of the degree to which the organization should be concerned about the likelihood that CMS would deny an application for a new contract.

We believe that questions regarding corrective action opportunities are not relevant to our process for reviewing past performance in making application determinations. The purpose of the past performance review is to determine whether the sponsor has demonstrated, over a 14-month period, whether it has operated its Part C or D contract in a manner that suggests that it is generally meeting and capable of meeting program requirements and that new Medicare business would not jeopardize that status. While some organizations take corrective action to address any and all compliance issues prior to the expiration of the 14-month review period, such corrective action would not change the fact that during that period of time, the organization demonstrated a pattern of noncompliance that may raise questions about its ability to take on new Medicare business.

Comment: Some commenters advised that the 14-month review period is too long, while others stated that a longer period (for example, 3 years) would provide a more comprehensive view of a sponsor's contract performance.

Response: We believe that the 14 month look-back provides an adequate amount of time for us to review an MA organization's or Part D sponsor's performance and the choice of 14 months as the look-back period was not arbitrary. As we noted previously, and in the proposed rule, 14 months covers the period spanning the start of the previous contract year to the time we receive applications for the following contract year. To shorten that time period to, say, 12 months would leave a gap in our past performance review. Similarly, limiting the period to the 14-month timeframe gives sponsors and organizations the opportunity and incentive to promptly establish a positive compliance track record so that the next CMS past performance review will find them eligible for additional Part C or Part D business.

Comment: Several commenters asked that CMS indicate whether the withdrawal from all or part of a service area, non-renewal of one or more plans (on the Part C or Part D sponsor's initiative), withdrawal of an application or bid, or termination of a contract after it has been executed would be counted against an organization for purposes of past performance analysis.

Response: We would not consider a sponsor-initiated non-renewal of all or a portion of an MA or PDP sponsor contract as an indication of poor contract performance. (However, under separate regulatory authority sponsors that non-renew their contracts may not be permitted to reenter the program for a period of 2 years.) We would treat non-renewed plan benefit packages similarly, assuming the organization had met the Part C or D requirements for providing timely notice to us and our enrollees. We do not consider the withdrawal of an application for qualification as Medicare contractor or of a bid prior to the publication of the annual benchmark calculation as relevant to a performance evaluation.

We do look unfavorably on organizations that withdraw bids after the benchmark has been announced. Also, we consider the termination of a contract for an upcoming benefit year after the organization has executed the contract as a failure to meet Part C and D program requirements. Accordingly, organizations should expect that these occurrences would be considered against them when we evaluate their past contract performance.

Comment: Several commenters offered suggestions on factors CMS should take into consideration when developing and applying our past performance review methodology. These included accounting for distinctions between national and local organizations, beneficiary impact of noncompliance (or lack thereof), unique characteristics of SNP plans, and whether difficulties in an organization's operation of a contract can be attributed to an entire organization or are limited to operation of only one or more of its contracts.

Response: As noted previously, we plan to address issues raised by some of the commenters more fully in guidance issued through our manual update process. At this time, we can provide a general discussion of some of the principles we intend to apply to the development of our past performance methodology. We are cognizant of the variety of products offered by Medicare contractors, and when an element of our past performance evaluation is affected by the unique feature of a particular plan type, we will adjust the application of our methodology as appropriate. We also want to emphasize that we intend to be conservative in our determinations. We expect to use our authority under this provision to exclude only those organizations demonstrating a pattern of poor performance. Finally, we acknowledge that not all types of noncompliance will be given equal weight, and our methodology will assign weights to different measures based on factors such as beneficiary impact or program stability.

Comment: A number of commenters suggested that CMS provide the results of its past performance analysis prior to the due dates for the submission of notices of intent to apply or for the applications for contract qualification.

Response: We will explore the feasibility of providing a preliminary analysis in response to sponsors' requests. However, we note that such a report would not be final, and in no case would even a preliminary report be available before December of each year.

Comment: A number of commenters requested assurance that the past performance review described previously in this final rule and in the October 2009 proposed rule would not include information concerning a sponsor's performance under contracts other than those governing Medicare managed care and prescription drug plan operations (such as, Medicaid, QIC contracts).

Response: Absent extraordinary circumstances, we plan to limit our past performance review to the operations of organizations in the performance of their Part C and D contracts only.

Comment: One commenter objected to CMS' use of past performance analysis asserting that is equivalent to taking a second punitive action for a single instance of noncompliance.

Response: In this final rule, we are clarifying the scope of our existing authority and we do not believe it is equivalent to an additional compliance or enforcement action taken against any of the organization's existing Medicare contracts. Our denial of an application based on an applicant's past contract performance is a reflection of our belief that an organization demonstrating significant operational difficulties

should focus on improving its existing operations before expanding into new types of plan offerings or additional service areas. Such a determination has no impact, punitive or otherwise, on a sponsor's current Medicare contract rights and obligations.

Comment: One commenter requested that organizations be permitted to attest that they will meet all Part C or D program requirements as of no earlier than January 1 of the upcoming contract year, as organizations are focused on enrollment and readiness activities prior to that date.

Response: This comment concerns an aspect of the Part C and D application and contracting processes unrelated to our exercise of the past performance review authority. Thus, it is outside the scope of our proposal, and we will not address it here.

4. Use of Data to Evaluate Continued Ability to Act as a Qualified Sponsoring Organization Under Parts C and D (§ 422.504, and § 423.505)

In the October 22, 2009 proposed rule, we clarified our authority to find organizations or sponsors out of compliance with MA and Part D requirements. We noted that under the authority of Sections 1857(e)(1) and 1860D–12(b)(3)(D) of the Act, the Secretary may add terms to the contracts with MA and Part D sponsors including terms that require the sponsor to provide the Secretary "with such information * * * as the Secretary may find necessary and appropriate." Additionally, under that authority, CMS established § 422.516 and § 423.514, which support the submission of Part C and D Reporting Requirements. We clarified that the data acquired through the reporting requirements are often used for the purpose of monitoring an organization's or sponsor's continued compliance with MA and Part D requirements. We also explained that in some instances, we may use an outlier analysis to determine a MA organization's or Part D sponsor's performance relative to industry standards established by the performance of all the other organizations and sponsors as described earlier in the preamble in our discussion of the development of our policies concerning the awarding, monitoring, and enforcement of Medicare contracts.

As part of the proposed rule, we added paragraphs § 422.504(m)(1) and (2) and § 423.505(n)(1) and (2) to make explicit our existing authority to find organizations or sponsors out of compliance with MA and Part D requirements when the organization's or sponsor's performance fails to meet performance standards articulated in statutes, regulations, and guidance or when an organization's or sponsor's performance represents an outlier relative to the performance of other organizations or sponsors. In this final rule, we adopt the provisions as proposed.

Comment: Some commenters supported this provision, specifically the development of consistent performance data evaluation processes.

Response: We appreciate the comments.

Comment: Many commenters recommended that CMS not use outlier data to make compliance determinations for a variety of reasons. Some commenters believed that CMS should only use specific, previously articulated criteria to determine non-compliance. Other commenters stated that the outlier analysis is arbitrary, inconsistent, and capricious at least in part because it would result in CMS holding sponsors to standards that are developed simply by measuring sponsors' performance relative to each other, not what is actually required to comply with Part C and D program requirements. One commenter noted that such an approach is inconsistent with the operation of a program where Medicare sponsor contracts are not awarded on a competitive basis. Still other commenters recommended that if an outlier analysis is used, it should only be used as a means by which CMS identifies plans in need of improvement not as a determination of non-compliance.

Response: We appreciate these comments, but we maintain our belief that outlier analysis remains a valid method for identifying non-compliant plan sponsors and a valuable tool in our efforts to monitor hundreds of contracting organizations in a timely and effective manner. Technically, the Part C and D regulations require 100 percent compliance with all program requirements. We acknowledge that it can be impractical to hold sponsors to such an absolute standard. When attempting to establish an acceptable level of noncompliance, it makes sense for us to compare a sponsor's performance to that of its peers. Such outlier analysis gives us a sense of the general performance capabilities of a set of sponsors. From such an analysis it is reasonable, in most instances, for us to conclude that organizations whose performance trails that of other similarly situated sponsors are not making reasonable efforts to provide an acceptable level of service to their enrollees. As we noted in the discussion of our proposed rule, inherent in the use of outlier analyses to evaluate compliance is the application of the well-accepted principle that we should look to evolving industry standards to establish program requirements.

We recognize our obligation, as both a business partner and a regulatory agency, to use the outlier analysis tool in a manner that is fair to sponsors and is legally supportable. For example, we want to reassure organizations that we understand that effective outlier analysis is concerned not just with which organizations' performance scores are lower than others, but also with the degree to which some sponsors may trail their peers. Therefore, an outlier analysis does not by definition and in every case result in a finding of non-compliance. Also, we remind organizations that we have adopted over the last several years, a graduated system of compliance notices, and we expect that in the large majority of instances, we will make organizations aware of their non-compliance with an outlier-based standard through the lower-level types of notice. These are the types of notices issued in the earlier stages of CMS' compliance efforts and would afford organizations reasonable opportunities to take corrective action. Finally, we are committed to publishing regularly outlier-based performance standards, as they are developed, in guidance materials, including our program manuals, HPMS memoranda, and our annual call letter, and to update these standards over time. Further, compliance communications to sponsors concerning an area of noncompliance where the basis for the finding relied on outlier analysis include an explicit description of the methodology employed to make such a determination.

Comment: Many commenters requested that CMS compare like plans with respect to several identifiers, including: plan types (with particular consideration given to SNPs), size, market conditions, open vs. closed formularies, and age of enrollees. Some commenters noted that meaningful comparisons across sponsors might be difficult.

Response: Where appropriate, we compare like sponsors and frequently take enrollment (both numbers and types of beneficiaries, such as, LIS-eligible) into consideration. Identifiers that the commenters mentioned are taken into consideration as part of our data analysis. Our goal is to do meaningful analysis that can aid us in identifying potential weaknesses.

Comment: Several commenters were concerned with how CMS will conduct outlier analysis and requested that CMS

define and develop standardized methods for determining outliers. One commenter recommended that CMS work with the industry to establish methods for outlier analysis. Another commenter recommended that the methodology should include different weights assigned to measures based on the magnitude of beneficiary impact and program integrity. One commenter requested that the outlier analysis be done at the contract level as opposed to the plan benefit package (PBP) level. Another commenter recommended that CMS be specific about whether compliance action would be taken for first-time outliers or only for sponsors with a history of being an outlier.

Response: We understand the importance of working with the industry to establish methodologies and do so where appropriate. For example, we have and will continue to share drafted or proposed plan rating (star ratings) measures and their analyses. Comments from sponsors are reviewed and considered as we finalize those measures. The Part C and D reporting requirements also undergo similar public comment periods.

The issue of assigning different weights to measures is not relevant here as the proposed change concerns the use of outlier analysis for particular, not aggregated, operational requirements. We incorporate weighting into our analysis of sponsors' overall contract performance. This analysis is typically done at the contract level at least in part because we collect data at that level, not the PBP level.

As discussed previously, we account for whether a sponsor is a first-time or repeat outlier when it determines the type of compliance notice to issue. Depending on the circumstances, organizations identified as first-time outliers may receive only a notice of noncompliance, while those that are repeat outliers may receive a CAP request or be subject to an enforcement action.

Comment: Several commenters urged CMS to make the outlier methodology available to all sponsors through, for example, the Call Letter or Technical Specifications. Many of these commenters requested an opportunity to review and comment on the methodology. A couple of commenters were concerned about CMS' use of outlier analysis and being able to predict how other sponsors will perform to ensure that their own performance is aligned and compliant.

Response: Where appropriate, we will make methodologies available to sponsors, as we discussed earlier in our response to comment on this proposal. An example of the importance we place on the need for clarity and transparency is the fact that we currently make available our methodologies in the technical specifications for the Reporting Requirements and the plan ratings (star ratings). In another example, we recently (January 2010) released an HPMS memo and incorporated into the Part D manual a comprehensive description of our outlier methodology for ensuring appropriate access to home infusion pharmacies. In an effort toward complete transparency, we also provided the underlying data and necessary information for Part D sponsors to conduct their own independent analyses on this topic.

Comment: Many commenters noted that there are reasons other than non-compliance that may result in a sponsor being an outlier. Outlier, by definition, means that there will always be a sponsor underperforming.

Response: We acknowledge that outlier status does not necessarily mean non-compliance. We review the list of statistical outliers and set thresholds on a number of factors for the purposes of identifying potential compliance problems. This is consistent with our goal to do meaningful analysis that can aid in identifying potential weaknesses. Most often, a sponsor will receive a request for information, as opposed to a compliance letter, to help us better understand why that particular sponsor was an outlier. These requests frequently result in the sponsor gaining a better understanding of our requirements and promote program improvement.

Comment: There were a few comments on the validity of current analyses performed by CMS. Some commenters discussed their observation that the findings resulting from some of CMS' outlier analyses methodology may penalize some organizations unfairly because—(1) the underlying data on which the analysis was based was flawed; or (2) analyses based on self-reported data may indicate that one sponsor is reporting data more accurately data than its peers. A commenter noted that the compliance letters that result from outlier analysis come months after the data has been collected and that there is little opportunity for an organization to correct its performance. A few commenters requested that CMS give sponsors the opportunity to appeal or explain the outlier status to CMS.

Response: We are always open to information and feedback from sponsors on our analyses and make corrections to our compliance determinations where the new information supports such a step. We also note that we are developing requirements concerning sponsors submitting audited data to address the concerns about data accuracy that the commenters raise.

Comment: One commenter believed that the annual audits and the outlier analyses appear to be duplicative.

Response: We use audits, outlier analysis, and other methods to ensure compliance with program requirements and to help identify potential compliance problems. Audits and outliers analyses are two distinct monitoring methods that utilize different sources of information and apply different types of analyses to evaluate sponsors' compliance with program requirements. Audits represent an in-depth review of selected sponsor's documentation related to the operation of their Medicare contracts. Outlier analysis, by contrast, consists of an agency review of performance data (generated by CMS or the sponsor) across all contracting organizations which results in the identification of potential noncompliance and the need for further investigation.

5. Compliance Programs Under Parts C and D (§ 422.503(b)(4)(vi) and § 423.504(b)(4)(vi))

In the October 2009 proposed rule, we proposed to modify the language at § 422.503(b)(4)(vi) and § 423.504(b)(4)(vi) to explicitly provide clarification as to what constitutes an "effective" compliance program. We also proposed clarifying language for each of the required elements of an effective compliance program in order to assist sponsoring organizations with implementing more effective compliance programs and to more clearly articulate our expectations.

We proposed to add language to the first element at § 422.503(b)(4)(vi)(A) and § 423.504(b)(4)(vi)(A) to require that written policies and procedures must describe a commitment to comply with all Federal and State standards, compliance expectations as embodied in the standards of conduct, implement the operations of the compliance program, provide guidance to others, identify how to communicate compliance issues to compliance personnel, describe how compliance issues are investigated and resolved and include a policy of non-intimidation and non-retaliation.

The second element requires a sponsoring organization to have a compliance officer and committee accountable to senior management. We proposed to add language at § 422.503(b)(4)(vi)(B) and § 423.504(b)(4)(vi)(B) that the

compliance officer must be employed by the sponsoring organization, and the compliance officer and committee must periodically report directly to the governing body and that body must be knowledgeable about the compliance program and exercise reasonable oversight over the implementation and effectiveness of the program.

The third element requires the sponsoring organization to have an effective training and education program. We proposed to add language at § 422.503(b)(4)(vi)(C) and § 423.504(b)(4)(vi)(C) to specify several key groups and individuals (the chief executive or other senior administrator, managers, and governing body members) among the sponsoring organization's employees who are required to have compliance training and education. We also proposed to add language that this training must occur at a minimum annually and must be made a part of the orientation for a new employee, new first tier, downstream and related entities, and new appointments of a chief executive, manager, or governing body member. The required compliance training must include training regarding the prevention and detection of fraud, waste and abuse. We proposed to add that providers who have met the requirement for fraud, waste and abuse training and education through enrollment into the Medicare program are deemed to have met that portion of the training and education requirement.

We noted that, in some instances, a particular pharmacy or other provider may contract with dozens of MA or PDP plans, each of which is required by the existing language at § 422.503(b)(4)(vi)(C) and § 423.504(b)(4)(vi)(C), read literally, to provide the required fraud, waste and abuse prevention and detection training to the pharmacy, or other provider, and its staff. Since we did not intend to require duplicative training, we offered two options in our proposed rule. One option was that the sponsoring organization "assures" or "obtains an assurance" that the first tier, downstream, and related entity has received such training. Another option was to leave existing language unchanged, but issue interpretive guidance on this point. We requested workable suggestions to assure that our objective is met, while eliminating unnecessary duplication.

The fourth element requires a sponsoring organization to have effective lines of communication. We proposed to add language at § 422.503(b)(4)(vi)(D) and § 423.504(b)(4)(vi)(D) that requires that these lines of communication be confidential and accessible to all employees and allow for compliance issues to be reported anonymously and in good faith as issues are identified.

The fifth element requires a sponsoring organization to enforce standards through well-publicized disciplinary guidelines. We proposed to add language at § 422.503(b)(4)(vi)(E) and § 423.504(b)(4)(vi)(E) that more specifically described that these guidelines must be implemented to include policies that articulate expectations for reporting issues and their resolution, identify noncompliance or unethical behavior, and provide for timely, consistent and effective enforcement of the standards when noncompliance or unethical behavior is detected.

The sixth element requires a sponsoring organization to have procedures for internal monitoring and auditing. We proposed to add language at § 422.503(b)(4)(vi)(F) and § 423.504(b)(4)(vi)(F) to more specifically describe that an effective system for routine monitoring and identification of compliance risks includes internal monitoring and audits and, as appropriate, external audits, in order to evaluate the sponsoring organization's compliance with our requirements and overall effectiveness of the compliance program. We also proposed to add language that these audits should include the sponsoring organization's first tier entities.

The seventh element requires a sponsoring organization to have procedures for ensuring prompt responses to detected offenses. We proposed to add language at § 422.503(b)(4)(vi)(G) and § 423.504(b)(4)(vi)(G) to more specifically describe the implementation of a system for promptly responding to compliance issues as they are raised, investigating potential compliance problems identified in the course of self-evaluations and audits, correcting such problems promptly and thoroughly to reduce the potential for recurrence and ensuring ongoing compliance with our requirements.

We are adopting all of these proposed changes into the final rule without further modification with the exception of changes made to § 422.502(b)(4)(vi)(B), § 423.504(b)(4)(vi)(B) and § 423.504(b)(4)(vi)(C), to provide that the compliance officer must be an employee of the sponsoring organization, parent organization or corporate affiliate and clarify that he or she may not be an employee of a first tier, downstream or related entity of the sponsoring organization and must be accountable to the governing board of the sponsoring organization. In addition, at § 423.504(b)(4)(vi)(C)(3), we adopt a new regulation for the Part D program to specify that first tier, downstream, and related entities that have met the fraud, waste, and abuse certification requirements through enrollment into the fee-for-service Medicare program and accreditation as a durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) supplier are deemed to have met the fraud, waste and abuse training and educational requirements.

We received the following comments on the first element, which requires written policies and procedures:

Comment: Two commenters raised concerns about the resources necessary to satisfy our requirements related to written policies and procedures. One commenter stated that sponsoring organizations are currently spending significant time and resources drafting and redrafting policies and procedures and are still uncertain if these policies and procedures will cover the items we expect to be covered in requisite detail. Both commenters suggested that we release our audit worksheets which outline CMS's expectations for the contents of policies and procedures, which would allow sponsoring organizations to tailor their policies and procedures accordingly. Additionally, one commenter suggested that CMS should not be dictating the scope or components of such policies and disagreed with our inclusion of more "prescriptive standards" into the regulatory text and alternatively suggested that certain requirements be issued through subregulatory guidance.

Response: Our proposals are intended to significantly strengthen our oversight of compliance programs, and provide more specificity and clarity to sponsoring organizations with regard to what we expect to see when we review a compliance program. We believe the proposals we have made are important changes and are necessary to maintain consistency and promote appropriate focus on these requirements and that going through the rulemaking process is the best way to promote these goals. We also believe that the proposed changes to the first element provide important information as to what we consider a framework for an effective compliance program. We do not intend to be prescriptive as to the choice of particular processes or procedures, only to provide the minimum amount of information we would expect to see in a comprehensive set of written policies,

procedures and standards of conduct. With respect to the comment regarding releasing audit materials, we must balance the goals of transparency regarding our audit program with the goals of conducting an effective evaluation of whether organizations have in fact instituted effective compliance programs (and not just "paper" compliance programs). To the extent that sponsoring organizations are looking to tailor their policies and procedures for compliance programs to materials released by us, they should be looking to our regulations, including the changes made by this final rule, and any subregulatory guidance issued by CMS, and not documents related to our audit program, as these may only be a subset of CMS' larger set of requirements.

We received the following comments regarding our proposed revisions to the second element, which addresses the designation of a compliance officer and a compliance committee who report directly to the organization's chief executive or other senior management:

Comment: Commenters expressed concern with CMS' proposal to require that the compliance officer, vested with day to day operations of the compliance program, be an employee of the sponsoring organization. Commenters recommended that CMS broaden this portion of the provision to permit the compliance officer to be employed by the sponsoring organization or an affiliate in its corporate group. These commenters indicated that "the entity who employs the compliance officer is a corporate structure issue that may have no effect or bearing on the issues of accountability and oversight." One commenter further insisted that in instances when related entities are MA organizations and PDP sponsors who hold separate contracts with CMS, having one centralized compliance officer is not only effective and efficient, but it also promotes consistency with respect to the implementation of the compliance program across the contracting entities. Several commenters also stated that having the compliance officer at a parent or affiliated group level would not lessen the accountability of the compliance officer with respect to each entity.

Response: We agree that having a compliance officer being employed at a parent company or corporate affiliate may not necessarily lessen the accountability of the compliance officer to the governing body of the sponsoring organization. Our proposal was intended to provide further clarity on how sponsoring organizations can meet the key requirement of having a compliance officer and compliance committee that is accountable to the governing body of the sponsoring organization. We have issued extensive subregulatory guidance on this issue, both in the 2007 call letter and in Chapter 9 of the Medicare Prescription Drug Benefit Manual ("Chapter 9"). This guidance was issued in part in response to us learning that sponsoring organizations were subcontracting the compliance officer function to their first tier, downstream and related entities. We do not view subcontracting that function as an acceptable alternative for a number of reasons, including the potential for conflicts of interest that would exist by virtue of the compliance function residing in a subcontracted entity that is being paid by the entity whose compliance the subcontractor is charged with monitoring. As a result of the comments received, we are modifying the language in this final rule to provide that the compliance officer must be an employee of the sponsoring organization, parent organization or corporate affiliate and to provide that the compliance officer may not be an employee of a first tier, downstream or related entity of the sponsoring organization.

Comment: Proposed sections § 422.503(b)(4)(vi)(B)(2) and § 423.504(b)(4)(vi)(B)(2) specify that the compliance officer and committee must periodically report to the governing body of the sponsoring organization on the activities and status of the compliance program. One commenter emphatically supported CMS' proposal to strengthen the compliance program by increasing the requirements with respect to interaction with the executive leadership and board members. One commenter recommended that CMS revise the language of this provision to state that the compliance officer and committee, "or their delegate", report directly to the governing body. Lastly, one commenter stated that although they supported CMS' goal of ensuring sponsoring organizations' senior leadership and governing body are informed of key developments, the commenter opposed CMS dictating internal reporting obligations and reporting structures.

Response: We disagree with the suggestion to add "or their delegate" to the language at § 422.503 (b)(4)(vi)(B)(2) and § 423.504(b)(4)(vi)(B)(2), which would expand the scope of individuals who could provide periodic reports to the governing body of the sponsoring organization. The purpose of this provision is to ensure communication between the compliance officer, committee and the governing board. We do not intend that this reporting responsibility be delegated to someone other than the compliance officer as that would defeat the purpose of the proposed provision. Therefore, we will not be incorporating the commenter's suggested change into the final rule.

We also do not believe that the proposed regulatory language in this section results in CMS dictating to MA organizations and Part D sponsors their internal reporting obligations and reporting structures. The proposed language does not specify the means or manner in which the report should be communicated to the governing body, nor does it provide specific requirements as to how often such reports are made.

We received the following comments concerning our proposed changes to the third compliance program element, which—(1) states that sponsoring organizations must establish and implement effective training and education between the compliance officer and the sponsoring organization's employees, governing board, first tier, downstream and related entities; (2) specifies that this training and education must occur at a minimum annually and must be made a part of new employee orientation; and (3) provides deeming of fraud, waste and abuse educational requirements to first tier, downstream and related entities who have met the fraud, waste and abuse certification requirements though Medicare program enrollment:

Comment: Some commenters stated that organizations should have the flexibility to modify and tailor the training for the governing body so that it is not a replication of the training needed for front line staff, and expressed specific concern with CMS requiring training of the governing body annually. Additionally, several commenters stated that requiring sponsoring organizations to conduct compliance training at new employee orientations and annually thereafter is administratively and financially burdensome, and may even result in organizations having to conduct such training on a weekly basis. Commenters made numerous recommendations, including providing sponsoring organizations with flexibility in determining the appropriate level and timing of training depending on the audience; modifying the education and training requirements to apply to only those involved in the administration of the Medicare Advantage and Part D lines of business within the organization; clarifying that the annual education and training requirement is limited to general compliance training, and does not include the specialized

training that sponsoring organizations have to implement in accordance with Chapter 9; and the suggestion that CMS develop a Web-based compliance training tool or certify an independent industry entity to provide consistent and efficient compliance training; and finally, providing additional clarification on the required training for downstream entities.

Response: We believe that the proposed regulatory language allows organizations the flexibility to tailor the content of the training and many aspects of how the training is provided. We have not specified the manner in which the training would be provided at new employee orientations, or to senior leadership or members of the governing body upon their appointment to these positions. Organizations can decide to provide new employees with a copy of the organization's compliance policies and procedures and ask new employees to attest that they have been provided with a copy and have read the material. We do not believe that such a requirement is overly burdensome or difficult for sponsoring organizations to implement.

We also do not believe that it is appropriate to clarify in regulation text that we are referring to general versus specific compliance training, as discussed in Chapter 9. The proposed language makes no reference to the training being specialized and we believe that the regulatory language should be left general as the level of training and education will vary depending on the level and responsibilities of the person receiving the training. We believe that the proposal is sufficiently clear in its description of what is expected of the sponsoring organization in the implementation of its compliance training and education program and the requirements are reasonable. If we determine in the future that further guidance is necessary, we will issue subregulatory guidance.

Lastly, in response to those commenters who suggested that CMS develop a Web-based compliance training tool, we have determined that additional analysis needs to be undertaken and additional information sought before providing guidance on how training of first tier, downstream, and related entities is to be provided and the content managed. Additional clarification will be issued in subregulatory guidance.

Comment: Some commenters stated that requiring sponsoring organizations to conduct compliance training for all delegated entities (first tier, downstream and/or related) or insuring that all delegated entities conduct such training on their own imposes a significant burden on sponsoring organizations.

Response: In response to those commenters who stated that requiring that first tier, downstream and related entities to receive compliance training is overly burdensome, we would like to reiterate that this is an existing requirement, not a proposed new requirement. We agree that duplicative training is inefficient and we believe that commenters have offered valuable suggestions. After reviewing these comments and recommendations, we have determined that additional analysis needs to be undertaken and additional information sought before providing guidance on how training of first tier, downstream, and related entities is to be provided and the content managed. Additional clarification will be issued in subregulatory guidance.

Comment: Commenters also suggested striking the word "effective" from the language of this section which specifies that the sponsoring organization must establish, implement and provide "effective" training and education. Alternatively the commenter requested that CMS at least clarify how we would determine if training were "effective" and clarify CMS' definition of sufficient oversight.

Response: The use of the term "effective" is existing regulatory language and has already gone through notice and comment rulemaking. "Effective" is not a new requirement, therefore, we do not believe it is necessary to remove the word "effective" from this regulatory provision.

Comment: Commenters suggested that CMS consider revising the requirement that fraud, waste, and abuse training and education occur at least annually and be a part of the orientation for a new employee, new first tier, downstream and related entities, and new appointments to chief executive, manager or governing body member. Commenters believe that CMS should require that training only at the time of initial hire or when there are significant changes in the laws and regulations related to fraud, waste, and abuse.

Response: We disagree and believe that annual training is a necessary component of an effective compliance program that addresses the detection, correction, and prevention of fraud, waste, and abuse in the MA and Part D programs. The intent of this regulation is to codify the existing CMS expectation that fraud, waste and abuse training be provided at a minimum on an annual basis, which is contained in Chapter 9 of the Prescription Drug Benefit Manual (Part D Program to Control Fraud, Waste, and Abuse). Chapter 9 can be viewed at: *http://www.cms.gov/PrescriptionDrugCovContra/Downloads/PDBManual_Chapter9_FWA.pdf.* We recognize that Chapter 9 was specifically developed for Part D (prescription drug plan) sponsors. In previous guidance, we have directed MA organizations to apply the provisions of Chapter 9 to Part C (Medicare Advantage) programs as well. We are in the process of updating this document to specifically address any particular Part C measures for detecting and preventing fraud, waste, and abuse.

Comment: Several commenters expressed support for our proposed revisions to § 422.503 (b)(4)(vi)(C)(2), which clarify that first tier, downstream, and related entities who have met the fraud, waste, and abuse certification requirements through enrollment into the fee-for-service Medicare program are deemed to have met the training and educational requirements for fraud, waste, and abuse under this rule. One commenter disagreed with the proposed revision.

Response: We believe that the proposed regulatory language eliminates redundant certification made when these entities enroll in the Medicare program. We also wish to clarify that the reference to deeming in this regulation is distinct from the MA deeming and accreditation program described at § 422.156, § 422.157, and § 422.158.

Comment: A number of commenters recommended that CMS extend the regulatory change proposed for the Part C program at § 422.503(b)(4)(vi)(C) to the Part D program at § 423.504(b)(4)(vi)(C). The commenters noted that Part D first tier, downstream, and related entities that have enrolled in the Medicare program as a supplier of Part B covered medications or as a supplier of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) go through the same application and certification process as MA providers. They contend that including Part D providers in this deeming would ensure the requirements for Part D sponsors will be identical to those for MA organizations and would reduce unnecessary additional burden.

Response: We agree with the commenters and have adopted a new regulation for the Part D program at § 423.504(b)(4)(vi)(C)(3) to specify that first tier, downstream, and related entities who have met the fraud, waste, and abuse certification requirements through enrollment into the Medicare program accreditation as a DMEPOS supplier are deemed to have met the

training and educational requirements for fraud, waste, and abuse training. We wish to clarify that the reference to deeming in this regulation is distinct from the Part D deeming and accreditation program described at § 423.165, § 423.168, and § 423.171.

We received the following responses to our request for comments on whether or how to best revise the requirement that first tier, downstream, and related entities receive training in how to prevent and identify fraud, waste, and abuse to address the issue of duplication of training for providers or entities that contract with multiple MA organizations or Part D sponsors:

Comment: Several commenters recommended requiring MA organizations and Part D sponsors to create training materials or approve first tier, downstream, and related entity-created materials and require attestations that the training was provided to all appropriate parties. These commenters noted that in order to avoid duplicative training, all sponsoring organizations would be required to accept attestations from their first tier, downstream, and related entities that they completed training provided by any other sponsoring organization in order to fulfill this requirement. Commenters also suggested that another option to ensure consistent training content and minimize duplication is for CMS to create a standardized training and require all sponsoring organizations to use it for training their first tier, downstream, and related entities. Commenters also recommended that CMS permit first tier, downstream, and related entities to create and implement their own training programs and attest to their contracting MA organizations and/or Part D sponsors that they have fulfilled the training requirement.

Response: We believe the commenters have offered valuable suggestions. After reviewing these comments and recommendations, we have determined that additional analysis needs to be undertaken and additional information sought before providing guidance on how training of first tier, downstream, and related entities is to be provided and the content managed. Additional clarification will be issued in subregulatory guidance.

Comment: A few commenters requested that CMS provide more specificity regarding which entities must complete fraud, waste, and abuse training. These commenters believe that CMS should limit the training requirement for first tier, downstream and related entities to only staff of those entities that are involved in patient care and/or claims submission, and should not require administrative or retail clerk/cashier staff to complete the training.

Response: The requirement for fraud, waste, and abuse training applies to all MA organization and Part D sponsor employees (including chief executive or other senior administrator, managers and governing body members) and first tier, downstream and related entities. We will issue additional clarification in subregulatory guidance.

The fourth element requires a sponsoring organization to have effective lines of communication. We did not receive comments regarding this element.

We received the following comment concerning the proposed revisions to the fifth compliance program element which details a sponsoring organization's obligation to ensure its compliance program has well publicized disciplinary standards.

Comment: The commenter requested that CMS provide guidance regarding its expectations as to sponsoring organization's enforcement of disciplinary standards, and asked for clarification as to whether a policy identifying the different types of disciplinary actions a sponsoring organization may impose would be sufficient to meet the requirement.

Response: We believe that our proposal is sufficiently detailed to provide sponsoring organizations with necessary guidance on how to implement an effective compliance program.

We received the following comment regarding the proposed revisions to the sixth compliance program element concerning requirements for sponsoring organizations monitoring and identification of compliance risks.

Comment A commenter requested that CMS specify that its reference to external audits, especially of first tier entities, does not require sponsoring organizations to hire an independent, external auditor to perform this function but rather that sponsoring organizations may undertake the auditing of these contractors through their internal audit units.

Response: Our expectation, when referring to a sponsoring organization conducting an external audit of itself or a first tier entity, was that that sponsoring organization would utilize an auditor who is external of both the sponsoring organization and the first tier entity being audited.

Comment: A commenter recommended that CMS share its preamble language that further defines the expectations for an effective compliance program with other areas of the Federal government, such as the Department of Defense, so that all government contractors will have the same compliance program expectations.

Response: We believe that this comment is outside the scope of this regulation.

The seventh element requires a sponsoring organization to have procedures for ensuring prompt responses to detected offenses. We did not receive comments regarding this element.

6. Network Adequacy of Coordinated Care and Network-Based Private Fee-for-Service Plans Under Part C (§ 422.112)

In the October 22, 2009 proposed rule (74 FR 54644), we requested comments on proposed criteria for determining whether an MA plan network meets the network availability and accessibility requirement in section 1852(d)(1) of the Act. As we discussed in the proposed rule, we have developed an automated system for reviewing network adequacy on a continuing basis based on the elements that we have determined reasonably reflect community patterns of health care delivery. As we noted in the proposed rule, our operational experience has demonstrated that the concept of community patterns of health care delivery provides a useful benchmark for measuring a proposed provider network, because it allows for varying geographical and regional conditions to be taken into consideration in determining what constitutes "reasonable" access in a given area.

In the proposed rule, we described the elements of community patterns of health care delivery that we proposed to include in our evaluations of provider networks, and stated that our goal was to make the standard of community patterns of care more transparent and consistent across the country. Specifically, we proposed adding a new paragraph (a)(10) to § 422.112 to specify the factors comprising community patterns of health care delivery that we would use as a benchmark in evaluating a proposed MA plan health care delivery network. Under proposed § 422.112(a)(10), these factors would include, but not be limited to—

- The number and geographical distribution of eligible health care providers available to potentially contract with an MAO to furnish plan covered services within the proposed service area of the MA plans;
- The prevailing market conditions in the service area of the MA plan—specifically, the number and distribution of health care providers

contracting with other health care plans (both commercial and Medicare) operating in the service area of the plan;

- Whether the service area is comprised of rural or urban areas or some combination of the two;
- Whether the MA plan's proposed provider network meets Medicare time and distance standards for member access to health care providers including specialties; and
- Other factors that we determine to be relevant in setting a standard for an acceptable health care delivery network in a particular service area.

We proposed providing more detail about how we would operationalize these requirements through subregulatory guidance (for example, the annual Call Letter). We solicited comment on whether our proposed regulatory provisions are sufficiently clear and whether clarification should be provided through regulation or subregulatory guidance, such as the annual Call Letter.

After considering all the timely comments we received on our proposal, we are adopting § 422.112(a)(10) without modification in this final rule.

Comment: Many commenters expressed concern that the proposed CMS approach to evaluating network adequacy based on community patterns of care would be too limiting, and would not allow organizations sufficient flexibility to develop networks in rural areas or areas with unique conditions. Several commenters were concerned that CMS' interpretation of what constitutes community patterns of care would result in an approach that would not adequately take into account special plan-specific factors, such as the size of a plan or the quality of its providers. Also, a number of commenters were concerned that unique characteristics of a particular community, such as provider willingness to contract, would not be captured in the CMS network adequacy standards. One commenter expressed concern that the proposed requirements for network adequacy appear to encourage a fee-for-service and fragmented care model based on geographic access rather than a defined network of high quality primary care practices, supported by a limited network of sub-specialists. One commenter was concerned that CMS would only use the prevailing community standard of care to evaluate network adequacy, citing as an example a plan with a network that did not meet the prevailing community standard of care but was nevertheless adequate or even better in terms of the access it actually provides health care services to enrollees.

Response: In developing standards for network adequacy we chose the overarching principle of community patterns of care because it is a robust model that allows CMS the necessary flexibility to develop standards that can be adapted to the significant variations that exist in health care delivery in the United States. Our proposed regulation outlined the broad elements that we have found from years of experience to be relevant in evaluating a particular community pattern of care. However, we are cognizant of the fact that there exist a number of unique local circumstances related to such factors as geography, market conditions, and provider availability. Accordingly, this final rule codifies an approach to determining network adequacy that builds on our experience with evaluating health plan provider networks but is also flexible enough to adapt to evolving and unique local market conditions. The automated process we have established to assess network adequacy is likely to be refined as we gain more experience, and maintaining flexibility in our regulatory requirements for network adequacy supports this goal. We also note that the automated system we are using does not specify the providers with which a plan contracts. Rather, it furnishes a benchmark so we can determine if a plan's provider network is adequate given the availability of providers in the area where the plan is being offered and the expected enrollment in the plan. In other words, our standards address the relative size and scope of an acceptable MA provider network given the community patterns of care. However, MA plans still have discretion to select the providers they contract with as long as that network is adequate to meet the health care needs of its enrollees. In addition, we will have an exceptions process by which plans can highlight special circumstances that affect their ability to meet our access standards.

Comment: Many commenters had very detailed, specific questions about our automated system for assessing network adequacy, and much of this feedback has already been provided to CMS through other mechanisms. For example, one commenter asked for certain adjustments to the ratio of providers to beneficiaries. Other comments questioned how CMS would implement various features of network adequacy and whether they would be codified in regulations text.

Response: As noted previously, we have developed and implemented automated systems to evaluate the network adequacy of MA plans. As part of that implementation, we have provided considerable subregulatory guidance regarding implementation of community patterns of care through this automated process. An example of this subregulatory guidance is the provision of time and distance standards (available on the CMS Web site) by category of health care provider for a number of rural and metropolitan counties throughout the United States. Because we did not propose to incorporate the technical specifics of our automated system into regulation text, we believe it is most appropriate to address specific technical suggestions in the context of implementing and fine-tuning the automated network adequacy system.

Comment: Several commenters expressed concern about how CMS would implement time and distance standards for determining network access. One commenter asked that CMS be mindful of the impact of imposing time and distance standards equally among different types of providers. One commenter stated that the prevailing 30 minute/30 mile access to services standards need to be fine-tuned specifically for urban, rural, and other medically underserved areas. Other comments included recommendations to establish separate and distinct network adequacy standards for Parts A and Part B services, as well as standard for measuring network adequacy in rural areas for services that are only in hospitals.

Response: As noted in the October 22, 2009 proposed rule, we have historically used the 30 minute/30 mile access to services as a rough standard for evaluating provider networks. However, we agree that this standard is not sufficiently nuanced to stand on its own, and does not fully address our needs. Our operational experience has demonstrated that the concept of community patterns of health care delivery furnishes a more useful benchmark for measuring a proposed provider network because it allows for varying geographical and regional conditions to be taken into consideration.

Comment: One commenter asked CMS to consider Medicaid provider networks as part of the assessment of network adequacy for dual eligible integrated products. This commenter also suggested comparing contracting rates across plans serving duals as an additional measure of network adequacy. In addition, the commenter suggested that a comparison of the plan's provider availability to those actually open to new Original Medicare enrollees might indicate the value of the plan to potential enrollees. Another

commenter asked that CMS include in its regulation defining network adequacy the following factors derived from the Medicaid access standards under § 438.206: (1) The mode of transportation used by Medicare beneficiaries, particularly those who are dually eligible and those who rely on transportation for the disabled; (2) whether the location furnishes physical access for enrollees with disabilities; and (3) delivery of services in a culturally competent manner.

Response: We recognize that special needs plans (SNPs) that specifically serve the dual eligible population have unique requirements. It is for that reason that in 2011, SNPs that exclusively serve the dual eligible population will be required to have contracts with State Medicaid agencies where they operate. While transportation is not a Medicare covered benefit, it is our expectation that MA plans' facilities are available and accessible to plan enrollees.

7. Deemable Program Requirements Under Parts C and D (§ 422.156(b)(7), § 422.156(f), § 423.165(b), and § 423.165(f))

In the October 2009 proposed rule, we proposed to clarify what regulatory requirements are "deemable" for MA organizations that offer prescription drug benefit programs by modifying the language at § 422.156(b)(7) to refer to the list of deemable requirements for Part D sponsors set out at § 423.165(b)(1) through (b)(3). In addition, we proposed modification to § 422.156(f) and § 423.165(f) to add language clarifying that CMS may use its statutory authority to impose intermediate sanctions and civil money penalties (CMPs), initiate contract terminations, and perform evaluations and audits of a sponsoring organization's records, facilities and operations, notwithstanding our deeming provisions. We also proposed to remove language at § 423.165(b)(4) regarding programs to protect against fraud, waste and abuse from the items listed as deemable program requirements. After considering the comments we received in response to these proposals, we are adopting all of these proposals without further modification into this final rule.

Comment: One commenter asked if CMS will create an avenue for accrediting organizations who are currently approved under the Medicare Advantage program to apply for deeming under the Prescription Drug program.

Response: Our proposal did not address the process for becoming an accrediting organization. Any organization that wishes to be an accrediting organization for the Medicare Prescription Drug program must first apply and be approved by CMS in accordance with existing requirements.

Comment: One commenter asked if we will define possible roles and responsibilities for accrediting organizations under the revised Part D monitoring and oversight audit program.

Response: Our proposal did not address the Part D accrediting process and we do not intend to address this process in this final rule. We will evaluate whether or not there is a need to release more detailed information in the future through subregulatory guidance or other appropriate means.

Comment: One commenter indicated that Part D plan sponsors have not been given information on accrediting organizations that could grant plans deemed status for Part D. The commenter further recommended that there be an opportunity to work with us to identify accredited organizations for pharmacy benefit manager operations in order to simplify the audit process.

Response: Our proposal did not address the Part D accrediting process and we do not intend to address this process in this final rule. However, as of the date of the publication of this regulation, CMS has not approved any accrediting organizations to grant deemed status for Part D sponsors. We will evaluate whether or not there is a need to release more detailed information in the future through subregulatory guidance or other appropriate means.

Comment: We received a few comments indicating that the regulatory provisions provided in this section should be further clarified either through rulemaking or subregulatory guidance.

Response: We will evaluate whether or not there is a need to release more detailed information in the future through subregulatory guidance or other appropriate means.

Comment: One commenter suggested that we provide clarification on the criteria we would use to determine whether to perform evaluations, conduct audits, or impose sanctions or civil money penalties relative to a sponsoring organization's compliance with deemable requirements.

Response: Our proposal did not intend to modify or affect the manner in which CMS conducts compliance evaluations, audits or the process for imposing intermediate sanctions. These processes are not directly affected by whether the underlying subject of the deficiency is a deemable requirement.

Comment: One commenter encouraged us to consider adding additional deemable requirements based on differences between the Part D program and the Part C program.

Response: We have been granted limited statutory authority regarding what specific requirements are deemable. Our proposals reflect our current statutory authority.

Comment: One commenter requested that since the fraud, waste and abuse program was being removed as a deemable requirement we consider allowing "certification" from an external qualified source to serve in the deeming capacity.

Response: We have been granted limited statutory authority regarding what specific requirements are deemable. We proposed modifications to our regulations to mirror our current statutory authority. To the extent the commenter is proposing that CMS consider ways of assessing an organization's compliance with fraud, waste, and abuse requirements that suggestion would be outside the scope of this proposal.

8. Modify the Corrective Action Plan (CAP) Process as It Relates to Procedures for Termination and Nonrenewal of a Part C or D Contract by CMS (§ 422.506(b)(3), § 422.510(c)(1), § 423.507(b)(3), and § 423.509(c)(1))

In the October 2009 proposed rule, we proposed eliminating the existing language contained in regulations at § 422.506(b)(3), § 422.510(c)(1), § 423.507(b)(3), and § 423.509(c)(1) that require corrective action plans (CAPs) to be submitted for our approval prior to us issuing a notice of intent to terminate or nonrenew a contract. Instead, we proposed that the sponsoring organization be solely responsible for the identification, development, and implementation of its CAP and for demonstrating to us that the underlying deficiencies have been corrected within the time period afforded under the notice and opportunity for corrective action.

We also proposed amending the existing language at § 422.506(b)(3), § 422.510(c)(1), § 423.507(b)(3), and § 423.509(c)(1) which sets forth the specific timeframes afforded sponsoring organizations for the development and implementation of a CAP prior to CMS issuing a notice of intent to terminate or nonrenew. Specifically, we proposed to afford sponsoring organizations with at least 30 calendar days to develop and implement a CAP, prior to issuing the notice of intent to terminate or nonrenew. CMS is adopting the proposed language into the final rule

with a few technical changes to § 422.506(b)(3)(i) and (ii), § 422.510(c)(1)(i) and (ii), § 423.507(b)(3)(i) and (ii), and § 423.509(c)(1)(i) & (ii). First, we are deleting the phrase "that formed the basis for the determination to non-renew the contract" from the proposed revised regulations governing non-renewals at § 422.506(b)(3)(i) and § 423.507(b)(3)(i) and deleting the phrase "that formed the basis for the determination to terminate the contract" from the proposed revised regulations governing terminations at § 422.510(c)(1)(i) and § 422.509(c)(1)(i). The reason for this revision is that, upon further consideration, we have concluded that this language is superfluous and has the potential to cause confusion concerning when CMS must provide notice and reasonable opportunity to correct deficiencies.

Next, we are modifying § 422.506(b)(3)(i), § 423.507(b)(3)(i), § 422.510(c)(1)(i), § 423.509(c)(1)(i) to state that CMS will provide the sponsoring organization a "reasonable opportunity" of "at least 30 calendar days" to develop and implement a corrective action plan. This modification made the propose provision at § 422.506(b)(3)(ii), § 423.507(b)(3)(ii), § 422.510(c)(1)(ii), and § 423.509(c)(1)(i) duplicative and unnecessary, therefore we are deleting that provision.

These revisions do not alter the meaning and purpose of the proposed revised regulations and are strictly editorial changes.

Comment: We received numerous comments regarding our proposal to modify the overall approach and timeframe sponsoring organizations are afforded for developing and implementing a CAP prior to CMS issuing a notice of intent to terminate or nonrenew. Although almost all commenters were supportive of CMS' proposal to move to an outcome oriented approach for reviewing CAPs, some commenters believe that 30 days is not enough time for sponsoring organizations to develop and implement a CAP. Commenters provided several reasons to support this concern, including the fact that CAPs may involve complex and time consuming programming or modification of systems and that the proposed change could result in sponsoring organizations pursuing a more cursory or manual remediation rather than a fuller remediation. Other commenters recommended that rather than specifying a time period, CMS and sponsoring organizations should mutually agree on a time period that is best for completing a CAP. A few commenters expressed that 30 days was more than enough time to correct deficiencies and that the regulations need to state more clearly that the corrective action should be completed within the same 30-day period.

Response: Our proposal specifically stated that the time period afforded sponsoring organizations would be "at least" 30 days, thereby proposing the minimum amount of time that CMS would afford a sponsoring organization to develop and implement a CAP. We believe our proposal is reasonable and accounts for those situations where we determine that longer periods of time are warranted to demonstrate correction (for example, when corrections must be made to electronic information systems). Our proposal does not intend to limit the development and implementation of a CAP to 30 days in all cases because we agree that there are some deficiencies of a complex or technical nature that may require additional time to rectify.

Comment: A few commenters requested that CMS clarify how it will determine if a sponsoring organization has attained compliance (for example, what are CMS' expectations and what supporting documents would we require in such situations to demonstrate compliance).

Response: Our proposal to change to an outcome based approach is not making modifications in the current methodologies for assessing whether an entity is in (or out of) compliance with our requirements. For example, CMS currently conducts validation activities based on account management data and information, audit results, beneficiary complaints, sponsoring organization reporting requirements and performance data indicators to determine whether a sponsoring organization is in compliance with our requirements. We will continue to determine if the sponsoring organization in is in compliance with our statutory, regulatory and program requirements by utilizing these kinds of monitoring and oversight measures. The proposed language is only clarifying that for non-renewal and termination actions, we will not be requiring the sponsoring organization to submit its corrective action plans for approval by us, but instead the sponsoring organization must submit proof that identified deficiencies have been corrected.

Comment: One commenter suggested that if CMS retains the authority to reject a CAP based on the process used to fix the deficiency, the sponsoring organization should be allowed to submit its CAP to CMS for approval, and if not disapproved by CMS within a specified period, assume that the CAP is approved from a process perspective.

Response: The commenter has misunderstood our proposal. We are proposing to modify the current CAP process to be entirely outcome oriented and we will no longer be requiring sponsoring organizations to submit corrective action plans for approval (that is, the process for how the plan goes about correcting its deficiencies will not be approved or disapproved by CMS). Rather, the process will be independently developed and implemented by the sponsoring organization and our focus will be on determining whether the deficiencies/problems that created the need for the CAP have been corrected.

Comment: A commenter requested that CMS not apply the 30-day CAP timeframe to "routine or ad-hoc audits."

Response: The procedures governing the corrective action plan process associated with routine or ad-hoc audits are not specified in regulation. To the extent, however, that we would initiate a termination or nonrenewal action against a sponsoring organization based on a routine or ad-hoc audit CAP, we would follow the procedures outlined in this regulation.

Comment: A commenter recommended that sponsoring organizations, which are currently under a CAP, be allowed to engage the services of an independent auditor to evaluate whether the sponsoring organization is in compliance with CMS' requirements.

Response: Our proposed language was not intended to prevent a sponsoring organization from taking the initiative to use an independent auditor to help identify and correct underlying compliance deficiencies.

9. Procedures for Imposing Intermediate Sanctions and Civil Money Penalties Under Parts C and D (§ 422.756 and § 423.756)

In the October 2009 proposed rule, we proposed two changes to the regulations to provide additional tools to assist us in making the determination to lift an intermediate sanction as stated in § 422.756(d)(3) and § 423.756(d)(3). First, we proposed providing CMS with the discretion to require a sponsoring organization, under an intermediate sanction, to hire an independent auditor to provide us with additional information that we will use to determine if the deficiencies upon which the sanction is based have actually been corrected and are not likely to recur. We also proposed an alternative proposal in which we would

grant sponsoring organizations the discretion to hire an independent auditor to evaluate the sponsoring organization's compliance with our requirements and would afford the results of the independent auditor's review some weight in our determination of whether the bases for the sanction have been corrected and are not likely to recur. After considering the comments we received in response to this proposal, we are adopting the proposal without modification, which provides CMS with the discretion to require a sponsoring organization, under an intermediate sanction, to hire an independent auditor.

Second, we proposed changes to § 422.756(d)(3) and § 423.756(d)(3) to provide CMS with the discretion to require a sponsoring organization, subject to a marketing and enrollment sanction, to go through a test period during which the organization could market and accept enrollments for a limited time in order for us to determine if the sponsoring organization's deficiencies have been corrected and are not likely to recur. Additionally, we proposed to revise these provisions to provide that following the test period, if we determine the deficiencies that formed the basis for the sanction have not been corrected and are likely to recur, the intermediate sanction will remain in effect until such time that we are assured the deficiencies have been corrected and are not likely to recur. The sponsoring organization, in these instances, would not have a right to a hearing to challenge our determination to keep the sanction in effect. We are finalizing this proposal without modification.

We also proposed deleting existing provisions at § 422.756(c) and § 423.756(c) because these provisions are duplicative of the list of sanctions at § 422.750(a) and § 423.750(a) and are unnecessary. In this final rule, we are adopting all of these proposals without further modification.

Comment: CMS received numerous comments regarding the engagement of an independent auditor by a sponsoring organization under sanction by CMS, with most commenters supporting the alternative proposal in which CMS may allow the sponsoring organization the discretion to hire an independent auditor. Commenters provided various rationales for their support of the alternative proposal, including the potential financial and operational burden to sponsoring organizations when required to engage an outside auditor; that sponsoring organizations may already have the internal resources available to provide the information to CMS; and that absent standards, CMS could impose this requirement in an arbitrary and capricious manner. A commenter opposing both proposals because the commenter did not believe it was necessary for CMS to grant the sponsor the discretion to hire independent auditors, and that by allowing discretion to hire an independent auditor, a sponsoring organization that did not hire the auditor would then be viewed in a negative light. Finally, one commenter expressed concern with our alternative proposal that when an independent auditor was not required by CMS, but was retained by the sponsoring organization at their discretion, CMS would merit only "some weight" in the decisionmaking process to lift the sanction. Specially, the commenter recommended that the independent auditor's evaluation should have the same standard of weight regardless of whether the independent auditor was required or was discretionary.

Response: When a sponsoring organization has been sanctioned, the organization's deficiencies have risen to a serious and significant level. We believe that we should have the flexibility to require the sponsoring organization to hire an independent auditor for the benefit of both us and the sponsoring organization. To ensure that the use of the independent auditor will be beneficial for the sponsoring organization and to us, we intend to consider the sponsoring organization's ability to afford an independent auditor as well as the sponsoring organization's ability to demonstrate through its own resources that it has corrected its deficiencies and they are not likely to recur. To determine whether or not we would require an independent auditor, we would check to see if the sponsoring organization was on our financial watch list as well as on the financial watch list of any of the States or commonwealths in which the sponsoring organization was licensed. Also, whenever a sponsoring organization is under sanction, we engage in ongoing discussions with its senior leaders and management. If we were considering the use of an independent auditor, we would discuss this with the sponsoring organization and solicit their feedback in order to fully comprehend the financial makeup and stability of the organization.

As the proposed regulatory language reflected, this authority will not be exercised in all circumstances because we recognize that an independent auditor may not be needed or beneficial in all circumstances. For these reasons, we are maintaining the requirement in the final rule that when a sponsoring organization has been sanctioned CMS may require that the sponsoring organization hire an independent auditor.

Comment: CMS received a number of comments requesting that CMS provide more clarification related to our use of the term independent auditor in our proposal, including providing a definition, minimum qualifications, and whether conflict of interest rules would apply. One commenter suggested that CMS provide a list of auditors for sponsoring organizations to choose from. Another commenter seemed to be concerned that an independent auditor is generally used in the context of a financial audit and referred to "Sarbanes Oxley" stating that it has fairly clear rules with regard to conflicts of interest. In that respect, commenters requested that CMS clarify what context it used the phrase "independent auditor."

Response: We intend that sponsoring organizations will choose the independent auditor. We will work with sanctioned organizations to determine if the independent auditor they are proposing is appropriate. Some basic examples, however, of standards that we will require for independent auditors are knowledge of the Part C and Part D programmatic requirements and experience evaluating an organization's performance in the areas specific to the deficiencies. To the extent that one commenter was referencing financial audits under the Sarbanes Oxley Act of 2002 (Pub. L. 107–204, 116 Stat. 745, enacted July 30, 2002), this proposal is not governed by the standards in Sarbanes Oxley. The type of audit contemplated by Sarbanes Oxley is a financial audit and not a program compliance audit. The audits proposed here would involve an independent evaluation of whether the sponsoring organization is in compliance with CMS requirements. We will evaluate whether or not there is a need to release more detailed information in the future through subregulatory guidance or other appropriate means.

Comment: Several commenters requested that CMS provide standards for when an independent auditor would be needed. Commenters wanted clarity on when an independent auditor would be required, what types of issues the auditor would be called to review, and the parameters under which an auditor would perform its work. One commenter requested that we limit the focus of the audit to the bases for the sanction.

Response: During the period of the sanction, we communicate regularly with the sponsoring organization and,

therefore, we intend to fully discuss with the sanctioned organization the basis for concluding an independent auditor is necessary prior to requiring the organization to retain the independent auditor. We intend to utilize the requirement in our proposal when we determine that an independent auditor would be beneficial, such as in situations where the deficiencies are highly technical in nature. Also, if the sanctioned organization is having difficulty demonstrating to us that its deficiencies have been corrected, an independent auditor can provide us with assurances that the deficiencies have in fact been corrected through a neutral third party evaluation. We intend to determine what areas the independent auditor should assess depending on the nature and extent of the deficiencies. We do not believe it is possible or appropriate to provide this information in regulation since each sanctioned organization may require a different assessment based on its particular deficiencies. With respect to the comment that the focus of the audit should be limited to the bases for the sanction, based on our experience, we believe the independent auditor would need the flexibility to broaden the assessment because new or related issues may arise in the period after the sanction is imposed that need to be evaluated in order to ensure that the deficiencies have been corrected and are not likely to recur.

Comment: Several commenters were concerned with our comparison of the independent auditor in this requirement to the Corporate Integrity Agreements (CIA) used by the HHS Office of Inspector General (OIG) because information found under the CIA is not publicly disclosed, and the commenters believe that the results should be publicly disclosed. Commenters also stated that in the case of nursing homes, experience has shown that CIAs have not been effective and that nursing homes have not improved as a result of CIAs.

Response: When a sponsoring organization is subjected to an intermediate sanction, this information, along with the bases for the sanction, is publicly disclosed through the CMS Web site. Additionally, the public subsequently is notified as to whether we have determined that these deficiencies have been corrected and are not likely to recur. We do not believe that there is any significant value in making the public aware of audit results related to an internal technical assessment of the correction of these deficiencies that may be relied on to make our ultimate determination. However, to the extent these documents would be required under existing law to be disclosed we fully intend to comply with those requirements.

With regard to the commenters who were concerned about the overall effectiveness of using independent auditors to assist us in evaluating compliance, correcting the deficiencies is ultimately the responsibility of the sanctioned organization. Although, the independent auditor may consult with the sanctioned organization on the best way to fix its deficiencies, the main purpose of the independent auditor is to provide evidence and additional assurances which would assist us in making the determination that those deficiencies have been corrected. We intend that independent auditor results will be weighed with a host of other validation activities conducted by us and will not be the sole source of information concerning whether deficiencies have been corrected and are not likely to recur.

Comment: One commenter stated that the audit findings of an independent auditor should be subject to attorney-client privilege and that they would only be subject to release to CMS if the sponsoring organization waived the privilege.

Response: We disagree with the commenter that results of the independent auditor are protected by attorney client privilege. The purpose of the independent auditor is to provide a neutral third party evidenced-based evaluation of whether a sanctioned organization is in compliance with CMS requirements. Attorney-client privilege is a legal concept which protects communications between an attorney and his or her client and keeps certain communications between the parties confidential. Independent audit findings are by no means necessarily subject to the attorney-client privilege and, in this case, the sole purpose of the audit being performed is to provide information to CMS.

Comment: One commenter stated that CMS' determination not to lift the sanction after the results of the independent audit should be appealable and such appeal is required by law.

Response: There is no statutory right to appeal a decision by CMS to keep a sanction in effect. Appeal rights are afforded at the time the sanction is imposed.

Comment: One commenter requested that we remove the language "not likely to recur" from the independent auditor requirement. The commenter stated that it was not general practice for an auditor to opine as to whether the deficiencies were not likely to recur.

Response: We did not propose and do not intend to require the independent auditor to opine as to whether the deficiencies are not likely to recur. The independent auditor will perform an assessment to determine if the sponsoring organization is in compliance with our requirements and we would use that evaluation, along with other information provided by the sponsoring organization, to make our determination as to whether the deficiencies that formed the basis for the sanction have been corrected and are not likely to recur. The independent auditors report is evidentiary and not dispositive as to whether the deficiencies have been corrected and are not likely to recur. We make that determination.

Comment: We also received a number of comments on the proposal that in instances where marketing or enrollment sanctions have been imposed, CMS may require a sponsoring organization to engage in a marketing or enrollment "test period" in order to assist CMS in making a determination as to whether the deficiencies have been corrected and are not likely to recur. Most commenters wanted more clarity regarding the parameters of the "test period," including any limitation on enrollment during the test period, the duration, when it would be required and the level of performance required during the test period.

Response: The details concerning implementing a test period will vary from organization to organization depending on the nature and extent of the deficiencies that formed the basis for the sanction and other factors such as the organization's size, complexity of operations, etc. We intend to work closely with any sanctioned organization prior to establishing a "test period" and the organization will receive specific notice of the standards the organization must meet to demonstrate that its deficiencies have been corrected during the test period.

Comment: Several commenters asserted that sanctioned organizations should be afforded appeal rights if, after the marketing and enrollment "test period," CMS determines to keep the sanction in effect.

Response: Under our proposed provision, the "test period" is a validation activity that will help us to determine that the deficiencies that formed the basis for the sanction have been corrected and are not likely to recur. For example, when we validate a sponsoring organization's compliance with appeals and grievances requirements, we may perform an audit to test those areas. If the audit

demonstrates that the sponsoring organization has not corrected its deficiencies or that they are likely to recur, the sanction will remain in effect and the sponsoring organization cannot appeal that determination. Appeal rights are afforded at the time the sanction is imposed.

Comment: Several commenters expressed concern that sponsoring organizations subject to a "test period" would be under heightened scrutiny and that CMS would have sole discretion to determine the point at which the sponsoring organization has corrected the basis for the sanction. One other commenter questioned the value of a "test period" as well as the independent auditor and seemed to equate these validation activities to a situation where the sponsoring organization has been issued a corrective action plan (CAP).

Response: We intend to use a "test period" as one of a host of validation activities and we intend to work closely with any sanctioned organization prior to imposing a "test period" to ensure the sponsoring organization receives specific notice of the standards it must meet to demonstrate that its deficiencies have been corrected and are not likely to recur. We fully intend to subject all sponsoring organizations placed under a sanction to heightened scrutiny both during the sanction period and for some period afterwards to ensure that the deficiencies that formed the basis for the sanction are corrected and are not likely to recur. The "test period" requirement simply provides organizations under marketing/enrollment sanctions the same opportunity other organizations would have to demonstrate compliance with our standards for releasing the organization from the sanction during an established enrollment test period. The provision is not applicable to an organization that has been asked to implement a CAP and has not had a marketing and enrollment sanction imposed. This provision is limited to sponsoring organizations subject to intermediate sanctions.

Comment: One commenter requested that CMS adopt alternative approaches for evaluating whether it is appropriate to lift a marketing and enrollment sanction imposed on a sponsoring organization when the deficiencies that led to the sanction are ones where CMS cannot appropriately evaluate the extent of remediation through a trial enrollment and marketing period.

Response: We fully intend to continue to explore other ways to effectively validate whether deficiencies have been corrected while a sponsoring organization is under sanction. The test period proposal was intended to address the specific dilemma faced by CMS and the sponsoring organization when a sanctioned organization cannot market and enroll during the sanction period so as to demonstrate that the deficiencies have been addressed.

Comment: One commenter suggested that CMS specify that any decision not to lift an intermediate sanction at the end of such "test period" is a separate decision from, and shall not automatically result in, an action to terminate a contract.

Response: We do not intend to use the decision not to approve a sponsoring organization's request to release the sanction, in and of itself, as a basis for reaching a determination to terminate a contract. Termination determinations must always meet our specific statutory and regulatory requirements.

10. Termination of Contracts Under Parts C and D (§ 422.510(a) and § 423.509(a))

In the October 2009 proposed rule, we proposed to delete the enumerated bases for termination contained at § 422.510(a)(5) through (12) and § 423.509(a)(5) through (11). We proposed to modify language at § 422.510(a) and § 423.509(a) to separate the language into two paragraphs with the first paragraph, (a)(1), listing the statutory bases for termination and the second paragraph, (a)(2), clarifying that a sponsoring organizations (i) failure to comply with our regulations, (ii) failure to meet performance standards; and/or (iii) participation in false, fraudulent, or abusive activities, may constitute a basis for CMS to determine that the sponsoring organization meets the requirements for contract termination in accordance with paragraph (a)(1).

Based on the comments we received on the proposed rule, we have decided not to finalize our proposal and as an alternative to slightly modify existing regulations. First, we are finalizing the proposed modified language in provisions § 422.510(a)(1)–(3) and § 422.509(a)(1)–(3) so that the regulatory text mirrors the statutory language. Second, we are finalizing proposed modified language for § 422.510(a)(4) and § 423.509(a)(4), which states that CMS may now terminate under this provision when Medicare, Medicaid, or other State or Federal health care programs are affected. Next we are finalizing our proposed deletion of existing § 422.510(a)(5) and § 423.509(a)(5) because we believe that the provision is a basis for expedited termination and therefore inappropriately located in this part. We have decided to retain the remaining enumerated bases for termination that we previously proposed to delete at § 422.510(a)(6) through (12) and § 423.509(a)(6) through (11). We are, therefore, redesignating § 422.510(a)(6)–(12) and § 423.509(a)(6)–(11) as § 422.510(a)(5)–(11) and § 423.509(a)(5)–(10) respectively. Finally, we are adding the two new proposed bases, with modified language, to the existing enumerated list at § 422.510(a)(12) and § 423.509(a)(11) (failure to comply with regulatory requirements) and § 422.510(a)(13) and § 423.509(a)(12) (failure to comply with performance standards). The discussion of these revisions is set forth in more detail below.

Comment: A number of commenters expressed specific concerns about our proposed changes to § 422.510(a) and § 423.509(a), namely our proposal to remove the enumerated standards for termination and proposal to mirror the statutory language. Commenters stated that the proposed language is too broad and vague, gives CMS unprecedented discretion and authority and invites arbitrary or inconsistently applied determinations by CMS. One commenter suggested that CMS maintain the existing language.

Response: We disagree that the proposed changes to § 422.510(a)(1) through (3) and § 423.509(a)(1) through (3) provide CMS with unprecedented authority and discretion. The proposed language merely mirrors the authority provided to CMS through statute. We have, however, after considering all of the comments, decided to retain the existing provisions from § 422.510(a)(6) through (12) and § 423.509(a)(6) through (11) into the final rule. These examples of substantive bases are now redesignated as § 422.510(a)(5) through (11) and § 423.509(a)(5) through (10) respectively.

Comment: A number of commenters expressed concern with the proposed language at § 422.510(a)(12) and § 423.509(a)(11) (formerly § 422.510(a)(2)(i) and § 423.509(a)(2)(i)) which provided that CMS may determine that a basis exists to terminate a sponsoring organization's contract if the sponsoring organization fails to comply with *any* regulatory requirement contained in parts 422 or 423. While one commenter strongly supported the proposed change, many commenters believed that the revision removed the "substantiality" or "materiality" tests explicit or inherent in each of the existing requirements, and in effect it would allow CMS to terminate on the basis of a single instance in which a particular requirement is not met.

Response: We have considered the comments and have decided to remove the word "any" from the proposal to avoid confusion and have modified the regulatory text in the final version of the regulation to reflect this change. Adherence to all our regulatory requirements is important and necessary, but we acknowledge that in making a decision to terminate a contract, we would take into account the nature and extent of the failure to meet our regulatory requirements and the materiality of the requirement as compared to other requirements.

Comment: A number of commenters also expressed concern about the proposed language at § 422.510(a)(13) and § 423.509(a)(12) (formerly § 422.510(a)(2)(ii) and § 423.509(a)(2)(ii)) supporting the use of outlier analysis to reach a termination decision. These commenters opposed this proposal and argued that it is inconsistent with law and unfair to equate outlier status to noncompliance. Another commenter stated that it was improper to make contract termination decisions based on a determination that a sponsoring organization is the lowest performer among a cohort when the organization may still be performing adequately. Some commenters stated that they needed more clarity on the specifics associated with the outlier standards and access to the data underlying these standards. Additionally, commenters asserted that the outlier standards are too vague of a standard to serve as a basis for contract terminations, particularly when CMS has not disclosed the relevant standards or methodology and organizations have not be notified in advance of these standards in order to be afforded an opportunity to improve. Two commenters recommended that CMS allow sponsoring organizations to appeal CMS findings as a result of outlier analysis.

Response: Outlier analysis is an oversight mechanism by which we can more effectively focus our limited resources in determining which sponsoring organizations to target for further compliance analysis and assessment. We do not intend to use this analysis in and of itself as a basis to terminate a contract. Therefore, we have decided to remove this outlier language from the final rule, to avoid misunderstandings and confusion among sponsoring organizations concerning the use of this data to take termination actions.

Comment: CMS proposed to modify language at § 422.510(a)(4) and § 423.509(a)(4) (formerly § 422.510(a)(2)(iii) and § 423.509(a)(2)(iii)) to revise the agency's existing regulatory authority to allow CMS to terminate a sponsoring organization when there is credible evidence that shows that the sponsoring organization has committed or participated in false, fraudulent or abusive activities affecting the Medicare, Medicaid, or other State or Federal health care programs. Two commenters on this proposed provision, one in support and the other opposing the provision, stated that CMS should not terminate contracts in cases where the employees committing the fraudulent acts have no involvement with the administration of the Medicare lines of business offered by the sponsoring organization.

Response: Our proposal was not intended to indicate that we will terminate a contract in the case of employee fraudulent acts unrelated to Medicare, Medicaid, or other State or Federal health care programs.

11. Request for Hearing Under Parts C and D (§ 422.662 and § 423.651)

In the October 2009 proposed rule, we proposed to modify the language at § 422.662(a) and § 423.651(a) stating that the sponsoring organization must file a request for a hearing in accordance with the requirements specified in the notice of the contract determination or intermediate sanction. This proposed change would ensure that the proper officials within CMS receive the request and are able act upon it in a timely manner. Current regulations at § 422.662(a) and § 423.651(a) governing the hearing procedures require sponsoring organizations to file a request for a hearing on contract determinations with the Hearing Officer and to also file it with "any CMS office." As we stated in the preamble to the proposed rule, we believe this procedure is ineffective and inefficient because it is likely to result in a request for hearing not being received by the appropriate officials within CMS.

We also proposed a conforming change at § 422.662(b) and § 423.651(b) which governs the timeframes for filing the request for hearing to provide that the request must be filed within 15 calendar days after receipt of the notice (versus the existing language which states 15 calendar days from the "date CMS notifies" the sponsoring organization of its determination). This proposed change was made to ensure consistency with the way deadlines are described in other regulatory provisions of parts 422 and 423 governing contract determinations or the imposition of intermediate sanctions (including related appeals processes).

Since we received no comment on these sections, these changes are adopted without modification in this final rule.

12. Burden of Proof, Standard of Proof, Standards of Review, and Conduct of Hearing (§ 422.660, § 423.650, § 422.676, and § 423.658)

In the October 2009 proposed rule, we proposed to delete the references to "substantial compliance" as a standard of review at hearing and delete the existing regulations which provide for an "earliest of" test from § 422.660 and § 423.650. We also proposed to explicitly state that the preponderance of the evidence is the standard of proof that we believe applies during the appeal of a contract determination or intermediate sanction. We also proposed to delete the existing language contained at § 422.660(b) and § 423.650(b) and replace it with language that provides that the sponsoring organization has the burden of proving by a preponderance of the evidence that our determination was inconsistent with the requirements of the applicable part. Additionally, we specified in our proposal that the applicable requirements are § 422.501 and § 422.502 for the processes and standards for applicants for the MA program, § 423.502 and § 423.503 for applicants for the Part D program, § 422.506 or § 422.510 for MA contract determinations, § 423.507 or § 423.509 for Part D contract determinations, and § 422.752 or § 423.752 for intermediate sanctions.

We proposed to modify § 422.660(c) and § 423.650(c), which specified that the notice of any decision favorable to a Part C or D applicants appealing a determination that it is not qualified to enter into a contract with us must be issued by July 15th for the contract in question to be effective on January 1st of the following year. We proposed a change from the July 15th deadline to September 1st.

Finally, we proposed to modify existing regulations at § 422.676(d) and § 423.658(d) governing the conduct of the hearing to provide that, consistent with the burden of proof, during the hearing the sponsoring organization bears the burden of being the first to present its argument to the Hearing Officer according to any briefing schedule determined by the Hearing Officer.

We are adopting all of the proposed changes as the final rule without further modification.

Comment: Several commenters opposed CMS' removal of the "substantial compliance" standard

asserting that this standard was well established and well understood as opposed to the new language that CMS proposed, which these commenters stated was vague and unclear.

Response: We disagree that the "substantial compliance" standard is clear and easy to apply in making a determination. As explained in the preamble to the October 2009 proposed rule, the "substantial compliance" language has led to confusion among parties to the hearing, has been difficult for the Hearing Officer to apply, and does not reflect the nuances of the different legal standards provided in the Act for making contract determinations and imposing intermediate sanctions. Our proposal, which provided that the standard of review is whether CMS' determination is inconsistent with the regulatory requirements for taking the underlying action (for example, application denial, non-renewal, termination or intermediation sanction) provides the requisite specificity to be applied by the hearing officer and the parties to these actions. We also believe the proposal properly focuses the hearing officer and all parties to the hearing on the correct standard, and the pertinent issue under review at the hearing.

Comment: Several commenters expressed concern that the proposed changes result in the sponsoring organizations bearing the burden of proof in appeal proceedings and one commenter added that CMS' proposal is inconsistent with the general rule articulated by the Supreme Court that the party seeking to take action ordinarily bears the burden of persuasion and cited to *Schaffer* v. *Weast,* 546 U.S. 49 (2005).

Response: The commenters have misunderstood the scope of our proposals because we did not propose a change as to which party bears the burden of proof. Existing regulations explicitly state that the sponsoring organization bears the burden of proof. Also, we believe that the commenter is mistaken in its reading and interpretation of the ruling in *Shaffer* v. *Weast.* In that case, the Supreme Court held that the burden of proof in an administrative hearing is properly placed upon the party seeking relief ("[T]he burdens of pleading and proof with regard to most facts have been and should be assigned to the plaintiff who generally seeks to change the present state of affairs and who therefore naturally should be expected to bear the risk of failure of proof or persuasion.") In our appeal proceedings, the party seeking relief is the sponsoring organization, thereby making it appropriate for that party to bear the burden of proof. Thus, existing regulations which require that the sponsoring organization bear the burden of proof are consistent with the legal precedent cited by the commenter.

Comment: One commenter requested that CMS provide a definition for the "preponderance of the evidence standard."

Response: The preponderance of the evidence standard is a well established and defined legal standard. To make a showing by the preponderance of the evidence, one must show that it is more likely than not that the fact that the claimant seeks to prove is true.

Comment: Some commenters opposed changing the notification date from July 15th to September 1st. Some commenters noted that notification by September 1 of a favorable determination would not leave a sponsor with sufficient time to prepare for the upcoming year given that sponsors are permitted to start marketing for the upcoming year on October 1. One commenter recommended moving the application deadline to March to allow for adequate preparation of the application and suggested that adequate preparation may reduce the number of appeals.

Response: In most cases, we do not believe a favorable determination issued by the CMS hearing officer will be rendered as late as September 1st. However, moving the notification date of the favorable determination from July 15th to September 1st affords applicants that receive a favorable decision the opportunity to be sponsors in the contract year for which they applied. In all instances, this regulatory change works to the benefit of sponsors.

We believe that sponsors are given adequate time and instruction to complete the application. We believe changing the application due date would not significantly impact the number of appeals.

13. Expedited Contract Terminations Procedures (§ 422.510, § 423.509, § 422.644, § 423.642, § 422.664, and § 423.652) Under Parts C and D

In the October 2009 proposed rule, we proposed to delete the references to expedited terminations based on false, fraudulent or abusive activities and severe financial difficulties contained in the termination procedures at § 422.510(b)(2)(i), § 423.509(b)(2)(i), § 422.510(c)(2) and § 423.509(c)(2) and in the appeal procedures at § 422.644(c)(2), § 423.642(c)(2), § 422.664(b)(2) and § 423.652(b)(2). We proposed to modify these provisions instead to reflect the more general statutory language concerning our ability to take an expedited termination when we determine that a delay in termination caused by adherence to the required procedures would pose an imminent and serious risk to the health of the individuals enrolled with the sponsoring organization. We are adopting our proposal to include this statutory language, and based on the comments we have decided to retain and amend the two existing bases for expedited termination currently located at § 422.510(a)(4) & (a)(5) and § 423.509(a)(4) &(a)(5).

Comment: We received several comments on our proposals. Commenters were concerned that our proposal was overly broad, lacked specificity and that there were no examples of situations where we would pursue an expedited termination. Additionally, a few commenters were concerned that a sponsoring organization might be subjected to an expedited termination for a single, isolated incidence of non-compliance and that sponsoring organizations would not be afforded the opportunity for a hearing before the termination took effect.

Response: After considering all of the comments we received, we have decided to retain the two existing examples for when CMS may pursue an expedited termination as well as incorporate the statutory language into the final rule.

The existing regulation references § 422.510(a)(5) and § 423.509(a)(5) as one example of a situation where CMS would pursue and expedited termination, but it is also listed as a basis for termination. In the proposed regulation, we proposed removing this instance as a basis for termination, thereby removing its associated reference in expedited termination. We believed that this language created some confusion because it intertwines a basis for termination (that is, failure to make services available) with the statutory standard for making an expedited termination. Based on the comments we received, however, we see that the reference to this basis provided sponsoring organizations with a clear example of the instances under which CMS may decide to take an expedited termination. In order to resolve this issue, we have decided to add the language from § 422.510(a)(5) and § 423.509(a)(5) to the regulatory provisions on expedited terminations in the final rule. We have decided to finalize our proposal to delete this language as a basis for termination because we maintain that the circumstances in this provision would

lead CMS to pursue an expedited termination.

The second example in the existing regulation references § 422.510(a)(4) and § 423.509(a)(4) which concerns situations where there is credible evidence that a sponsoring organization committed or participated in false, fraudulent or abusive activities affecting the Medicare, Medicaid, or other State or Federal health care programs, including the submission of false or fraudulent data. Based on the comments we received, this reference also provided sponsoring organizations with a clear example of the circumstances under which CMS may decide to take an expedited termination. Therefore, we have decided to retain the reference to § 422.510(a)(4) and § 423.509(a)(4) as a basis for expedited termination.

Finally, we are moving forward with our proposal to incorporate the statutory language in the revised regulations governing expedited termination, thereby permitting CMS to expedite a termination if we determine that a delay in termination caused by adherence to the required procedures would pose an imminent and serious risk to the health of the individuals enrolled with the sponsoring organization. We do not agree that our proposal to include the statutory language is overly broad or vague, and believe that by retaining the two existing examples, it provides sponsoring organizations with some guidance on the types of issues that might lead CMS to pursue an expedited termination while still allowing us the flexibility we need to ensure we can act quickly in situations where adherence with the standard termination procedures would pose an imminent and serious risk to the health of Medicare beneficiaries.

14. Time and Place of Hearing Under Parts C and D (§ 422.670 and § 423.655)

In the October 2009 proposed rule, we proposed adding new language to § 422.670(b) and § 423.655(b) to state that either the sponsoring organization or CMS may request that a hearing date be postponed by filing a written request no later than 5 calendar days prior to the scheduled hearing, and that when either the sponsoring organization or CMS requests an extension, the Hearing Officer must provide a one-time 15-calendar day postponement, and additional postponements may be granted at the discretion of the Hearing Officer. We also proposed revising the language in § 422.670(a) and § 423.655(a) to provide that the CMS Hearing Officer schedule a hearing to review a contract determination or the imposition of an intermediate sanction within 30 calendar days after the "receipt of the request for the hearing." This change was made to ensure consistency with the way deadlines are described in other regulatory provisions of parts 422 and 423 governing contract determinations or the imposition of intermediate sanctions (including related appeals processes). We are adopting all the proposed changes into the final rule without further modification with the exception of the timeframes outlined in § 422.670(b) and § 423.655(b) as set forth below.

Comment: Several commenters questioned CMS' proposal to allow sponsoring organizations or CMS to request an extension for the hearing by filing a written request no later than 5 calendar days prior to the scheduled hearing. Most commenters believed that allowing requests for extensions until 5 days prior to the scheduled hearing would not allow enough time for sponsoring organizations to change travel arrangements and commenters proposed different timeframes they thought would be more suitable.

Response: We agree with the commenters concerns and have decided to extend the timeframe for requesting an extension to the hearing date from 5 calendar days to 10 calendar days prior to the scheduled hearing in our final rule.

Comment: One commenter raised concerns that there may be times when an automatic, 15-day extension may not be workable due to previous commitments on the part of the Hearing Officer or non-requesting party and suggested CMS add language to the requirement to allow for an alternate, mutually agreed upon hearing date if the Hearing Officer or the non-requesting party is not available on the hearing date that would otherwise result from postponement.

Response: We believe that the addition of such language is not necessary because current regulations at § 422.670(b)(1) and (2) and § 423.670(b)(1) and (2) already provide that the Hearing Officer has the authority on his or her own motion, to change the time and place for the hearing.

15. Discovery Under Parts C and D (§ 422.682 and § 423.661)

In the October 2009 proposed rule, we proposed to delete the formal discovery process contained in § 422.682 and § 423.661. In the December 5, 2007 **Federal Register** (72 FR 68700), we published a final rule with comment period that finalized our revisions to § 422.682 and § 423.661 to provide for a formal discovery process prior to hearing. However, based on our experience since the promulgation of this rule, we do not now believe a formal discovery process is necessary or appropriate for these kinds of proceedings. In addition, the existing timeframe in which the hearing normally must take place, 30 calendar days after request for a hearing, does not easily accommodate a formal discovery process. We also proposed to amend § 422.682 and § 423.661 to require that witness lists and documents be identified and exchanged at least 5 calendar days prior to the scheduled hearing. We are adopting § 422.682 and § 423.661 without further modification into this final rule.

Comment: Several commenters opposed CMS' removal of the formal discovery process from regulations. Commenters specifically stated that deleting discovery is a violation of their due process rights, and would deny sponsors the only opportunity they have to obtain the full breadth of information they are entitled to for a fair hearing. One commenter stated that the discovery process is the appropriate forum for the sponsoring organization to learn of the criteria CMS used in reaching its decision and that sponsoring organizations have a statutory right under 5 U.S.C. 552 to this information.

Response: We disagree with the commenters who stated that the removal of discovery from regulations is a violation of their due process rights and a violation of their statutory right to obtain information in this manner. Our hearings are informal administrative proceedings and as the court held in *Lopez* v. *U.S.,* "[t]here is no general constitutional right to discovery in administrative proceedings" *Lopez* v. *U.S.,* 129 F.Supp.2d 1284 (2000). Also, we do not believe that finalizing our proposal to remove discovery will create unequal or prejudicial treatment that will lead to a violation of due process. Both CMS and sponsoring organizations will be equally limited to producing and receiving witness lists and documents that must be exchanged at least 5 calendar days before the hearing. Also, we do not believe that full discovery for sponsoring plans is required to receive the necessary information from us for adequate and proper preparation for the hearing. Prior to the hearing, we will have already provided sponsoring organizations the specific information relied upon by CMS in reaching the determination which they are appealing. In cases of contract terminations or intermediate sanctions, we will have previously provided the specific basis for the determination within the notice

of intent to terminate or impose intermediate sanctions. Therefore, we believe that a witness list and documents are sufficient to meet the evidentiary needs of the parties. Additionally, any prior decisions of hearing officers are public record, and therefore, obtainable by sponsoring organizations. Sponsors have numerous statutory rights under 5 U.S.C. 552 which govern the agency's disclosure of public information; agency rules, opinions, orders, records, and proceedings. The removal of the discovery process does not circumvent the rights provided to the public under 5 U.S.C. 552.

Comment: One commenter also requested that if CMS moves forward with the proposal to eliminate the formal discovery process that we revise our proposal to include a list of the specific documents to be shared and to indicate the action that will result when the required documents are not shared prior to the hearing.

Response: Appeal proceedings will vary dependent on what type of determination is being appealed and we cannot possibly specify which documents would be necessary in each and every type of case. Also, if documents are not shared prior to the hearing, it is within the discretion of the hearing officer to determine what the consequences of that action or inaction for the parties to the hearing.

16. Review by the Administrator Under Parts C and D (§ 422.692(a) and § 423.666(a))

In the October 2009 proposed rule, we proposed revisions to the language at § 422.692(a) and § 423.666(a) to provide that the sponsoring organization may request review by the Administrator within 15 calendar days after "receipt of the hearing decision." In addition, we revised the language at § 422.692(c) and § 423.666(c) governing the notification of Administrator determination to state that the Administrator must notify both parties of his or her determination regarding review of the hearing decision within 30 calendar days after "receipt of the request for review" (versus the existing language which provides within 30 calendar days of "receiving the request for review"). These changes were made to ensure consistency with the way deadlines are described in other regulatory provisions of parts 422 and 423 governing contract determinations or the imposition of intermediate sanctions (including related appeals processes). We received no comment on this section, and are adopting these changes without modification.

17. Reopening of an Initial Contract Determination or Decision of a Hearing Officer or the Administrator Under Parts C and D (§ 422.696 and § 423.668)

In the October 22, 2009 proposed rule, we proposed revising the regulations governing the reopening of an initial contract determination or decision of a Hearing Officer or the Administrator under Parts C and D by replacing the language "initial determination" with "contract determination" in the section headings of § 422.696 and § 423.668 and in the text of § 422.696(a) and § 423.668(a). We noted that the term "initial determination" is not used elsewhere in Subpart N (Contract determinations and appeals). We received no comment on our proposals and are adopting these changes without modification.

18. Prohibition of MA and Part D Applications for 2 Years After a Mutual Termination (§ 422.503(b)(6) and § 423.504(b)(6))

In the October 22, 2009 proposed rule, we proposed prohibiting an MA organization or Part D sponsor, as a condition of the consent to a mutual termination, from applying for new contracts or service area expansions for a period of 2 years, absent circumstances that warrant special consideration as provided under section 1857(c)(4)(A) of the Act. Specifically, under Part D, we proposed modifying § 423.508 by adding paragraph (e), which states that as a condition of the consent to a mutual termination, CMS requires as a provision of the termination agreement language prohibiting the Part D sponsor from applying for new contracts or service area expansions for a period of 2 years, absent circumstances warranting special consideration. Similarly, in § 423.504(b), we proposed adding a new paragraph (b)(6) stating that organizations may be qualified to apply for new contracts to the extent that they have not terminated a contract by mutual consent under which, as a condition of the consent, the Part D sponsor agreed that it was not eligible to apply for new contracts or service area expansions for a period of 2 years per § 423.508(e). We also proposed redesignating the current § 423.504(b)(6) to § 423.504(b)(7).

Similar modifications were proposed for the MA regulations. Specifically, we proposed modifications to § 422.508 by adding paragraph (c), which states that as a condition of the consent to a mutual termination, we require as a provision of the termination agreement language prohibiting the MA organization from applying for new contracts or service area expansions for a period of 2 years, absent circumstances warranting special consideration. Similarly, in section § 422.503(b), we added a new paragraph (b)(7), stating that organizations may be qualified to apply for new contracts to the extent that they have not terminated a contract by mutual consent under which, as a condition of the consent, the MA organization agreed that it was not eligible to apply for new contracts or service area expansions for a period of 2 years per § 422.508(c).

In proposing these changes, we noted that in practice, a voluntary nonrenewal of a contract by a Part D sponsor or MA organization is not dissimilar from an organization requesting and being granted a mutual termination of their contract under § 422.503 and § 423.508. Under § 422.506(a)(4) and § 423.507(a)(3), if a sponsor voluntarily nonrenews a contract, we cannot enter into a contract with the organization for 2 years unless there are special circumstances that warrant special consideration, as determined by CMS. The primary difference between a nonrenewal and a mutual termination is often timing. For a nonrenewal request to take effect at the end of the current contract year, it must be received by us on or before the first Monday in June (the bid deadline), as specified in § 423.507(a)(2)(i) and § 422.506(a)(2)(i). However, once an organization submits a bid, it can no longer voluntarily nonrenew its contract for the following year. Rather, the Part D sponsor or MA organization must request a mutual contract termination. The later in the year the organization requests such a mutual termination for the following contract year, the more disruptive and difficult the process becomes. In the October 2009 proposed rule, we noted that this is particularly true if a request for a mutual contract termination occurs once plan information has become publicly available, marketed to beneficiaries, and beneficiaries have been given the opportunity to enroll. These late terminations create significant disruption for beneficiaries and for us. Similarly, even greater disruption results from mutual terminations requested to take effect during the course of a contract year.

In light of the disruptions that may occur, we proposed that a termination by mutual consent, which involves a termination by an MA organization or a Part D sponsor as well as by us, be considered a termination of a contract for purposes of the 2-year ban on entering into new contracts under section 1857(c)(4)(A) of the Act, which

is incorporated for Part D under section 1860D–12(b)(3)(B) of the Act.

After considering the comments we received in response to these proposals, in this final rule, we are adopting our proposals without modification.

Comment: One commenter stated that it is important to inform beneficiaries immediately when—(1) their plan is not in compliance with CMS requirements; (2) sanctions have been implemented; or (3) a plan is prohibited from applying for new contracts or service area expansions for a 2-year period. By notifying beneficiaries immediately of these situations, they will be afforded more time to plan. Immediate notification will increase the likelihood that the information will not be lost in the extraordinary amount of information given during the open enrollment period. The commenter recommended that CMS strengthen compliance in general in order to hold plans accountable through CMS monitoring and oversight.

Response: Although mutual terminations are often requested when a contract is, or will soon be, out of compliance with CMS requirements, a mutual termination can occur even when there is no current or expected compliance violation. Our proposed revision to this portion of the regulation only addresses the period of time during which a mutually terminated sponsor would be precluded from applying for a new or expanded contracts. As a result, this comment addressing the issue of beneficiary notice concerning Part C and D plan performance is outside the scope of the proposed regulatory change.

Comment: One commenter stated that it did not support the proposal for a 2-year ban because market conditions can create the need for contract terminations and service area reductions. The commenter requested that CMS allow flexibility on market re-entry based on environmental conditions and appropriate negotiations with and approval by the agency.

Response: Terminations can cause beneficiary confusion and disruption. Additionally, if a sponsor responds to market conditions through the nonrenewal process, a 2-year application ban would apply. Accordingly, we believe it is reasonable and appropriate to apply the same 2-year application ban in situations when a sponsor terminates a plan after the nonrenewal deadline. We also note that, the proposed regulation changes preserve our authority to permit affected organizations to submit applications in less than 2 years when special consideration is warranted.

Comment: One commenter stated that it did not oppose the proposed changes, but requested that CMS clarify that the 2-year moratorium is based on a sponsoring organization terminating all of its MA or Part D contracts, not a subset of each line.

Response: The regulation as proposed would apply to a licensed legal entity that mutually terminated any of its MA or PDP contracts. A complete exit from either program by an organization is not required for CMS to invoke the 2-year application prohibition.

Comment: One commenter requested additional clarity regarding "nonrenewal" and "mutual termination." The commenter urged CMS to be especially cautious about any presumption by CMS that termination may be due to some type of poor performance. The commenter stated that it is possible that after the first week in June a plan will determine that it is not feasible to continue with the contract. The commenter included the example of a State-initiated dramatic midyear reduction in payment for Medicaid services in a dually integrated product. The commenter also stated that the references in § 422.508 to § 422.510 seem to imply some type of failure to perform. The commenter supported providing adequate notice of terminations to beneficiaries, but suggested that a 60-day timeframe may be adequate for end-of-year terminations. The commenter indicated that the 2-year prohibition against applying for new contracts or services areas is reasonable given the language "absent circumstances warranting special consideration." The commenter stated that an example of such a circumstance should include the situation of when a plan is trying to be responsive to state purchasing initiatives on behalf of dual eligibles.

Response: With this proposal, we were not addressing whether a sponsor is a poor performer. Rather, the proposal was intended to make the consequences to a sponsor of a mutual contract termination the same as that for a non-renewal. Without this change, a plan might opt for a mutual termination rather than the less disruptive non-renewal in order to avoid the 2-year ban. Additionally, the existing 2-year ban on non-renewing sponsors is not meant to address those sponsors' performance, although it may help us to identify good business partners. The 2-year application ban, as it has been applied to non-renewing organizations and, once this proposed change is adopted by CMS, to mutually terminating organizations, is intended to ensure continuity in the Part C and D programs by imposing longer-term consequences on sponsors that might otherwise make annual decisions to exit and re-enter the programs.

Comment: A commenter asked CMS to clarify that this change applies only to mid-year mutual terminations and not to a plan electing to non-renew with ample notice to CMS (such as at the time of bid submission or per non-renewal guidance).

Response: Consistent with § 422.506(a)(4) and § 423.507(a)(3), the 2-year ban already applies to sponsors electing to nonrenew. The proposed regulatory change is an effort to extend the application of that rule to the analogous situation of a mutual contract termination, regardless of the effective date of that termination.

Comment: Commenters stated that while they understood the importance of the change, they would encourage CMS to be flexible as there may be instances where an MAO will conduct the right level of due diligence on its providers, yet a provider may experience a disruption that causes the organization to withdraw. The commenters stated that there is significant merit in those instances of an MAO acting in the best interest of Medicare beneficiaries and not effectuating the new plan or contract.

Response: Regardless of the degree of due diligence performed prior to contracting, the sponsor assumes all risks associated with complying with an MA or PDP contract, including a 2-year ban on new contracting resulting from a mutual termination. Also, as indicated in the proposed rule, CMS will retain the authority to accept applications where special consideration is warranted.

Comment: A commenter asked how this provision would be applied if an acquisition or merger is pending.

Response: The acquiring sponsor should assume that it is acquiring all the Medicare contract assets and liabilities of the selling organization, including a 2-year ban on new applications.

Comment: A commenter stated that plans should be allowed to terminate prior to the start of the benefit year if an adequate network cannot be obtained. The commenter also stated that if the termination occurs after the start of open enrollment, CMS should wait 30 days and allow beneficiaries to make their own elections before assigning them to an alternate plan. Additionally, it was suggested that there should be a mechanism in place to make sure that a plan cannot use termination as a tool to shift beneficiaries into a higher cost plan offered by the terminating sponsor.

Response: This comment does not concern the proposed application of the 2-year ban on mutually terminated sponsors. We will not address the comment as it is outside the scope of the proposed change.

Comment: A commenter stated that there are a variety of circumstances, including but not limited to the loss of an adequate network that may be beyond the control of the plan but force it to withdraw a contract. Such withdrawal may be in the best interest of the beneficiaries. Therefore, overall plan performance should not be judged on this one factor. If a plan can remedy the issue for the following contract year it should be allowed to re-contract. The commenter suggests that this issue be looked at on a case-by-case basis.

Response: This provision does not address whether a sponsor is a poor performer. Rather, the provision is intended to make the consequences of a mutual contract termination the same as those for a nonrenewal. The 2-year ban on nonrenewing sponsors is not meant to address those sponsors' performance; rather, it is intended to ensure continuity in the Part C and D programs by imposing longer-term consequences on sponsors that might otherwise make annual decisions to exit and re-enter the programs.

Comment: One commenter asked if CMS intends to apply this provision to all types of applications regardless of plan type or geographic location.

Response: In the context of voluntary nonrenewals, our policy has been to apply this prohibition based on plan type and service area (for example, non-renewal of a PFFS contract does not prohibit the same organization from applying immediately for an MA–HMO contract for the same service area). We anticipate applying the same policy to mutual terminations.

B. Changes To Strengthen Beneficiary Protections

This section includes provisions aimed at strengthening beneficiary protections under Parts C and D. Under Part D, we address proposals in the area of eligibility and enrollment policy, transition period requirements, coordination of benefits policy, retroactive claims adjustment reimbursements and recoveries, and use of standardized technology. We also finalize Part D rules regarding timeframes and responsibility for making redeterminations. Under Part C, we finalize rules to—

- Authorize us to annually establish limits on member cost sharing;
- Prohibit PPO, PFFS, and MSA plans from using compliance with voluntary prior notification procedures in determining cost-sharing amounts;
- Establish new requirements for organization determinations; and
- Offer two definitional revisions.

We also finalize Part C and D marketing requirements by distinguishing marketing materials from enrollee communications materials and mandating the use of standardized marketing material language and format to ensure clarity and accuracy among plan documents. We also clarify notice requirements, and require that sponsoring organizations disclose information concerning the organization's performance and compliance deficiencies to enable beneficiaries to make informed choices. This information is detailed in Table 2.

TABLE 2—PROVISIONS TO STRENGTHEN BENEFICIARY PROTECTIONS

Provision	Part 422		Part 423	
	Subpart	Section	Subpart	Section
Broker & Agent Requirements under Parts C and D.	N/A	N/A	N/A	N/A.
Beneficiary Communications Materials under Parts C and D.	Subpart V	§ 422.2260, § 422.2262.	Subpart V	§ 423.2260 § 423.2262.
Required Use of Standardized Model Materials under Parts C and D.	Subpart V	§ 422.2262	Subpart V	§ 423.2262.
Extend the mandatory minimum grace-period for failure to pay premiums.	Subpart B	§ 422.74	Subpart B	§ 423.44.
Maximum allowable out-of-pocket cost amount for Medicare Parts A and B services.	Subpart C	§ 422.100	N/A	N/A.
Maximum allowable cost sharing amount for Medicare Parts A and B services and prescription drugs.	Subpart C	§ 422.100	Subpart C	§ 423.104.
Prohibition on prior notification by PPO, PFFS, and MSA plans.	Subpart A	§ 422.2 § 422.4, § 422.105.	N/A	N/A.
Requirements for LIS eligibility: expand the deeming period for LIS-eligible beneficiaries to cover at least 13 months.	N/A	N/A	Subpart P	§ 422.773(c)(2).
Expand auto-enrollment rules to entire LIS-eligible population.	N/A	N/A	Subpart B	§ 423.34.
Special Enrollment Period (SEP) Policies	N/A	N/A	Subpart B	§ 423.38.
Transition Process	N/A	N/A	Subpart C	§ 423.120(b)(3).
Sponsor responsibility for retroactive claims adjustment reimbursements and recoveries.	N/A	N/A	Subpart J	§ 423.464. § 423.466. § 423.800.
Time Limits for Coordination of Benefits	N/A	N/A	Subpart J	§ 423.466.
Pharmacy use of Standard Technology (ID cards) under Part D.	N/A	N/A	Subpart C	§ 423.120.
Allow members in stand-alone Part D plans to be temporarily out of area for up to 12 months.	N/A	N/A	Subpart B	§ 423.44.
Prohibit mass SPAP reenrollments during plan year.	N/A	N/A	Subpart J	§ 423.464(e).
Non-Renewal Public Notice 60-day non-renewal beneficiary notification requirement.	Subpart K	§ 422.506	Subpart K	§ 423.507.

TABLE 2—PROVISIONS TO STRENGTHEN BENEFICIARY PROTECTIONS—Continued

Provision	Part 422		Part 423	
	Subpart	Section	Subpart	Section
Notice of Alternative Medicare Plans	Subpart K	§ 422.5(a)(2)(ii)	Subpart K	§ 423.507(2)(ii).
Timeframes and Responsibility for making Redeterminations under Part D.	N/A	N/A	Subpart M	§ 423.590.
Requirements for Requesting Organization Determinations.	Subpart M	§ 422.568	N/A	N/A.
Organization Determinations under Parts C ..	Subpart M	§ 422.566 & § 422.568	N/A	N/A.
Refine/clarify definitions related to authorized representatives.	Subpart M	§ 422.561, § 422.574 & § 422.624.	N/A	N/A.
Sponsors may be required to disclose to enrollees compliance and performance deficiencies.	Subpart C	§ 422.111(g)	Subpart C	§ 423.128(f).
Revise definition of "service area" to exclude facilities in which individuals are incarcerated.	Subpart A	§ 422.2	N/A	N/A.

1. Broker and Agent Requirements Under Parts C and D

In the preamble to our October 22, 2009 proposed rule, we recognized the important role that agents and brokers play in assisting beneficiaries with accessing and understanding plan information, making informed choices, and enrolling them in Medicare health plans. However, we also stated our continuing concern about the inherent financial incentives independent agents and brokers have when selling Medicare products. For this reason, while not proposing any specific changes in the October 2009 proposed rule, we solicited comments suggesting ideas for effectively providing Medicare health plan and drug plan information and enrollment assistance that ensures beneficiaries select the plan that best meets their needs, including whether additional changes are needed in recently established requirements relating to plan sponsors' use of agents and brokers. We specifically requested comments regarding the tools we currently use (for example, our print publications and our online resources) to assist beneficiaries with their health care decisions; whether State Health Insurance Assistance Programs (SHIPs) have the capacity to serve significantly more Medicare beneficiaries; and the effectiveness of limiting the use of independent agents and brokers by MA organizations and PDP sponsors to certain times of the year, specifically, the open enrollment period (OEP) and annual enrollment period (AEP), or to selected groups of beneficiaries.

Comment: Several commenters provided very specific suggestions for an enrollment broker demonstration. Comments we received on an enrollment broker demonstration included suggestions for guiding principles that should govern such a demonstration as well as recommendations on specific features that should be included. Some commenters expressed the concern the proposed enrollment broker demonstration would prevent plans from continuing to use plan-employed agents. Other commenters recommended that independent agents and brokers be permitted to make referrals and receive a referral fee, with the enrollment broker merely assisting with actual enrollment. One commenter suggested that the demonstration initially focus on one State that already uses a third party enrollment assistance approach for Medicaid managed care plan enrollment as a pilot. The same commenter provided a very detailed plan for how the commenter believed an enrollment broker demonstration should work. Under this suggested plan, the enrollment broker would receive applications, record oral scope of appointment confirmations, conduct third-party enrollment verification calls, and conduct general marketing activities providing high-level, standardized general information on plan options. The enrollment brokers would refer beneficiaries with detailed questions or needing more tailored plan presentations to plan-employed agents. The commenter also expressed concerns about the enrollment broker demonstration, suggesting that coordination and communication between the enrollment broker, plans, and beneficiaries would be crucial to the success of the demonstration; the ability to assure the quality of information provided to beneficiaries would be important; and enrollment broker training would also be a critical component of the program. This commenter suggested that CMS solicit additional input from MA plans on operational and information issues involved with effective communication, coordination, and training. The commenter also had concerns about the role an enrollment broker would play in the disenrollment process.

Response: We thank the commenters for this feedback and will consider it as we continue to improve our tools for assisting beneficiaries with their health care decisions and as we continue to assess the impact of our current rules regarding independent agents/brokers.

Comment: A number of commenters provided us with responses to our request for comments on the idea of limiting the use of agents and brokers to the AEP and OEP, or to selected groups of beneficiaries. The majority of these commenters expressed concerns that limiting the use of agents and brokers in this way could disadvantage age-ins, dual-eligibles, and those eligible for the low-income subsidy. They believe strongly that these limits would decrease the service and support that beneficiaries depend on to understand plan benefits and make enrollment decisions. They also indicated that CMS' current support tools are not sufficient to replace the function that agents and brokers serve.

Commenters also indicated that limiting the use of agents and brokers to certain times of the year is not feasible given that plans use agents and brokers throughout the year and that current CMS oversight of agents and brokers is sufficient. Along these same lines, one commenter supported the view set forth in the proposed rule preamble that sufficient time has yet not passed to fully evaluate the impact of the new marketing requirements codified by CMS following enactment of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). Several commenters suggested that limiting the use of agents and brokers to the AEP

and OEP or to select beneficiary groups would, in fact, result in increases of the marketing abuses we are trying to eliminate and would force good agents out of business, leaving behind agents only interested in short-term gains.

Several commenters provided alternatives to limiting the use of agents and brokers to the OEP and AEP or with selected groups. The suggested alternatives can be grouped into three categories—(1) Recommendations to strengthen current rules, processes, and oversight of agents and brokers; (2) Recommendations to require better collaboration among stakeholders; and (3) Recommendations that may require regulatory changes.

Recommendations for strengthening current rules, processes, and oversight of agents and brokers included—

- Strengthening agent and broker education/training;
- Creating a Medicare license and industry designation that all agents must have in order to sell Medicare products; standardizing agent compensation by geographic area;
- Creating and requiring the use of a "replacement/suitability" form that agents would use when moving a beneficiary to a new plan;
- Strengthening CMS surveillance efforts;
- Stabilizing CMS' guidance in this area by limiting the frequency of future policy changes; and
- Tightening our current rules regarding the use of independent agents and brokers.

Commenters' recommendations for requiring better collaboration with stakeholders included—

- Working with plans, advocates, and associations to develop alternatives;
- Creating a list of agents/brokers prohibited from selling Medicare plans that would be shared with all stakeholders;
- Providing more support to and coordination with the States; and
- Periodically publishing best practices.

Additional recommendations that may require regulatory or statutory changes included—

- Requiring plans to share information on agent misconduct and terminations;
- Creating uniform compensation rates for MA plans and PDPs;
- Requiring agents and brokers to register with the National Insurance Producer Registry (NIPR);
- Precluding agents from selling MA plans or PDPs or selling to LIS beneficiaries;
- Allowing a one-time "new enrollment payment"; and
- Renewal compensation for all subsequent moves (regardless of plan type change).

Commenters also recommended—

- Rescinding "lock-in";
- Limiting agent/broker involvement in marketing, but not limiting their involvement to certain periods during the year;
- Shortening the AEP; and
- Eliminating the additional three month OEP for MA plans at the beginning of the year and applying the enrollment period uniformly to MA plans and PDPs.

A number of commenters also provided recommendations with respect to our question about whether and how to expand the role of SHIPs. Almost all of these commenters expressed concerns about SHIP funding, capacity, and capability. They expressed concern about—

- Inadequate funding;
- The fact that SHIPs' reliance on volunteers limits their ability to fully replace the role of independent agents and brokers;
- The lack of capacity of existing SHIP networks to service entire States; and
- The lack of knowledge by SHIP volunteers about plans in every local market within a State.

Several commenters suggested that by limiting plan options and standardizing benefits, SHIP counselors would be better able to handle questions from beneficiaries about plan differences. Other commenters suggested that by strengthening SHIP networks, their capacity could also be expanded.

Response: While we did not propose any changes to our regulations governing plans' use of independent agents and brokers to sell Medicare plans in our October 22, 2009 proposed rule, we appreciate the thoughtful ideas and recommendations commenters offered. We recognize the important role agents and brokers play in assisting beneficiaries with accessing and understanding plan information, making informed choices, and enrolling them in Medicare health plans. However, we still have concerns about the inherent financial incentives independent agents and broker have when selling Medicare products. We recently implemented regulations (§ 422.2274 and § 423.2274) intended to reduce agent and broker incentives to enroll beneficiaries in plans inappropriately. We continue to agree with the commenter that suggested it is still too soon at this time to fully evaluate whether these new rules have achieved MIPPA's goal of creating incentives for agents and brokers to assist beneficiaries with selecting plans based on their health care needs. As we continue to monitor and evaluate our marketing rules and oversight activities, we will evaluate the need for any future notice and comment rule making.

2. Beneficiary Communications Materials Under Parts C and D (§ 422.2260, § 422.2262, § 423.2260, and § 423.2262)

In the October 22, 2009 proposed rule, in implementing sections 1851(h) and 1860D–1(b)(1)(vi) of the Act, we proposed narrowing the definition of the term "marketing materials" at § 422.2260 and § 423.2260 to exclude a new proposed category of "current enrollee communications materials," which we proposed defining to include either situational materials or beneficiary specific customized communications. We proposed this change in order to streamline the review and approval of beneficiary communication notices to current members.

Specifically, we proposed revising § 422.2260 and § 423.2260 to exclude from the definition of marketing materials communications targeted to current enrollees that are customized or limited to a subset of enrollees or a specific situation, or that involve claims processing or other operational issues. In the preamble to the proposed rule, we cited the following examples of the types of materials that would be excluded from our proposed revised definition of "marketing materials": Part D explanations of benefits (EOBs); notifications about claims processing changes or errors; and other one-time or situational, beneficiary specific letters to current enrollees.

In addition, we proposed to revise § 422.2262 and § 423.2262 to specify that, while the current enrollee communications excepted from the definition of marketing materials would not be subject to the statutory requirement that they be submitted to CMS for review and approval prior to use, we retained the right to review such materials, and their use could be disapproved (or disapproved subject to modification) by CMS.

In this final rule, we adopt these provisions with some modification. For reasons discussed below, we have in this final rule revised paragraph § 422.2260(5) (vii) to retain materials about membership rules and procedures, which we are calling "membership activities" (for example, materials on rules involving nonpayment of premiums, confirmation of enrollment or disenrollment, or non-claim specific notification materials) in

the definition of marketing materials subject to CMS prior approval. In addition, we have added a new paragraph § 422.2260(6) to expressly exclude from the definition of marketing materials ad hoc customized or situational enrollee communications.

Comment: A number of commenters supported our proposal to modify the definition of the term "marketing materials" to distinguish materials used to market to new potential enrollees from current enrollee communication materials. However, these commenters raised an ambiguity in our proposed revision to the definition of marketing materials at § 422.2260(5)(vii) and § 423.2260(5)(vii). These commenters noted that, as written, the revised paragraph (5)(vii) merely defines "current enrollee communications materials" without making it clear that such materials are excluded from the revised definition of marketing materials.

Response: We agree that, as written, the proposed revisions to the definition of marketing materials did not make it sufficiently clear that we were excluding customized or situational current enrollee communications from the definition of marketing materials, and that certain materials directed at current members should still be included in the definition. Accordingly, as noted above, in response to these comments, we have revised paragraph § 422.2260(5) (vii) to retain materials about "membership activities" (such as, materials on rules involving non-payment of premiums, confirmation of enrollment or disenrollment, or non-claim specific notification materials) in the definition of marketing materials. In addition, we have added a new paragraph § 422.2260(6) to specifically exclude from the definition of marketing ad hoc customized or situational enrollee communications from the definition of marketing materials.

Comment: Several commenters suggested that, in the absence of a clear definition of claims processing or operational issues, we should define the terms "situational" and "beneficiary specific" narrowly. Several commenters requested that we specify those situations where beneficiary communications would be considered current enrollee communications materials and be excluded from the proposed revision to the definition of marketing materials. These commenters also suggested that we allow operational letters that pertain to enrollment, disenrollment and appeals issues to be excluded from the definition of marketing materials. Some commenters suggested that we specify that any materials excluded from the definition of marketing materials are not subject to the Medicare Marketing Guidelines' requirements that plans include certain plan mailing statements on envelopes regarding the contents of the materials enclosed within. In addition, these commenters requested additional guidance regarding how we intend to operationalize the process for review and approval of situational enrollee communications that would, if the proposed provisions were finalized as proposed, be outside CMS's current marketing review and approval processes.

Response: We disagree that it is necessary, and do not believe it would be appropriate, to attempt to specify in the regulations text an exhaustive listing of enrollee communications that are not considered marketing materials per our revised definition of the term "marketing." Our intent is to define these exclusions from the definition of marketing materials narrowly to include communications that are either customized or intended for a subset of current enrollees and which deal with specific situations or cover member-specific claims processing or other operational issues. Our intent was not to exclude from the definition of marketing materials communications that are used more broadly or that convey information about plan benefit structures. As noted previously, in response to earlier comments and this comment, we have revised our proposed definition of current enrollee communications materials in the final rule to add a new § 422.2260(6) to better describe our intent in the proposed rule, and now refer to these materials as "ad hoc enrollee communications materials." The final definition encompasses materials that are targeted to current enrollees; are customized or limited to a subset of enrollees; do not include information about the plan's benefit structure; and apply to a specific situation or cover member-specific claims processing or other operational issues. We envision that ad hoc enrollee communications materials could include the following types of materials;

- Communications about a shortage of formulary drugs due to a manufacturer recall letter.
- Letters to communicate that a beneficiary is receiving a refund or is being billed for underpayments.
- Letters describing member-specific claims processing issues.

Although we mentioned the Part D EOB in the preamble to the October 2009 proposed rule as an example of a customized current enrollee communications material in the preamble to our proposed rule, in light of the comments we received on the scope of the exemption from the marketing definition, we no longer believe that example was appropriate, particularly given the importance of our review of EOB templates. Thus, under this final rule, we will continue to require submission and approval of EOB templates through the CMS marketing review and approval process as part of the new definition of marketing materials, and distinguish this general, regularly issued notice from documents pertaining to the processing of an individual claim. We intend to provide further guidance on the types of marketing materials that would be considered ad hoc enrollee communications materials, as well as any alternate processes for their review and approval, in the Medicare Marketing Guidelines.

Comment: One commenter suggested that all prospective and current member materials be submitted to CMS as file and use materials so that there is a centralized and consistent place for beneficiary communication to be housed within CMS. This commenter suggested, as an alternative, that the plan develop internal processes to monitor materials for consistency with CMS requirements rather than filing those materials with CMS. We note that MA organizations and PDP sponsors already have the responsibility to ensure, from a monitoring and compliance perspective, that their marketing materials are complete, accurate, and consistent with marketing rules. A few commenters suggested that we require plans to submit a report on beneficiary communications and audit these communications periodically to ensure that plans are not engaging in inappropriate beneficiary marketing practices, and that we retain oversight responsibilities for these materials.

Response: As stated previously, we have revised the definition of "customized current enrollee communications materials" in this final rule such that it covers a narrow class of ad hoc, customized beneficiary communications materials. We will provide more information about alternative review and approval processes for customized current enrollee communications materials in the Medicare Marketing Guidelines. We note that we periodically audit marketing materials. We will also ensure that ad hoc enrollee communications materials meet all relevant requirements and are reviewed, approved, and used appropriately.

Comment: One commenter recommended that we extend our

current waivers of marketing review and approval requirements for employer group waiver plan marketing materials to employer group waiver plan enrollment materials. Some other commenters requested that our current regulations concerning review and approval of marketing materials be expanded to apply to third party entities, as these commenters believe third party entities tend to send inaccurate or incorrect information to beneficiaries.

Response: These comments address our exercise of employer group waiver authority, and accordingly are outside the scope of this rulemaking, and not addressed in this final rule.

3. Required Use of Standardized Model Materials Under Parts C and D (§ 422.2262 and § 423.2262)

In order to reduce variability of marketing materials and to ensure documents are more accurate and understandable to beneficiaries, we proposed, under the authority of sections 1851(h) and 1860D–1(b)(1)(vi) of the Act, to move toward greater standardization of the information provided in plan marketing materials. Specifically, we proposed revising § 422.2262 and § 423.2262 to require that MAOs and PDP sponsors use standardized marketing material language and format, without modification, in every instance in which we provide standardized language and formatting. We noted that we will provide MAOs and PDP sponsors with standardized marketing materials through the annual Call Letter, Health Plan Management System (HPMS) memoranda, or other guidance documents. We believe this change will ensure beneficiaries receive more accurate and comparable information to make informed decisions about their health care options, as well as lead to increased efficiencies and greater consistency in our marketing material review protocols and processes. In this final rule, we adopt these provisions as proposed. For the upcoming 2011 plan year, we plan to update some of our current standardized documents later this spring through guidance, but we are unlikely to standardize new types of documents. For 2012 and future years, we will consider and explore standardizing additional forms and materials.

Comment: Several commenters strongly supported our proposed rule to require MAOs and PDP sponsors to use standardized language and formats in marketing materials in instances where we provide them. Other commenters supported this proposal but urged CMS to use consumer research and testing to determine the terms and features consumers want and the best ways to disclose that information to assist beneficiaries with making informed decisions about their health care options.

Several commenters suggested we collaborate with the industry, advocates, and State agencies to develop standardized models, or convene a workgroup to explore ways of improving the wording of model materials. In addition, some of these commenters suggested, as an alternative, that we solicit document examples and suggestions from plans regarding the creation of standardized materials and establish from these examples best practices for model language, content, and format.

Response: Given the support for our proposed requirement, we are adopting it as set forth in the proposed rule. We agree with the commenters' recommendations that CMS should research and consumer test standardized model marketing materials, when practical, as well as engage in dialogue with the industry, advocates and State agencies as part of our efforts to standardize more marketing model materials. As we did when we reissued the standardized annual notice of change/evidence of coverage (ANOC/EOC) models for contract year 2010, we intend to continue to consumer test our marketing materials, as practical, to ensure that they accurately describe plan benefits and assist beneficiaries with making the best health care decisions for their particular needs. As part of the process of revising the standardizing ANOC/EOC models, we also conducted listening sessions with the industry to solicit input on improving standardized documents. We received a great deal of useful information as a result of those sessions, which we believe was critical to improving the consumer friendliness of those models. In addition, we will continue to provide opportunities for external stakeholders to comment on draft versions of model documents prior to finalizing them.

Comment: Many commenters requested clarification on whether, in developing standardized model marketing materials, we will continue to allow plans the flexibility to modify model documents to accurately convey specific or unique plan information. Many commenters argued that our existing models do not adequately capture the range of variation in plan types and benefits and that standardizing additional models could impede effective communications with members and potentially lead to beneficiary confusion.

These commenters also expressed concern that without such flexibility and space for free form text, plans will be unable to adequately capture the nuances and unique features of the various plan types. Commenters specifically indicated that it was imperative for us to allow flexibility within standardized models for special needs plans (SNPs), cost plans, point-of-service (POS) plans and employer group plans. A few commenters requested the option to waive standardized language for SNPs, or to develop separate standardized documents for these plans if we do not provide sufficient flexibility within standardized models. A commenter suggested that CMS develop documents specifically for low-income subsidy (LIS) eligible beneficiaries and that we provide documents translated into non-English languages, as well as documents in Braille.

Response: We agree that standardized materials should be sufficiently tailored to the intended recipients to relay plan information as clearly as possible. Accordingly, we intend to continue to allow plans flexibility to accurately convey specific plan information. As with the current ANOC/EOC standardized models, we will permit plans to capture the unique features and nuances of their various plan types and plan benefits through variable text, as appropriate. Our requirement to use standardized models when we make them available does not change this practice; we are simply moving toward standardizing more marketing documents.

We will consider how best to provide information to LIS-eligible individuals as we standardize models. With regard to providing translated materials, our Medicare Marketing Guidelines currently require plans to provide translated and alternative format documents to beneficiaries. Specifically, plans are required to translate materials in service areas where at least ten percent of the population speaks a non-English language as its primary language. In addition, plans must make basic enrollee information available to individuals with disabilities (for example, visually impaired beneficiaries) and must ensure that information about their benefits is accessible and appropriate for Medicare beneficiaries who have disabilities.

To ensure that beneficiaries understand materials translated into a non-English language, we require that plans translating their marketing materials into other languages use

standardized language. For example, plans translating materials into Spanish or Cantonese should use a standard Spanish or Cantonese language resource (such as, "Real Academia Española" [Royal Spanish Academy], the most widely-recognized institution responsible for regulating the Spanish language).

Comment: Several commenters suggested we clearly identify the documents we intend to standardize, while two commenters suggested we limit the documents we intend to standardize. One commenter wanted clarification on what "when specified by CMS" means. In addition, many commenters urged us to release standardized documents to plans early in the year to allow plans sufficient time to disseminate plan information to beneficiaries.

Response: In addition to the ANOC/EOC, we indicated in the 2009 Call Letter that we intended to standardize the Part D explanation of benefits (EOB), pharmacy directory, provider directory, plan formulary, and transition notice. We are currently in the process of consumer testing and revising some of these models to include plain language.

With regard to the comment about what "when specified by CMS" means, as with the ANOC/EOC, CMS will specify which documents must be used without modification through guidance documents such as the annual Call Letter or HPMS memoranda. Finally, we are committed to releasing final standardized models as early as possible in the year in order to permit plans sufficient time to prepare and disseminate those documents to beneficiaries for the following contract year.

Comment: A commenter suggested that, as an alternative to our proposed requirement that plans use standardized documents as specified by CMS, we should allow for review of requested changes to standardized language similar to our review of hard copy change requests for the Summary of Benefits.

Response: We disagree with the commenter's suggestion. As stated elsewhere in this preamble, we believe standardization leads to improvements in accuracy, comparability, and understandability, as well as increased efficiencies and greater consistency in our marketing material review protocols and processes. Permitting hard copy changes would undermine our efforts to reduce variability in marketing materials. In addition, we believe that we can address the commenter's concerns by permitting plans to use variable text fields throughout standardized documents so that they accurately reflect unique plan information.

Comment: One commenter understood and appreciated the need to standardize models but was concerned that requiring a standardized format limits options, may expand the length of current model documents, and could potentially drive up costs of printed materials.

Response: We believe the benefits of increased standardization outweigh the commenter's concerns. The move toward standardizing more documents will reduce the variability and errors in marketing materials, and will ensure that standardized documents provide more accurate, understandable, and comparable information across plans, thereby helping beneficiaries to make the best possible health care decisions for their particular needs.

4. Involuntary Disenrollment for Failure To Pay Plan Premiums Under Parts C and D (§ 422.74 and § 423.44)

We proposed to amend the regulations at § 422.74(d)(1) and § 423.44(d)(1) regarding disenrollment for nonpayment of premiums to require a minimum grace period of 2 months before any involuntary disenrollment occurs, in order to provide adequate time for organizations to respond to instances in which individuals fail to pay their premiums, and for affected enrollees to take steps to remedy the situation and avoid disenrollment. Furthermore, we proposed to codify existing subregulatory guidance regarding the beginning of the grace period for Part D. In this final rule, we adopt these provisions as proposed.

Comment: Several commenters supported our proposed regulatory revision to increase the length of the minimum grace period and further requested that CMS exempt beneficiaries from having to pay plan premiums if the organization fails to request payment of the premiums in a timely manner. Another commenter supported this change and further recommended that CMS also require plans to provide for exceptions in cases of financial hardship or other special circumstances.

Response: We appreciate the support for this proposal and are adopting it as proposed. Although we do not believe that it is appropriate to exempt beneficiaries from paying premiums for periods of coverage based on late notification, we strongly encourage plans to work with such individuals to implement payment plans where financial hardship could be involved. Also, we note that a change in policy with respect to an individual's eventual obligation to pay his or her premiums is not within the scope of this rulemaking.

Comment: Another commenter who supported the proposed regulatory revision further requested that CMS develop a method for beneficiaries to engage CMS in resolving premium payment disputes, such as whether individuals who qualify for the Part D low income subsidy or are enrolled in a state pharmaceutical assistance program (SPAP) owe plan premiums, in addition to disputes regarding individuals who experience problems with premium withhold from their Social Security benefits.

Response: Although there is no formal CMS administrative process for dealing with these issues, we do play an important role in resolving premium payment disputes through our existing casework procedures. CMS caseworkers often deal directly with individuals who have their premiums withheld from their SSA benefit payment, and we also work with plans to resolve both premium issues involving individuals or groups of enrollees, such as the LIS population in a plan. We also facilitate discussions between plans and SPAPs about such payment issues. We will continue to look at ways to better address these issues.

Comment: One commenter supported the change and recommended that the 2-month grace period begin the first of the month for which the enrollee is delinquent and not from the point of notification.

Response: Current regulations state that the grace period begins the first day of the month for which the premium is unpaid. Subregulatory guidance (§ 50.3.1 of Chapter 2 of the Medicare Managed Care Manual and § 40.3.1 of Chapter 3 of the Medicare Prescription Drug Benefit Manual) further clarifies that the premium is "unpaid" only after the member is notified of, or billed for, the actual premium amount due. We clarified that the grace period not begin prior to the member being notified of the delinquency was established to ensure that members have the full grace period in which to resolve the premium payment issue. We agree with the commenter that the grace period should begin the first day of the month for which the enrollee is delinquent, but only if the organization has previously requested payment of the premium and has provided the member an opportunity to pay. Accordingly, in this final rule, we are revising § 422.74(d)(1) and § 423.33(d)(1) to include the requirement that the grace period begin on the first day of the month for which the premium is unpaid or the first day

of the month following the date on which premium payment is requested, whichever is later.

Comment: Several commenters representing plans opposed the proposed change. One commenter contended that the change would not result in a reduction in disenrollments and requested that CMS instead maintain the minimum 1-month grace period and allow organizations to offer a longer grace period at their discretion. Another commenter cited the potential costs that may be incurred by organizations to make systems enhancements and to modify current administrative processes, policies, and procedures. Another commenter feared lengthening the minimum grace period from 1 month to 2 months would potentially expose the organization to increased financial liability.

Response: We believe that providing additional time for individuals to pay their premiums will assist a great number of individuals in meeting their financial obligations and avoid disenrollment. As discussed in the preamble to the October 22, 2009 proposed rule (74 FR 54657), under current rules, individuals may have less than a month a resolve payment delinquencies. Thus, we believe this proposal will provide a valuable beneficiary protection, particularly in view of the significant potential gap in coverage that could result from such a disenrollment, given that in many cases an individual may not be able to re-enroll until the following annual election period. It will also help to reduce the number of situations where individuals pay their premiums shortly after their disenrollments take effect but the plan has already submitted a disenrollment transaction.

Many organizations currently offer a grace period in excess of the one month minimum that is currently required. As such, the impact of the proposed change is limited to those organizations that have chosen to implement the minimum requirement. For these organizations, we believe any administrative costs that may result from changing from a one month to a two month grace period are fully justified by the benefits to be gained by both the organization and its members by providing a more reasonable time frame for all parties to resolve premium payment issues and avoid disenrollment. With respect to the financial liability issue, we also note that the proposed change would not affect an organization's ability to pursue collection of past due premium payments from current and former members.

Comment: One commenter requests that CMS change the requirement for issuing disenrollment notices, stating that a timeliness standard of 5 or 7 days would be more manageable than the current three business day requirement.

Response: The 3-day requirement referred to by the commenter is not for provision of the disenrollment notice; rather, it is the deadline for organizations to submit the ensuing disenrollment transaction to CMS. This timeframe was established to provide adequate time for data to be transmitted to CMS to ensure the timely processing of any necessary auto-enrollments for those individuals who receive the Part D low income subsidy. Therefore, we are not adopting this suggestion.

Comment: One commenter requested that CMS clarify that the grace period applies only to members for whom CMS makes payment to the organization.

Response: Our interpretation of this comment was that it was intended to address situations where a plan's enrollment records may not immediately match CMS records, and thus there is some question as to whether an individual is enrolled in the plan. Given that the plan has determined the beneficiary eligible for the plan, has notified the beneficiary of the enrollment, has submitted the enrollment to CMS and the discrepancy in the enrollment record is not caused by any action of the beneficiary but instead is an issue to be resolved between CMS and the plan, we believe it would be appropriate for the same grace period policies to apply to such a beneficiary as to a confirmed plan enrollee.

5. Maximum Allowable Out-of-Pocket Cost Amount for Medicare Parts A and B Services (§ 422.100)

In our October 22, 2009 proposed rule, under the authority of sections 1852(b)(1)(A), 1856(b)(1), and 1857(e)(1) of the Act, we proposed to amend § 422.100(f)(3) by adding a new paragraph (f)(4) to specify that all local MA plans must establish a maximum out-of-pocket (MOOP) liability amount inclusive of all Medicare Parts A and B services, the amount of which would be set annually by CMS. We also noted that, under our proposal to require that a MOOP amount be established for local MA plans, the MOOP limit for local preferred provider organization (PPO) plans would be inclusive of all in-network and out-of-network beneficiary cost sharing. As discussed in the proposed rule, we believe that requiring the inclusion of such a limit in plan design is necessary in order not to discourage enrollment by individuals who utilize higher than average levels of health care services (that is, in order for a plan not to be discriminatory in violation of section 1852(b)(1) of the Act).

In the preamble to our October 22, 2009 proposed rule, we generally described the process we have established to comprehensively review the proposed cost sharing of each plan benefit package and determine if MA plans' cost sharing designs—both in terms of aggregate expected out-of-pocket cost-sharing and particular cost-sharing amounts for certain health care services—discriminate against those beneficiaries with higher than average health care needs. We noted in the preamble to the proposed rule that we have annually established, through subregulatory guidance, a voluntary maximum out-of-pocket limit on Parts A and B services that, if adopted by an MA plan, would allow the plan greater cost sharing flexibility than it would otherwise receive absent the voluntary MOOP. We also noted that we have identified certain health care services that beneficiaries with higher than average health care needs are likely to need (for example, in-patient hospital, dialysis, skilled nursing facility (SNF), mental health services, Part B drugs and home health care) and described our process for conducting outlier analyses by which we consider the distribution of cost sharing levels submitted by MA organizations to identify levels in the upper end of the range for the purpose of reviewing whether cost sharing levels for submitted benefit designs are discriminatory. We believe these efforts have resulted in reduced discriminatory cost sharing and improved the transparency of plan design. For example, in contract year 2010, about 39.2 percent of all non-employer MA plans representing about 3 million MA enrollees adopted the voluntary MOOP limit on beneficiary cost sharing.

In the preamble to the proposed rule, we stated our intent to use a similar method for establishing a mandatory MOOP amount for Parts A and Part B services for all local MA plans as we used to establish the voluntary MOOP limit for contract year 2010. Therefore, the MOOP would be set by CMS at a certain percentile of fee-for-service (FFS) beneficiary out-of-pocket spending. We also noted that we set the voluntary MOOP limit at the 85th percentile of FFS spending for contract year 2010 but could set the limit at a different percentile or through a modified approach as determined by us in future years. We also proposed to continue to furnish information to MA organizations on our methodology and

the amounts for acceptable MOOP amounts on a timely basis through the annual Call Letter or Health Plan Management System (HPMS) memoranda. We solicited comments on this approach.

After considering the comments we received on this issue, we are finalizing § 422.100(f)(4) largely as proposed but, as discussed in greater detail below, are adding a new paragraph (f)(5) to address concerns raised by commenters about applying our proposed MOOP amount to PPO out-of-network services. Specifically, we are specifying in paragraph (f)(5) that the mandatory MOOP amount under paragraph (f)(4) would only apply to PPO network services, while a higher catastrophic maximum would apply to both in- and out-of-network liability. In setting a higher catastrophic maximum, we will take into consideration standard practices in commercial benefit design as well as protecting beneficiaries who use out-of-network providers.

Comment: Several commenters noted that a MOOP amount protects beneficiaries from catastrophic medical costs and supported our proposal. Another commenter noted that it was important that all Parts A and B services be included in the MOOP amount. Another commenter supported our proposal on the grounds that it will bring an element of standardization to the MA program.

A number of Medicare Advantage organizations (MAOs) expressed concern that Original Medicare does not have a MOOP and argued that it would therefore not be equitable to require one for MA plans. These commenters were also concerned that a mandatory MOOP would increase plans' costs and result in increased premiums for beneficiaries, particularly if the dollar limit is too low. Some commenters were also concerned that a mandatory MOOP amount would result in adverse selection, with "sicker" Medicare beneficiaries dropping out of Original Medicare and selecting MA plans. One commenter advocated that we continue our current process of allowing voluntary MOOP limits with a more stringent review for plans that do not adopt the voluntary MOOP limit.

Response: As discussed in the proposed rule, we believe that requiring the inclusion of a MOOP limit is an important step to ensure that individuals who utilize higher than average levels of health care services are not discouraged from enrolling in MA plans that do not have such a limit in place. Given that regional PPO plans are required by statute to have such a liability limit in place, and a substantial number of local plans have adopted one voluntarily, we were concerned that high cost enrollees would be discouraged from enrolling in MA plans that did not include a MOOP limit. We believe that requiring a mandatory MOOP limit does not unduly disadvantage MA plans relative to original Medicare. We note that beneficiaries in original Medicare have the option of selecting between two Medigap policies, K and L, that afford them an annual cap on out-of-pocket expenses (currently at $4,600). In addition, enrollees in the original Medicare program can select among other Medigap polices that limit their cost-sharing liability for Parts A and B services. As noted previously, a significant number of MA plans have already successfully designed benefit packages that include MOOP limits and have continued to effectively compete in the marketplace.

We agree, however, that retaining a voluntary MOOP amount that is lower than the mandatory maximum we have proposed would preserve current incentives for further reducing enrollee out-of pocket liability. Therefore, in addition to establishing a mandatory MOOP amount, we also plan to continue our current policy of offering MA plans the option of establishing a lower voluntary MOOP amount in exchange for more flexibility in cost-sharing thresholds than available for plans that adopt the higher mandatory MOOP for contract year 2011. Under this approach, the voluntary MOOP amount would be set at an amount lower than the mandatory MOOP, and would therefore not disadvantage those MA plans that have adopted the voluntary MOOP in previous contract years. We would in effect establish two sets of Parts A and B service cost-sharing thresholds under this approach, one applicable to plans selecting the higher, mandatory MOOP amount, and the other applicable to those choosing the lower, voluntary MOOP. To incent plans to adopt the lower MOOP amount, we would allow plans greater cost sharing flexibility for Parts A and B services if they adopt the lower, voluntary MOOP. We plan to articulate this voluntary MOOP policy through subregulatory guidance such as the annual Call Letter or a similar document.

Comment: Several commenters were concerned that a mandatory MOOP amount should not be set so high as to discourage low income individuals from joining MA plans. Other commenters recommended that we ensure that the MOOP amount is low enough to benefit low income individuals. One commenter also expressed concern that a MOOP limit may disadvantage smaller local plans compared to larger plans, potentially resulting in those smaller plans being priced out of the MA market. One commenter recommended that we use a fixed benchmark for the MOOP amount, rather than the 85th percentile of expected FFS spending cited in the preamble to our proposed rule, as the cut-off established for contract year 2010, which they believe would still be too high an amount for low income enrollees. Another commenter supported a cut-off at a higher percentile of FFS to ensure that plans do not have to increase their premiums or, alternatively, that the MOOP amount be set no lower than $7,500 in order not to affect the sustainability of the MA program. Another commenter supported a mandatory MOOP amount, but argued that plans should be allowed to establish their own MOOP amounts.

Response: In establishing the mandatory MOOP amount, we will be cognizant of the balance we must strike between affording beneficiaries reasonable protection from high out-of-pocket expenses and our desire that the MA program remain viable for health plans and beneficiaries. We will carefully assess the impacts of the MOOPs we establish, annually adjusting the limit as necessary based on the previous year's experience, as well as other factors as appropriate, to ensure that this balance is maintained. As noted previously, we believe the approach of establishing a higher, mandatory MOOP amount and a lower, voluntary MOOP amount will allow us to better strike this balance.

Comment: A couple of commenters did not believe their systems would support tracking of out-of-pocket expenses relative to a mandatory MOOP limit, and that the imposition of one would therefore introduce a significant new administrative burden. One commenter argued that we should furnish additional funding to MA plans due to the costs of implementing a mandatory MOOP amount.

Response: We recognize that those plans that have not already voluntarily introduced a MOOP may need to invest resources in ensuring their systems are designed to implement this requirement. We believe, however, these costs need to be weighed against the benefits of ensuring that MA plan designs without a MOOP limit do not discourage enrollment by high cost individuals.

Comment: Several commenters requested clarification regarding the applicability of our proposed

requirement to establish a mandatory MOOP amount to MA plans.

Response: Because a statutory MOOP requirement is already in place with respect to regional PPO plans, we proposed applying the new mandatory MOOP requirement only to local MA plans in our proposed rule. While we now believe regional PPOs should be subject to the same requirements with respect to a MOOP as local MA plans, since our proposed rule did not give MA organizations offering regional PPOs an opportunity to comment on such a proposal, we will need to address this discrepancy in future notice-and-comment rulemaking. However, we note that regional PPOs will have the option of implementing any mandatory or voluntary MOOP amounts we establish for local MA plans.

Comment: A number of commenters recommended that we announce the mandatory MOOP amount, and the methodology we use to set it, as early as possible in the year preceding the contract year in which we will apply that amount (for example, in the Advance Notice of Methodological Changes). Another commenter recommended that this information be provided in our annual Call Letter.

Response: As specified in the preamble to the proposed rule, we intend to continue to furnish information to MA organizations on our methodology and the amounts for acceptable out-of-pocket caps on a timely basis through the annual Call Letter or a similar guidance docunent.

Comment: Two commenters were concerned that the mandatory MOOP would apply to all in- and out-of-network PPO services, and contended that such an arrangement could lead to a reduction in the number of PPOs offered given the potential increase in plan costs that would result. One of these commenters believed including cost-sharing applicable to out-of-network plan covered services will undermine incentives to use preferred providers that are central to the design of a PPO.

Response: As stated in the proposed rule, we believe that some protection against out-of-pocket liability should apply to enrollee cost-sharing for both in- and out-of-network services covered by PPOs. However, we agree with the concerns of the commenter highlighting the effect a single MOOP applying to all services would have on incentives to use preferred providers. In addition, for reasons of beneficiary transparency and consistency, we believe that local PPOs should be subject to the same type of MOOP requirements as regional PPOs, which have a different MOOP for out-of-network cost-sharing than that which applies to use of PPO in-network services. Therefore, we are revising § 422.100 by adding a new paragraph (5) that specifies that, in addition to the MOOP for Medicare Parts A and B services that all local MA plans will be subject to—which would apply only to the use of network providers—all local PPO plans must also establish a total catastrophic limit on beneficiary out-of-pocket expenditures for both in-network and out-of-network Parts A and B services consistent with the requirements applicable to regional PPOs at § 422.101(d)(3). This total catastrophic limit will be no greater than an annual limit set by CMS. In addition, we will also offer local PPO plans the option of implementing any voluntary MOOP amount CMS establishes for local MA plans.

Comment: One commenter requested clarification regarding whether all Medicare Parts A and B services would be included in the MOOP amount.

Response: As noted in the preamble to our proposed rule, cost-sharing for all Parts A and B services would be included in the MOOP amount. Such cost-sharing includes any plan deductibles applicable to Parts A and B services, but excludes monthly plan premiums.

Comment: A commenter argued that since States pay cost sharing for members of dual-eligible special needs plans (SNPs), there is no need to apply a MOOP to these plans. Another commenter contended that dual-eligible SNPs cannot charge their enrollees a premium as a practical matter, which would further disadvantage this plan type if they were required to implement our MOOP limit. Another commenter recommended that we provide guidance on how the MOOP will apply to SNP enrollees, particularly those in dual-eligible SNPs. This commenter was specifically interested in guidance regarding what States' obligation would be with respect to premiums and cost sharing, as well as the actual out-of-pocket liability for a dual-eligible SNP enrollee. Additionally, this commenter was concerned that dual-eligibles may experience an unnecessary reduction in supplemental benefits if our final requirement does not clearly distinguish what these individuals actually pay as out-of-pocket costs versus what Medicaid should pay.

Response: We disagree with comments recommending that SNPs be exempted from MOOP requirements. Dual-eligible individuals entitled to have their cost sharing paid by the State and enrolled in a SNP may experience midyear changes in their Medicaid eligibility. In those cases, these individuals may be required to directly pay the plan cost sharing that otherwise would be the obligation of the State. Accordingly, we will not exempt SNPs from the requirement that they implement a MOOP amount as established annually by CMS.

Comment: Another commenter recommended exempting employer plans from our MOOP requirements because such a benefit design would be inconsistent with the benefits employer plans currently offer.

Response: We disagree with this commenter that such a regulatory exception is warranted. The same considerations involving discrimination against high cost enrollees could also apply in the employer plan context, particularly if the employer allows more than one plan option. In exceptional cases in which CMS agrees that a waiver of this rule would be in the interest of Medicare beneficiaries served by an employer group, CMS could consider waiving the regulations through the employer group waiver authority under section 1857(i) of the Act. Employer plans will therefore be subject to the regulatory MOOP requirement finalized in § 422.100(f)(4) that applies to all MA plans.

6. Maximum Allowable Cost Sharing Amount for Medicare Parts A and B Services and Prescription Drugs (§ 422.100, and § 423.104)

In our October 22, 2009 proposed rule, we proposed to amend our regulations on the general requirements related to Medicare Advantage (MA) benefits and qualified prescription drug coverage to expressly authorize us to establish cost sharing thresholds for individual services below which cost sharing will be considered non-discriminatory.

For Part C plans, we proposed to annually review bid data to determine specific cost sharing levels for Medicare A and B services below which we would not consider there to be a discriminatory effect, and therefore may be approved in an MA benefit package. Specifically, we proposed amending § 422.100 by adding a new paragraph (f)(5) to specify that cost sharing for Medicare A and B services may not exceed levels annually determined by us to be discriminatory.

Similarly, for Part D plans, we proposed to annually review bid data to determine acceptable cost sharing tiers for benefit packages offering non-defined standard prescription drug coverage. To this end, we proposed revising § 423.104(d)(2) by adding a new paragraph (iii) to specify that tiered cost

sharing for non-defined standard benefit designs may not exceed levels annually determined by us to be discriminatory.

We also explained in the preamble to the proposed rule that we would furnish information to MA organizations and Part D sponsors on our methodology and the cost sharing thresholds for the following contract year based on the prior year's bids, and on a timely basis either through the annual Call Letter or Health Plan Management System (HPMS) memoranda. We solicited comments on this approach, including the extent to which we provided sufficient clarity on how we would determine whether cost-sharing levels are discriminatory.

After considering comments we received on this issue, we are adopting proposed § 422.100(f)(5) (which, in light of the new subparagraph (f)(5) discussed above, is recodified as subparagraph (f)(6)) and § 423.104(d)(2) with minor revisions made in response to comments discussed below that are intended to clarify that limits will only be established for those Parts A and B services specified by CMS. We note that section 3202 of the Patient Protection and Affordable Care Act (PPACA) (Pub. L. 111–148) "Benefit Protection and Simplification" will apply to MA plans offered in 2011. Section 3202 of PPACA specifies that, unless a specified exception applies, the cost sharing charged by MA plans for chemotherapy administration services, renal dialysis services, and skilled nursing care may not exceed the cost sharing for those services under Parts A and B. Where these new limits apply, they will constitute an absolute limit on cost-sharing for the service in question by operation of statute, and we will not set limits under this final rule. After the publication of this rule, we will issue clarifying guidance concerning section 3202 and other provisions of PPACA that impact this regulation.

Comment: A number of commenters supported our proposed requirement to specify that cost sharing for Medicare A and B services may not exceed levels annually determined by us to be discriminatory. One of these commenters supported us in continuing our current approach to applying a discrimination test.

A number of commenters opposed our proposed requirement to establish individual Parts A and B service category cost-sharing thresholds, suggesting that individual service category thresholds would result in higher premiums. Other commenters believed that cost-sharing limits would present significant additional administrative costs for plans. A number of commenters contended that individual service category thresholds would limit the availability of unique benefit designs and, consequently, limit beneficiary choice. One commenter argued that we should not limit plans' ability to use cost sharing as a tool to encourage beneficiary choice of cost effective and clinically appropriate services. Another commenter recommended that, rather than adopting cost-sharing thresholds, we should evaluate other options for identifying and preventing discriminatory benefit designs, such as evaluating the prevalence of utilization control mechanisms (for example, prior authorization) on services frequently used by patients with a particular high-cost conditions.

Response: We believe establishing individual service cost-sharing thresholds is necessary to ensure that beneficiaries who utilize higher than average levels of health care services will not be discouraged from enrolling in MA plans with cost-sharing in excess of thresholds set by CMS and that our proposal to set specific amounts in advance improves the transparency of, and comparability between, plan choices for beneficiaries.

We are therefore finalizing our proposal to allow us to annually set cost sharing thresholds for Medicare Parts A and B services.

In establishing service category cost-sharing thresholds, we will be cognizant of the balance we must strike between affording beneficiaries reasonable protection from high out-of-pocket expenses that could discourage enrollment and our desire that the MA program remain viable for health plans and beneficiaries. We will carefully assess the impacts of the cost-sharing thresholds we establish, annually adjusting the limits and the particular Parts A and B services that are subject to such limits as necessary based on the previous year's experience and other factors as needed, to ensure that this balance is maintained. As we have in previous years, we plan initially to establish cost-sharing thresholds for those Parts A and B services that we have, through a number of years of experience with plan benefit reviews, identified as particularly likely to have a discriminatory impact on sicker beneficiaries. Specifically, under our current cost sharing review process which has developed from our past experience in reviewing benefit packages we focus our review on 14 service categories we have identified a particularly likely to have discriminatory impact on "sicker" beneficiaries: inpatient catastrophic (90) days, inpatient short stay (10 days), inpatient mental health (15 days), SNF (42) days, home health (37) days, physician mental health visits, renal dialysis (156) visits, Part B drugs, chemotherapy, radiation, DME, equipment, prosthetics, supplies and diabetes tests.

As discussed elsewhere in this preamble, in addition to establishing a mandatory maximum out-of-pocket (MOOP) limit on overall cost-sharing for Parts A and B services, we also plan to continue our current policy of offering MA organizations the option of adopting a lower voluntary MOOP with greater flexibility in Parts A and B cost sharing than available for MA plans that meet only the higher mandatory MOOP. Under this approach, the voluntary MOOP would be set at an amount lower than the mandatory MOOP and would therefore not disadvantage those MA plans that have adopted the voluntary MOOP in previous contract years. In implementing thresholds for discriminatory cost-sharing for individual services, we plan to establish two sets of Parts A and B service cost-sharing thresholds, one applicable to plans choosing the higher, mandatory MOOP, and the other applicable to those choosing the lower, voluntary MOOP. We plan to articulate the cost-sharing thresholds associated with the lower, voluntary MOOP through subregulatory guidance such the annual Call Letter or similar guidance document.

In establishing cost-sharing thresholds, we will consider an MA organization's need to use cost-sharing as a tool for preventing overutilization of services. While we have not been provided evidence that this requirement would increase plans' administrative costs, we also note that MA organizations will be able to account for any increased administrative costs in their annual bids. Finally, with respect to the comment about reviewing prior authorization, we believe that establishing cost-sharing thresholds is a more efficient and effective method for eliminating discriminatory MA plan designs.

Comment: One commenter questioned our authority to impose individual service category thresholds, and urged us to withdraw our proposal.

Response: We disagree with this commenter. As discussed in the preamble to the October 22, 2009 proposed rule, our proposal relies upon the authority in section 1852(b)(1) to ensure that an MA plan would not substantially discourage enrollment by certain MA eligible individuals and our authority under section 1857(e)(1) of the

Act, under which we may add "necessary and appropriate" contract terms; and, with respect to MA plan cost sharing, the authority in section 1856(b)(1) of the Act, under which we may establish MA standards by regulation.

Comment: Some commenters sought clarification on how we will address cost sharing thresholds with regard to dual-eligible special needs plans (SNPs). These commenters specifically asked whether we would exempt dual-eligible SNPs from our proposed establishment of mandatory Parts A and B service thresholds, since States pay dual-eligibles' cost sharing. These commenters argued that our proposed requirement could force dual-eligible and chronic care SNPs to charge a premium, thus making their plans unattractive to dual-eligibles and other low-income enrollees.

Response: We disagree with commenters recommending that dual or chronic care SNPs should be exempted from our service category cost-sharing thresholds. As long as a plan has at least some enrollees subject to all of a plan's cost-sharing amount, those enrollees could still be discouraged from enrolling or continuing their enrollment in the plan given particularly high cost-sharing for specific services. Even those SNPs that exclusively serve dual-eligible enrollees entitled to have their cost sharing paid by the Medicaid program can include some individuals who lose their Medicaid status midyear and become subject to plan cost sharing which would no longer be paid by the Medicaid program. Plans should not establish excessive cost-sharing regardless of whether the State is responsible for beneficiaries' cost-sharing. We are therefore not exempting SNPs from the mandatory MOOP and cost sharing limits that apply to other MA plans.

Comment: One commenter asked us to consider exempting employer plans from our cost-sharing threshold requirements, arguing that such a requirement would complicate their efforts to offer their current and retired employees parallel coverage.

Response: We disagree with this commenter. The nature of employer arrangements varies greatly. In some cases, an employer may offer more than one MA plan option, and one or more of those plans may still discourage enrollment by certain beneficiaries through their benefit design. Also, in the case of an employer plan, if a compelling reason exists for an exemption from the limits in this final rule, and if we determine an exemption would be in the best interests of beneficiaries, employers could request a waiver of these limits under the employer waiver authority.

Comment: Some commenters recommended that we establish cost sharing thresholds for Parts A and B services as soon as possible prior to the bid submission deadline (for example, in the Call Letter or Advance Notice of Methodological Changes) and provide stakeholders with an opportunity to provide comments regarding the thresholds and the methodology used to arrive at those thresholds. Some commenters representing non-plan stakeholders also requested that we provide this information via means other than the HPMS, since only plans have access to HPMS and advocates and other non-plan entities would like to receive the information we share with plans via HPMS. Another commenter recommended that we permit MA organizations to resubmit a bid and benefit package if the initial bid is rejected due to a finding by CMS of discriminatory cost sharing.

Response: As stated in the preamble to the proposed rule, we intend to furnish information to MA organizations and Part D sponsors on our methodology and the cost sharing thresholds for the following contract year on a timely basis either through the annual Call Letter or similar guidance document. We will consider ways of disseminating this information through other means to ensure that all stakeholders have an opportunity to comment and note that we generally post draft Call Letters to the CMS Web site to ensure broad public availability. With regard to opportunities to resubmit bids and benefit packages, given that we expect to provide guidance regarding cost-sharing thresholds prior to bid submission, we do not anticipate the need to allow plans to resubmit bids or benefit packages if their submissions are inconsistent with published guidance. As part of our review of submitted bids and benefit packages, we may contact plans to give them the option of modifying their bids and benefit packages if we have made a determination that the proposed plan benefit package or cost sharing contains discriminatory amounts not outlined in published guidance.

Comment: One commenter recommends that cost-sharing limits, and the service categories to which they apply, remain stable from year-to-year.

Response: We intend to implement cost-sharing thresholds carefully to ensure the right balance of ensuring against discriminatory effects of high cost-sharing and continued viability of the MA program. While we believe stability in the thresholds and the particular services to which those thresholds are applied is important, we also believe it is necessary to allow ourselves the flexibility to build on "lessons learned" each year, and to reevaluate both the thresholds and the Parts A and B service categories to which they apply, to account for any statutory changes in Original Medicare cost-sharing limits as well as other changes to the MA program, and refine our approach accordingly to maintain such a balance.

Comment: Some commenters believed that we were not clear in the proposed rule regarding whether we would set cost sharing thresholds for all Parts A and B service categories, or only for selected categories identified as potentially discriminatory. These commenters requested further clarification on our intended approach.

Response: As we have done in the context of benefits review in previous years, we intend to focus on service categories particularly likely to have a discriminatory impact on sicker beneficiaries. Initially, we will focus on the service categories we have targeted historically in our benefit review. We expect to refine our approach over time in order to achieve the right balance between plan choice and protection from high out-of-pocket costs. We intend to build on our experience, and potentially make modifications to the list of Parts A and B service categories to which we would apply cost-sharing thresholds.

Comment: A couple of commenters recommended that, in setting cost-sharing limits, CMS consider enrollees' cost-sharing both before and after members reach any deductible that may apply.

Response: We will consider whether to take plan deductibles into account as part of our methodology to establish cost-sharing thresholds.

Comment: One commenter requested clarification on how we will establish cost sharing thresholds based on the previous year's experience. One commenter urged that the thresholds not be adjusted based on current year data.

Response: As described in the preamble to our proposed rule, we intend to review the prior year's bid data, as well as actuarial equivalency relative to Original Medicare, to identify cost sharing outliers and establish a reasonable threshold. With this information, and other factors we may identify as we gain experience in establishing these thresholds, we will annually set cost-sharing thresholds as described in this preamble. We do not

anticipate that these levels will need to be changed after bids have been submitted. However, as previously noted, we will conduct a review of submitted bids and we reserve the right to address discriminatory cost sharing or benefit design we identify in these post bid reviews by asking the plan to either modify or withdraw its bid to resolve discriminatory cost sharing.

Comment: One commenter recommended that service category thresholds be set at fixed dollar amounts.

Response: We understand that copayment amounts are more transparent and predictable for beneficiaries than coinsurance, and will attempt to establish thresholds as copayment amounts rather than coinsurance percentages where appropriate. Given the fact that original Medicare employs coinsurance percentages in its cost-sharing, there may be cases, in which we may limit the coinsurance percentage that can be imposed.

Comment: One commenter recommended that we not set a cost sharing maximum for routine services, such as physician visits and lab services, where there is limited financial liability, or for durable medical equipment (DME), where they argue that any particular cost-sharing maximum would invariably penalize one subset of enrollees. One commenter recommended that we establish thresholds on a per day, per stay, and per benefit period basis for SNF and inpatient services. Another commenter recommended that any threshold for Part B drugs apply to all Part B covered drugs.

Response: We disagree that physician visits and lab services should necessarily be exempt from cost-sharing maximums, though we currently do not contemplate imposing limits in such cases, and would only do so to the extent that we saw cost-sharing imposed that had a discriminatory effect. As stated previously, we initially will focus on those service categories we have historically identified as particularly likely to have a discriminatory impact on sicker beneficiaries and will refine our approach as needed and in line with our ultimate goal of eliminating discriminatory benefit designs. We welcome the feedback provided by other commenters with regard to DME, SNF and Part B drug copayments and will consider these recommendations as we finalize our methodology and thresholds.

Comment: Several commenters supported the proposal to review Part D plan bids to determine acceptable cost-sharing tiers for benefit designs that deviate from the standard benefit package. One commenter indicated that this would bring a level of standardization to plans and make it easier for them to compare out-of-pocket expenses.

Response: We appreciate the comments.

Comment: Several commenters wanted to limit Part D cost sharing to a total maximum out-of-pocket amount.

Response: We do not believe that a regulatory overall liability limit for Part D would be practical or appropriate given the current design of Part D benefits (such as, the coverage gap). We also note that, under the Part D benefit, there is protection afforded to a beneficiary once they enter into the catastrophic phase of the benefit where there is nominal cost sharing.

Comment: One commenter wanted us to establish clear and definitive limits on cost sharing. Another commenter wanted us to consider the overall affordability of cost sharing that is imposed on non-low-income (LIS) Medicare beneficiaries. The commenter argues that this is particularly important when considering a plan design in which preferred formulary tiers do not include equally safe and effective drugs for the beneficiary's medical condition. Another commenter wanted us to take into account separate rules for cost contracts with HMOs under section 1876. Additionally, another commenter wanted clarification on how we will review plans with more than or fewer than a three tier benefit design. This commenter suggested that all tiers may not exceed levels determined by CMS to be discriminatory.

Response: We appreciate these comments. It is important to note that we review both formularies and benefit designs to ensure that a sponsor's prescription drug offering under Part D is not discriminatory. We have designed our yearly formulary reviews to ensure that all Part D plan formularies include a wide representation of drugs used to treat the Medicare population. As part of this review, we focus on identifying formularies with drug categories that may substantially discourage enrollment of certain beneficiaries, for example if the formulary places drugs in nonpreferred tiers without including commonly used therapeutically similar drugs in more preferred positions. As part of our yearly review of submitted benefit designs, we compare like plans to each other for the purpose of ensuring non-discriminatory cost-sharing. Specifically, we perform an analysis of cost sharing at the tier level, to look for outliers. The outlier analysis considers plan type (basic versus enhanced), tiering structure (for example, the number and type of tiers), and any differences among MA–PDs (including cost plans) and between MA–PDs and PDPs. When outliers are identified, we conduct negotiation calls with the relevant plan sponsors to ensure the cost sharing outliers are reduced prior to bid approval. We also require cost sharing levels for preferred tiers to be lower than cost sharing levels for nonpreferred tiers.

Comment: A commenter expressed concern that when coverage of a nonformulary drug is secured on appeal, the cost sharing under the nonpreferred tier can approximate, or even exceed, the negotiated price of the drug.

Response: The price charged to the beneficiary cannot exceed the negotiated price. The requirements related to qualified prescription drug coverage at § 423.104(g)(1) make clear that Part D sponsors are required to charge beneficiaries the lesser of a drug's negotiated price or applicable copayment amount.

Comment: Several commenters opposed setting cost sharing maximums, claiming that this will result in higher premiums for beneficiaries. One commenter asserted that CMS' proposal will limit the ability of Part D sponsors to design plans that provide choices for additional or richer benefits in other areas important to beneficiaries. For example, they argue that establishing maximum Part D brand cost-sharing levels will impact the ability to offer $0 copayment for generic drugs; therefore, ultimately inhibiting the greater affordability and access. A commenter contended that our proposal fails to consider a plan design that is associated with a robust formulary. The commenter believes that such a plan should have the flexibility to impose higher member cost sharing, particularly for nonpreferred drugs, compared to a formulary that meets minimum requirements and, coupled with low premium which may be attractive to those with minimal drug utilization who seek protection from potential future changes in health status.

Response: In determining a maximum cost sharing amount for a tier above which we will view the plan's benefit design as discriminatory, we attempt to strike a balance between appropriate coverage under the benefit and the potential affect on the premium. As part of our benefit design review, and consistent with previous reviews, we consider all beneficiaries under the plan, and not just those beneficiaries expected to have limited utilization. Therefore, any actuarially-equivalent

cost sharing arrangement is reviewed, along with the rest of a plan's benefit design, to ensure that it does not discriminate against certain Part D eligible individuals. This sometimes results in a sponsor not being able to support higher member cost sharing amount under a robust formulary design for nonpreferred drugs or being able to support zero dollar generics. However, these cases are usually the exception since our review is designed to ensure the maximum utility of the benefit design for potential enrollees.

Comment: One commenter wanted CMS to prohibit the use of both copayment and coinsurance tiers under nonstandard Part D benefit designs.

Response: We disagree with the commenter and believe such a prohibition would unnecessarily limit plan design. Moreover, we believe that such a proposal is beyond the scope of this proposed rule, which addresses the authority of CMS to establish limits on cost sharing for purposes of determining whether or not such cost sharing is discriminatory. Our proposal did not address whether nonstandard benefit designs utilizing coinsurance are discriminatory.

Comment: One commenter wanted us to require that at least one drug within each therapeutic class be on each tier.

Response: We believe that such a proposal is beyond the scope of this proposed rule, which only addresses the authority of CMS to establish limits on cost sharing for purposes of determining whether or not such cost sharing is discriminatory. We also note that due to the varying number of drugs that may be available in a therapeutic class, this proposal may require many exceptions and be impractical to implement.

Comment: Several commenters expressed concern about our specialty tier policy. A few commenters want us to eliminate the exemption from tiering exceptions for specialty tiers. Another commenter asserted that drugs in the specialty tier are so expensive, an argument could be made that specialty tier coinsurance above 25 percent is excessive. Another commenter argues that the use of specialty tiers is a discriminatory practice that targets individuals who have medical conditions that necessitate use of expensive medications.

Response: We appreciate the commenters' concern in this area, which is one we will continue to study. Any revisions to the specialty tier policy will be done in future rulemaking. We note specifically that the commenters' request for us to eliminate the exemption from tiering exceptions for specialty tiers is outside of the scope of this proposal. We also note that we have only allowed a higher coinsurance percentage greater than 25 percent for specialty tiers under alternative prescription drug coverage designs with decreased or no deductibles. Thus, overall, consistent with statutory and regulatory requirements, a basic alternative design must be actuarially equivalent to the defined standard benefit design.

Comment: One commenter wanted us to study the effects of high out-of-pocket costs, improve drug pricing disclosure, prohibit plans from changing the price of drugs, notify beneficiaries when a drug price is going to increase, ensure that Part D plan sponsors inform beneficiaries how to get medications free or at lower prices, and end discriminatory practice cost sharing.

Response: We appreciate the commenter's concerns over price fluctuations that may result in changes in cost sharing under a Part D plan benefit design that includes coinsurance and the effects that these changes may have on beneficiaries enrolled in these plans. However, several of these comments are outside of the scope of the proposed rule, which addresses our ability to establish threshold levels for cost sharing above which we would determine such cost sharing to be discriminatory. Moreover, we note that under section 1860D–11(i) of the Act, commonly known as the "Non-interference provision," we are prohibited from interfering in the negotiations among drug manufacturers, pharmacies, and sponsors of prescription drug plans (PDPs), and from requiring a particular formulary or price structure for the reimbursement of a covered Part D drug. Therefore, we do not have the authority to prohibit plans from changing the price of drugs.

Comment: Several commenters wanted information on discriminatory cost sharing made available through Call Letter and other public means, and want such information to be made available timely so that it can be taken into account prior to bidding.

Response: We appreciate the commenters' concern that we be as transparent and timely as possible with our guidance in this area. We will strive to make this information available as early as possible for sponsors to begin constructing their bids for the 2011 contract year.

Comment: One commenter stated that if a plan sponsor offers a plan design with zero co-payment amounts for certain mail order prescription drugs, it should be required to offer the same cost sharing at retail pharmacies.

Response: This comment is outside the scope of the proposed rule, which does not revise our level playing field policy between mail and retail drug offerings. We refer the commenter to section 50.2 of Chapter 5 of the Medicare Prescription Drug Benefit Manual at *http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/Chapter5.pdf* for our current policy in this area.

7. Prohibition on Prior Notification by PPO, PFFS and MSA Plans Under Part C (§ 422.2, § 422.4, and § 422.105)

In our October 22, 2009 proposed rule, we stated that we have become increasingly concerned about the use of prior notification by PPO and PFFS plans as a condition for lower cost sharing. Program experience has demonstrated that such prior notification provisions are confusing to beneficiaries, misleading in terms of cost-sharing transparency, and in some instances, are used inappropriately as a form of prior authorization. In the GAO report titled "Medicare Advantage: Characteristics, Financial Risks, and Disenrollment Rates of Beneficiaries in Private Fee-for-Service Plans (GAO–09–25)," the GAO stated that some PFFS plans it reviewed "inappropriately used the term prior authorization rather than pre-notification in the informational materials they distributed to beneficiaries, which may have caused confusion about beneficiaries' financial risks." We have determined that the complexity of cost-sharing designs using prior notification has made it more difficult for both enrollees and providers to understand the enrollee's cost sharing obligation in advance of receiving services. Therefore, in order to reduce the complexity of MA plans' cost sharing designs and improve transparency for both enrollees and providers, we proposed to prohibit PPO plans (for out-of-network services) and PFFS plans from providing for lower cost sharing where prior notification rules have been satisfied. Specifically, we proposed to revise § 422.4(a)(1)(v) and (a)(3) to provide that PPO and PFFS plans will be prohibited from establishing prior notification rules under which an enrollee is charged lower cost sharing when either the enrollee or the provider notifies the plan before a service is furnished. We are adopting § 422.4(a)(1)(v) and (a)(3) without further modification in this final rule.

In our October 22, 2009 proposed rule, we also proposed to prohibit MSA plans from establishing prior notification rules. We believe that prior notification rules established by MSA

plans are also confusing to enrollees of those plans and have similar negative effects as those described above for PPO and PFFS plans. Accordingly, we proposed to modify § 422.4(a)(2) such that MSA plans will also be prohibited from establishing prior notification rules under which an enrollee is charged lower cost sharing when either the enrollee or the provider notifies the plan before a service is furnished. We are also adopting § 422.4(a)(2) without further modification in this final rule.

Finally, the October 22, 2009 proposed rule discussed similar concerns about beneficiary confusion in connection with PPO plans that included a POS-like benefit. As we noted in the October 22, 2009 proposed rule and the Medicare Program entitled Establishment of the Medicare Advantage Program, published in the January 28, 2005 **Federal Register** (70 FR 4617 through 4619), we had stated that PPOs could offer a POS-like benefit under which beneficiary cost sharing would be less than it would otherwise be for non-network provider services, but still might be greater than it would be for in-network provider services, provided an enrollee follows preauthorization, pre-certification, or prenotification rules before receiving out-of-network services. For the same reasons discussed above, we determined that this approach is confusing, and is subject to abuse as a prior authorization mechanism for non-network services. Therefore, in order to reduce the complexity of PPO plans' cost sharing designs and improve transparency for both enrollees and providers, we proposed in our October 22, 2009 proposed rule to prohibit PPO plans from offering such a POS-like benefit. Specifically, we proposed to revise the definition of POS in § 422.2 and § 422.105(b), (c), and (f) to indicate that only HMOs may offer a POS benefit. The proposed change is consistent with section 1851(a)(2)(A)(i) of the Act, which states that an HMO may include a POS option. We are adopting § 422.105 without further modification in this final rule and revising § 422.2 as described below.

Comment: Several commenters supported our proposals to prohibit PPO plans (for out-of-network services), MSA plans, and PFFS plans from establishing prior notification rules and prohibit PPO plans from offering a POS-like benefit. Some of the commenters indicated that these practices are confusing and misleading and penalize members who are not able to give prior notification or who were unaware of the option. Some commenters also indicated that they found several plans that charge exorbitant cost-sharing (up to 75 percent) for expensive items such as durable medical equipment when prior notification requirements have not been met. A number of commenters opposed our proposals to prohibit PPO plans (for out-of-network services), MSA plans, and PFFS plans from establishing prior notification rules and prohibit PPO plans from offering a POS-like benefit. Other commenters stated that these practices permit plans to alert the enrollee in advance of receiving a service that it may not be covered; reduce enrollees' cost sharing obligations when obtaining covered services from out-of-network providers; enable plans to better monitor and oversee members' use of out-of-network providers, thus allowing plans to assess and expand their provider networks; and identify those plan members who may qualify for plan disease management and case management programs. One commenter indicated that MA plan premiums likely would increase if this cost control technique were eliminated. Commenters opposed to CMS' proposals provided several recommendations for addressing our concerns about prior notification rules and POS-like benefits. Commenters' recommendations included retaining existing policies; enforcing the existing requirement (for example, requiring greater clarity in enrollee materials) to address concerns raised in the proposed rule; requiring PPO plans with POS-like benefit to better describe the cost-sharing amounts under each set of circumstances that may arise; requiring plans to more clearly describe the distinction between prior authorization and prior notification, and expressly identify those covered services subject to each process; and encouraging providers' outreach to plans to confirm prior authorization/notification provisions and members' cost sharing obligations.

Response: We agree with the commenters supporting our proposals to prohibit PPO plans (for out-of-network services), MSA plans, and PFFS plans from establishing prior notification rules and prohibit PPO plans from offering a POS-like benefit. As we stated in the October 2009 proposed rule, we believe that prior notification is confusing to beneficiaries, misleading in terms of disclosure of cost-sharing, and in some instances, used inappropriately as a form of prior authorization. Also, the complexity of cost sharing designs using prior notification and POS-like benefits has made it more difficult for both enrollees and providers to understand the enrollee's cost sharing obligation in advance of receiving services.

We acknowledge the concerns raised by commenters who opposed our proposals. However, we believe that most of these concerns can be addressed if the plan takes an active role to educate enrollees and providers about their right to request a written advance coverage determination from the plan, in accordance with Subpart M of Part 422, before an enrollee receives a service in order to confirm that the service is medically necessary and will be covered by the plan. These MA plans should clearly explain the process for requesting a written advance determination in member materials and respond to requests from enrollees and providers on a timely basis. Plans may also encourage enrollees and providers to request advance coverage determinations prior to receiving costly services. These MA plans can also use requests for advance coverage determinations as a tool to identify enrollees who may qualify for disease management and case management programs or who require further care coordination. Plans can use the claims data submitted by non-network providers to expand their provider networks as well as identify those enrollees who would benefit from disease management and case management. We do not believe that prohibiting prior notification rules and POS-like benefits will lead to higher MA plan premiums. We believe that prohibiting PPO plans (for out-of-network services), MSA plans, and PFFS plans from creating prior notification rules and PPO plans from offering a POS-like benefit will reduce the complexity of these plans' cost-sharing designs and improve transparency for both enrollees and providers. Accordingly, we are adopting the proposals as set forth in the October 2009 proposed rule.

We are making a technical correction to the definition of point-of-service (POS) in § 422.2 in this final rule. We are deleting the word "additional" from the definition since it no longer applies to the definition of a POS benefit option.

8. Requirements for LIS Eligibility Under Part D (§ 423.773)

In the October 22, 2009 rule, we proposed amending the length of the period for which individuals are re-deemed eligible for the full low income subsidy to conform § 423.773(c)(2), with guidance we issued in section 40.2.2 of Chapter 13 of the Medicare Prescription Drug Benefit Manual. As we noted in the October 2009 proposed rule, we review data from State Medicaid

Agencies and the Social Security Administration (SSA) every year to determine whether individuals currently deemed eligible for the subsidy should continue to be deemed (that is, "re-deemed") eligible for the subsidy. These data, which are sent in July and August every year, allow us sufficient time to update individuals' records in our systems, if necessary, and to make appropriate notifications if an individual is losing deemed status for the subsequent calendar year.

We also noted that when we review data in July and August, we also identify individuals who are newly eligible for Medicaid, a Medicare Savings Program, or SSI, and deem them eligible for LIS for the remainder of the current calendar year. In addition, we also re-deem these individuals for the subsidy for the next calendar year, because we do not have sufficient time in the final months of the year to conduct a separate re-deeming process for them. Moreover, if we waited to re-deem these beneficiaries after the start of the next calendar year, they could incur greatly increased premium liability and cost sharing amounts at the start of the new calendar year than they would have otherwise.

To address these issues, we proposed to amend § 423.773(c)(2) to indicate that the deeming will be, at a minimum, for the following periods: If deemed status is determined between January 1st and June 30th of a calendar year, the individual is deemed subsidy eligible for the remainder of the calendar year. If deemed status is determined between July 1st and December 31st of a calendar year, the individual is deemed subsidy eligible for the remainder of the calendar year and the next calendar year. We have found that this policy promotes effective administration of the LIS benefit and decreases the administrative burden on CMS, the Social Security Agency, and State Medicaid agencies, as well as on subsidy eligible individuals. In this final rule, we adopt this provision as proposed.

Comment: Several commenters expressed support for our intent to put in regulation the minimum time periods for which beneficiaries are deemed eligible for the LIS.

Response: We appreciate this support for our intent to outline the minimum time periods of LIS eligibility.

Comment: One commenter urged us to consider making LIS deemed status permanent, or granting a 3-year period of presumptive eligibility. The commenter noted that while income and assets may fluctuate, most low-income Medicare beneficiaries are unlikely to experience increases that are enough to affect their eligibility. The commenter also noted that making eligibility permanent would eliminate the need for redeterminations of eligibility, thus reducing administrative costs for the program and inconvenience and stress for beneficiaries.

Response: We understand the potential benefits to the LIS population of extending or making permanent their eligibility for the subsidy, and reducing the inconvenience and stress to beneficiaries is an ongoing goal of our administrative processes. Currently, approximately 95 percent of LIS-eligible beneficiaries are re-deemed for the following year prior to the end of the current calendar year, and half of those who are not initially re-deemed (that is, another 2.5 percent) are re-deemed within next 6 months. In addition to this, the number of beneficiaries who actually receive the annual Loss of Subsidy Letter, also known as the gray notice, has been decreasing over the last 4 years. This suggests that CMS and State efforts to improve the administrative process are working, and that individuals who continue to qualify for the low income subsidy are being identified appropriately, while the small proportion of individuals who may no longer qualify for the subsidy also are being identified. We believe that the approach being adopted here strikes a balance between making the re-deeming process as efficient as possible while still ensuring that beneficiaries receiving the subsidy are truly LIS-eligible. For these reasons, we are not adopting the suggested modifications.

Comment: A few commenters recommended that we require States to continue providing Medicaid coverage to a dual-eligible until the individual's Part D enrollment actually takes effect.

Response: Section 1935(d) of the Act specifically precludes Federal medical assistance for Medicaid payments for prescription drugs for those Medicaid-eligible individuals who are also eligible for Part D, regardless of whether the person is enrolled in a Part D plan. Therefore, no modification to the regulations will be made.

Comment: One commenter requested additional regulatory changes to require improvements to the way we administer the LIS benefit, including improving the Web site, notices to encourage appropriate actions, and putting in place better "Best Available Evidence" policies and procedures to ensure that LIS status discrepancies are corrected.

Response: As noted previously, we continually consider ways to improve the administration of the LIS benefit and beneficiaries' understanding of it. We believe we have the authority to make the additional improvements the commenter suggested, as appropriate, without further modifying the regulation.

9. Enrollment of Full Subsidy Eligible Individuals and Other Subsidy Eligible Individuals Under Part D (§ 423.34)

We proposed to codify in regulation the enrollment procedures that we use for LIS individuals, which are similar to those specified in the regulation for the dual-eligible population. We believe that our regulations would be more accurate and complete if they specifically addressed this population. Therefore, we proposed to include information on how we enroll all LIS-eligible individuals, including full benefit dual-eligible individuals, through the following changes:

- In § 423.34(a), we expanded the general rule to refer to all LIS-eligible individuals, so that the rest of that section applies not only to full benefit dual-eligible individuals, but also to all LIS-eligible individuals.
- In § 423.34(b), we retained the definition of full benefit dual-eligible individual, and added a definition for "low-income subsidy eligible individual." We have identified the need for a technical correction to the definition of "low-income subsidy eligible individual." The proposed definition could be read to specify that the definition of full-benefit dual eligible—who are identified as a specific group of LIS eligibles—is that in § 423.722, which is limited to such individuals already enrolled in a Part D plan. However, the enrollment rules in § 423.34(b) applies to full-benefit dual eligibles not yet enrolled in a Part D plan. We made a technical correction to the regulation text to specify that the definition of full dual eligible individual is that in § 423.34.
- We amended the paragraph heading of § 423.34(c) to indicate that this paragraph describes the process we use to reassign LIS-eligible individuals during the annual coordinated election period. We indicate that the reassignment process applies to certain LIS eligible individuals (that is, not just full-benefit dual-eligible-individuals).
- We revised the paragraph heading of § 423.34(d) from "Automatic Enrollment Rules" to "Enrollment Rules." We made this change to reflect the inclusion of full subsidy and other subsidy eligible groups in the enrollment process, in addition to full benefit dual-eligible individuals. In our guidance, we refer to the process of enrolling full benefit dual-eligible individuals as "automatic enrollment,"

and the process for other LIS eligibles as "facilitated enrollment." (See section 30.1.4 of Chapter 3 of the Medicare Prescription Drug Benefit Manual.)

- We amended § 423.34(e) to indicate that the rules regarding declining enrollment and disenrollment also apply to all LIS-eligible individuals.
- In § 423.34(f), we clarified that the paragraph heading and contents of this paragraph are limited to the effective date of enrollment for full benefit dual-eligible individuals. We also amended § 423.34 (f)(3) to specify that, for individuals who are eligible for Part D and subsequently become eligible for Medicaid on or after January 1, 2006, the effective date of enrollment would be the first day of the month the individual becomes eligible for both Medicaid and Medicare Part D.
- In § 423.34(g), we added a new paragraph to specify that the effective date for LIS eligibles who are not full benefit dual-eligibles would be no later than the first day of the second month after we determine that the individual meets the criteria for enrollment into a PDP under this section. This change conforms to section 30.1.4 of Chapter 3 of the Medicare Prescription Drug Benefit Manual. Unlike full benefit dual-eligible individuals who may have retroactive Part D coverage, these individuals have only prospective Part D coverage.

In the proposed rule, we also acknowledged concern expressed by some commenters about auto-enrolling beneficiaries on a random basis. For example, focus groups of seniors suggest the possibility that some auto-enrolled beneficiaries may not realize they have been enrolled in a drug plan or that they have been reassigned to a different drug plan. We noted that we are committed to taking appropriate steps to improve this process and welcomed comments related to all aspects of these procedures. In this final rule, we adopt these provisions as proposed.

Comment: Several commenters expressed support for expansion of auto-enrollment and reassignment to all individuals with LIS.

Response: We appreciate the support for this policy and are adopting the proposal without change.

Comment: Commenters urged us to shorten the time period for a plan enrollment so that it would take effect as of the date the person becomes subsidy eligible. The current time period can leave an individual who has applied and qualified for the subsidy with a gap of over 2 months between the time they express an interest in getting help with drug costs (via the application for the LIS) and the time they are actually enrolled into a plan and receive that assistance. This timeframe may have made sense initially, since it was not clear that nondually eligible LIS recipients would have an ongoing SEP. Now that they have been extended that protection, there is less of a need to wait for their selection. Instead, the enrollment should happen quickly to ensure access to prescription drugs.

Response: Facilitated enrollment constitutes a passive enrollment process that requires advance notice of the opportunity to make an active election before the enrollment is effective. We have been unable to find a way to ensure that individuals who are facilitated at the end of the month can receive the required advance notice and have an opportunity to make an election on their own before that enrollment takes effect (though it is possible to do so for those at the beginning of the month). It is important to keep in mind that this population consists of individuals who have applied for LIS, are notified of their approved LIS eligibility, and informed via their LIS approval notice that they need to elect a plan in order to avail themselves of the subsidy. Thus, we believe they are likely to follow through on their previous actions and choose a plan on their own, leading to possible confusion if they receive a facilitated enrollment notice after they have already made an active election. Finally, we note that all individuals whose facilitated enrollment into a PDP has not yet taken effect may obtain coverage for immediate drug needs through the Limited Income NET demonstration.

We are committed to continue exploring ways of shortening the facilitated enrollment process without infringing on an individual's ability to make a choice, or adding to the possibility of beneficiary confusion. However, it is important to note that proposed regulation text that we are now finalizing specifies that the enrollment effective date is "no later than" the first day of the second month" after we determine that they meet the necessary enrollment criteria. Therefore, although we are declining to amend the regulation as requested while we continue to address a number of operational issues that remain unresolved, the regulation language does provide the flexibility to shorten the timeframe if warranted and feasible.

Comment: One commenter noted that plans and beneficiaries would benefit from us specifying for both plans and beneficiaries any premium liability in instances when the beneficiary has a 25, 50, or 75 percent premium subsidy, in the process of conducting facilitated enrollment. As part of this, the commenter suggested revising of the facilitated assignment letter to include that portion of premium for which the beneficiary is liable.

Response: When we notify plans of new facilitated enrollees, we do identify those beneficiaries who are partial versus full subsidy beneficiaries, both on the Transaction Reply Report confirming enrollments, as well as on the LIS History report. In addition, the individuals' subsidy level is fully explained in the LIS approval letter from the Social Security Administration. However, we appreciate the suggestion for modifying the facilitated enrollment letter to reference a partial subsidy beneficiary's premium liability, and will explore whether this is feasible. We believe the latter does not necessitate a regulation change since notification details are generally an operational issue, so we will not modify the regulation to reference this.

Comment: A few commenters requested that we require that plans notify dual-eligibles in advance of potential involuntary disenrollments. They noted that we conduct a special auto-enrollment early each month—

- To identify full benefit dual-eligibles who are disenrolled from their previous plan;
- Who have not chosen a new one; and
- Where there continues to be a risk of a coverage gap if the plan submits the disenrollment request to CMS after the special auto-enrollment occurs.

Response: Section 423.36(b) of the regulation and section 40.2 of Chapter 3 of the Medicare Prescription Drug Manual already require plans to provide advance notice of potential disenrollment, so there is no need for a regulation change to that effect. The special process we run each month to capture recently disenrolled individuals already represents a significant advance in our auto-enrollment procedures. However, we will continue to look at ways to modify auto-enrollment to more quickly place auto-enrolled beneficiaries in a new plan. Note that under any circumstances, full benefit dual-eligibles who are disenrolled will not encounter any coverage gap—instead their subsequent enrollment will be made retroactive to the date of the loss of coverage from the preceding plan.

Comment: One commenter suggested adding in § 423.34(f)(3) the phrase "unless the individual is not a full benefit dual-eligible as identified in § 423.34(g)" to the end of the sentence that comprises this subsection. The commenter believes this addition would

clarify that § 423.34(f)(3) does not apply to non-full benefit dual-eligibles who have LIS.

Response: Section 423.34(f), including subparagraph (f)(3), is already limited to full benefit dual-eligibles by virtue of the introductory regulation text before subparagraph (f)(1). Given this, we see no need to further specify that § 423.34(f)(3) does not apply to non-full benefit dual-eligibles, so we decline to amend the regulation as suggested by the commenter.

Comment: Several commenters suggested that we expand the PDPs to which it assigns or reassigns LIS beneficiaries to include enhanced benefit plans. One commenter further clarified that reassignments should include enhanced plans whose portion of the basic premium falls below the LIS benchmark, as this would be no more costly to the government and would give LIS beneficiaries the same options as available to other beneficiaries to enroll in enhanced benefit plans.

Response: While enhanced benefit plans may offer supplemental benefits, they always create a premium liability for the beneficiary, including those who are eligible for the 100 percent premium subsidy. This is because, by statute, the LIS does not cover the portion of the premium attributable to the enhanced benefit, even if the total premium is under benchmark, meaning that the beneficiary is liable for the enhanced portion of the premium. The statute clearly limits initial auto enrollments to plans where an individual has zero premium liability, and we have adopted the same policy approach for purposes of reassignments. Therefore, we decline to modify the regulation as requested. We note that LIS beneficiaries are always free to elect an enhanced benefit plan if they wish to access the enhanced benefits, but they would incur some premium liability.

Comment: Several commenters urged us to move away from random reassignment of LIS eligible individuals to a system of beneficiary-specific reassignment in which beneficiaries are matched with plans that include their current drugs and preferred pharmacy. They believe this would result in less disruption to beneficiaries, and increased adherence to currently-prescribed drug regimens, while potentially providing the LIS benefit at the lowest total cost to beneficiaries.

Response: We continue to explore alternatives to random reassignment that would minimize the potential for disruptions to continuity of care, and appreciate the commenters' support for a beneficiary-specific process. While we believe there is merit to beneficiary-specific reassignment, we decline to amend the regulation to require it, given that § 423.34(c) currently provides CMS the discretion to implement such changes if our ongoing exploration of such an approach indicates that revisions to the current reassignment methodology are warranted.

Comment: A few commenters suggested that instead of reassigning LIS beneficiaries from plans whose premiums are going above the LIS benchmark, we should permit them to stay in the plan and be held harmless. They recommended a number of ways to do so, including giving affected beneficiaries a grace period of one year to remain in the plan, with no additional premium payment; letting the plan "absorb" any premium difference between the benchmark and the bid amount (up to $2.00 per one commenter); or waiving the requirement that plans attempt to collect delinquent premiums.

Response: While we have discretion to determine which beneficiaries are subject to reassignment, we believe that section 1860D–13(a)(1)(F) of the Act, which requires uniform premiums, precludes us from adopting these recommendations (absent a demonstration such as the 2006–2008 "de minimis" demonstration, where premiums of "de minimis" amounts were waived). We note that we have already implemented a demonstration for the 2010 plan year that increased the LIS benchmark, which had the effect of substantially decreasing the number of beneficiaries who needed to be reassigned.

Comment: One commenter suggested that CMS should allow the plan (rather than CMS) to move the LIS members in to a zero-dollar premium plan offered by the same sponsoring organization.

Response: As outlined in section 30.1.5 of the PDP Eligibility, Enrollment, and Disenrollment Guidance, when we reassign a beneficiary, we first attempt to reassign to a PDP offered by the same organization. Only when that is not possible do we reassign to plans outside of the organization. Our experience has been that CMS-initiated actions are much easier to implement on a timely basis, and to monitor for accuracy and completion, than are actions that depend on sponsors to identify and submit enrollment transactions for the affected population. Therefore, we believe there is little or no benefit to delegating this responsibility to PDP Sponsors, and we decline to make the requested change.

Comment: One commenter urged us to let plans communicate sooner with LIS enrollees they may lose to reassignment. The commenter suggested such communication be permitted earlier than is currently permitted in the reassignment process, to ensure affected beneficiaries understand their options.

Response: Plan sponsors are already permitted to communicate with current enrollees, subject to Part D marketing guidelines; the reassignment regulations under discussion here do not contain additional constraints on these rules, and we make every effort to involve sponsors in the reassignment communications process as early as possible. Thus, we believe there is no need for changes to the regulation to address this issue.

Comment: One commenter recommended that we include LIS recipients with partial premium subsidy as opposed to only full premium subsidy recipients in the annual reassignment process. The commenter noted that while it is true that recipients with partial premium subsidy will pay some premium no matter which plan they select, the amount they pay is lower if they are enrolled in a plan with the premium at or below the benchmark.

Response: We acknowledge that a partial subsidy beneficiary's premium would be somewhat lower in a zero-premium plan versus a plan with a premium over the benchmark, but in either case, these beneficiaries would still have to pay some portion of the premium. As always, our policies with respect to reassignment are intended to strike a fair balance between our dual goals of limiting beneficiary exposure to premium costs and also avoiding any potential negative impact on an individual's prescription drug coverage (such as changes to a pharmacy network or drug regimen). Since reassignment cannot eliminate the premium liability for such individuals under any circumstances, in this situation, we believe that potential for disruption to the prescription drug coverage outweighs the potential financial risks associated with paying a higher premium. Therefore, we do not believe that there is sufficient benefit to reassigning these beneficiaries, and we decline to adopt the commenter's suggested change to our existing approach.

Comment: A few commenters asked us to reconsider our decision not to include beneficiaries who elect their current plan ("choosers") in the reassignment process. Our reconsideration of this issue should begin with an evaluation of how choosers have been affected by the current process. In particular, the

Agency should identify the number of choosers who—

- Affirmatively switch plans every fall;
- Affirmatively switch plans during the year; and
- Are involuntarily disenrolled due to nonpayment of premium.

Response: We share the commenter's interest in this issue, and recently solicited input on whether we should reassign choosers who will face a premium liability of $10.00 or more in the following year (*please see* page 84 of the Advance Notice of Methodological Changes for Calendar Year 2011 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2011 Call Letter, issued February 19, 2010). We will continue to assess choosers' experience in Part D plans above the benchmark, including the extent to which they subsequently elect another plan and the extent to which they experience problems with premium payments. As noted previously, the regulations do provide the flexibility to change the existing process should our reconsideration of our approach show it to be warranted.

Comment: Two commenters recommended that we send a notice to LIS choosers who have chosen to join or remain in plans in which they would incur a premium liability. The commenters suggested notifying them of their zero-premium options (including an analysis of drug utilization to determine most appropriate plan). The beneficiary would be permitted to respond to the mailing in an efficient manner (for example, via postcard, telephone call, or online) to indicate his or her choice.

Response: We continue to assess the experience of LIS choosers who face premium liability, and as noted above, have solicited input on whether we should reassign choosers who have a premium liability of $10.00 or greater for the following year. We remain committed to reaching out to choosers whom we do not reassign to let them know about their options for zero premium prescription drug plans.

Comment: A few commenters urged us to require State Medicaid Agencies to increase the frequency of state submission of MMA data exchange files, which is the primary vehicle for notifying CMS of new dual-eligible beneficiaries. This would further minimize enrollment delays for new dual-eligibles.

Response: We believe this comment is outside the scope of this regulation, so we decline to amend the regulation in this manner. However, we continue to encourage states to submit these files more frequently, and provide technical assistance on how to do so.

Comment: One commenter urged us to ensure that dual beneficiaries receive clearer information about all the options available to them, including information about Medicare Special Needs Plans that can provide their Part D benefits. The commenter was especially concerned about the new Limited Income NET demonstration, which will automatically enroll LIS-eligible individuals who fail to elect a plan and are in immediate need of drugs in one Part D plan. This could create obstacles to seamless conversion from a Medicaid-only managed care plan to a Medicare Special Needs Plan offered by the same organization. The commenter encouraged us to establish more effective procedures to find and transition new duals into their Medicare benefits, especially those who are becoming Medicare-eligible because they are reaching the end of their 24-month disability waiting period.

Response: We appreciate the commenter's concern about ensuring dual-eligible beneficiaries receive information about all their options, and the need for ensuring a smooth transition for these beneficiaries between Medicaid and Medicare drug coverage. We have taken several steps to do so, and believe the Limited Income NET demonstration is an important step in further improving that transition. With respect to the concerns about the Limited Income NET demonstration, we note that the Limited Income NET process only involves auto enrollment to a single Part D plan for a short, retroactive period. For all prospective periods, the long-standing process of random enrollment among all PDPs with a premium at or below the LIS benchmark would continue to apply. Further, we do not believe the Limited Income NET demonstration specifically, or auto enrollment generally, creates obstacles to seamless conversion. In both cases, our processes are designed to ensure that new dual-eligibles have access to Medicare drug coverage on the first day of their eligibility for it. However, both those processes are also designed to ensure that any beneficiary election will trump a CMS-generated auto enrollment.

Comment: One commenter expressed support for the Limited Income NET demonstration program, but raised other concerns that the commenter believes the demonstration will not address: enrollment delays, LIS recipients in non-benchmark plans, and the need for accurate, LIS-specific information in plan mailings.

Response: We appreciate the support for the Limited Income NET program, and will continue to work on improving other areas of the program referenced by the commenter.

10. Special Enrollment Periods Under Part D (§ 423.380)

In the October 22, 2009 rule, we proposed to expand the SEP described in § 423.38(c)(4), which currently applies to full benefit dual-eligible individuals, to all LIS-eligible individuals. This proposed change is consistent with our authority in section 1860D–1(b)(3)(C) of the Act and will conform our regulations to current practice as reflected in CMS guidance in section 20.3.8, item 7, of chapter 3 of the Medicare Prescription Drug Benefit Manual. In this final rule, we adopt the provision as proposed.

Comment: Several commenters expressed support for putting the continuous Special Enrollment Period (SEP) for non-full benefit dual-eligible beneficiaries that is currently in operational guidance into regulation.

Response: We appreciate the comments that support placing the SEP for non-full benefit dual-eligibles into the regulation.

11. Transition Process Under Part D (§ 423.120(b)(3))

In the October 22, 2009 proposed rule, under the authority of section 1860D–11(d)(2)(B) of the Act, we proposed to codify in regulation certain plan transition policies at § 423.120(b)(3) previously established through subregulatory guidance. We specifically proposed to codify in regulation that a Part D sponsor must provide for a transition for the following—

- New enrollees into PDPs following the annual coordinated election period;
- Newly eligible Medicare enrollees from other coverage;
- Individuals who switch from one plan to another after the start of the contract year; and
- Current enrollees remaining in the plan who are affected by formulary changes from one contract year to the next.

We also proposed, consistent with our current guidance, that a Part D sponsor's transition process be applicable to nonformulary drugs, meaning both—

(1) Part D drugs that are not on a sponsor's formulary; and

(2) Part D drugs that are on a sponsor's formulary but require prior authorization or step therapy under a plan's utilization management rules. Additionally, consistent with our current guidance, we proposed to codify the timeframes for the transition process

and the days' supply limit for a transition fill of an enrollee's medication. Specifically, we proposed to codify the transition process timeframe to apply during the first 90 days of coverage under a new plan.

In addition, noting that our existing guidance directs Part D sponsors to provide a temporary supply we proposed that Part D plan sponsors be required to ensure that the one-time temporary supply of nonformulary Part D drugs requested during the first 90 days of coverage in an outpatient setting be for at least 30 days of medication, unless the prescription is written by a prescriber for less than 30 days, in which case the Part D sponsor must allow multiple fills to provide up to a total of 30 days of medication. For a new enrollee in a LTC facility, the temporary supply may be for up to 31 days (unless the prescription is written for less than 31 days), consistent with the dispensing practices in the LTC industry. In addition, due to the often complex needs of LTC residents that often involve multiple drugs and necessitate longer periods in order to successfully transition to new drug regimens. For these reasons, we proposed to require sponsors to honor multiple fills of nonformulary Part D drugs, as necessary during the entire length of the 90-day transition period. Further, we proposed requiring up to a 31-day transition supply for enrollees in an LTC facility given that many LTC pharmacies and facilities dispense medication in 31-day increments. Thus, a Part D sponsor would be required to provide a LTC resident enrolled in its Part D plan at least a 31 day supply of a prescription when presenting in the first 90 days of enrollment (unless the prescription is written for less) with refills provided, if needed, up to a 93 day supply.

In addition to proposing to codify the preceding requirements, we also clarified our expectations of sponsors with respect to providing transition notices. Consistent with our guidance that specifies that Part D sponsors send a written notice, via U.S. First Class mail, to each enrollee who receives a transition fill, we proposed to codify the guidance that directs sponsors to send this notice to each affected enrollee within 3 business days of the temporary fill. In addition to this codification, we also proposed requiring plan sponsors to make reasonable efforts to notify prescribers, via mail, electronic or verbal communication, that the affected enrollees' prescription cannot be refilled, either because of utilization management requirements such as prior authorization or step therapy, or because the prescribed medication is not on the plan sponsor's formulary. All of these proposals were addressed by adding paragraphs (i) to (v) to our general transition policy requirement at § 423.120(b)(3). We are adopting paragraphs (i), (ii), and (v) as proposed without further modification. As explained below, we are modifying proposed paragraph (iii) by clarifying the existing language to state that the temporary supply of nonformulary Part D drugs (including Part D drugs that are on a sponsor's formulary but require prior authorization or step therapy under a sponsor's utilization management rules) must be for up to 93 days in 31 day supply increments, with refills provided, if needed, unless a lesser amount is actually prescribed by the physician, and paragraph (iv) by clarifying that transition notices must be sent to beneficiaries within 3 business days after adjudication of a temporary fill.

Comment: A number of commenters supported our proposal of requiring an extended transition supply be given to enrollees residing in a LTC facilities. However, commenters requested that CMS provide the same protections to individuals requiring LTC in community-based settings as provided to those in institutions.

Response: While we appreciate that there are community-based enrollees who have nursing facility level of care and may experience access to multiple pharmacies, we are not persuaded that we should extend the LTC extended transition requirement to such individuals. We believe that residents of LTC institutions are more limited in access to prescribing physicians hired by LTC facilities due to a limited visitation schedule and more likely to require extended transition timeframes in order for the physician to work with the facility and LTC pharmacies on transitioning residents to formulary products. We believe that community-based enrollees, in contrast, are less limited in their access to prescribing physicians and do not require an extended transition period to work with their physicians to successfully transition to a formulary product.

Comment: Several commenters disagreed with the proposed timeframe in which to send out the transition notice of 3 business-days and recommended 3 calendar days. The commenters argue that a requirement of 3 calendar days is clearer and easier to enforce, particularly during holiday periods, when holidays delaying U.S. mail combined with the normal delays in mail delivery can severely cut into the time a beneficiary needs to try a different drug and request a formulary exception.

Response: We disagree with these commenters that the proposed timeframe be changed to 3 calendar days, which includes weekends and holidays when standard businesses are closed. We do not believe that a calendar day timeframe will allow sponsors an acceptable period in which to mail out a transition notice. Rather, we believe that the 3 business day turnaround time for notice to be sent is consistent with current transition policy and it permits a beneficiary sufficient time to work with his/her prescriber to change to a therapeutically equivalent drug on a plan's formulary or begin the exceptions process.

Comment: Several commenters supported the proposed requirement that sponsors notify the prescriber when a transition fill has been made. One commenter stated that the proposal is a positive that allows consistency across the MA population and it provides protection of certain vulnerable populations. Many commenters requested that we develop a standardized transition format for notices and explanations to be provided to plans. Another commenter requested our review notices that sponsors provide to ensure that beneficiaries are not unknowingly being steered to mail order pharmacies.

Response: We appreciate the comments. We note that we have developed a model transition notice for plans to send beneficiaries and are considering for the future whether or not to make that model standardized. In addition, we have prepared model notices for sponsors to ensure that beneficiaries are not unknowingly being transferred to mail order pharmacies. Model transition notices may be found at *Part D Marketing Model Materials.*

Comment: Many commenters opposed the requirement to send the transition notice within 3 business days of the temporary fill being dispensed. These commenters requested changing the proposal to notice being sent within 3 business days after a temporary fill is processed. The commenters argue that this is consistent with the current language in Section 30.4.10 of Chapter 7 of the Prescription Drug Benefit Manual, where the phrase "within 3 business days of the temporary fill" has been understood by the industry to refer to the date the temporary fill is processed, since it is only when the claim is processed that a plan learns about it and can act on it.

Response: We agree and note that industry practice standards have interpreted the language to mean within

3 business days of a temporary fill being processed. Therefore, we are revising the language of § 423.120(b)(3)(iv) to read "within 3 business days of adjudication of a temporary fill."

Comment: Some commenters expressed concerns with our proposal that Part D plan sponsors make reasonable efforts to notify the prescriber of the transition fill, with some commenters recommending that we make the prescriber notice requirement optional so that plans may exercise discretion to determine whether it is warranted. Another commenter stated that for the notification to be successful their master DEA file would need constant updating and that the requirement does not take into account emergency room or urgent care physicians covered by a blanket DEA number from the hospital. Another commenter suggested we should dialogue with the industry to review operational challenges to the prescriber notification. Yet another commenter suggested that we not implement the requirement unless we provides plan sponsors with access to databases with complete and accurate physician contact information cross-referenced with physician identifiers.

Response: We disagree with the commenters' request to make the prescriber notice optional and leave it to the plan's discretion whether such notification is warranted. The prescriber notification is a means of further strengthening beneficiary protections when dealing with formulary changes or utilization management protocols for necessary medications because the prescriber is in the best position to advise the beneficiary on the benefits or risks of switching to a different medication. Prescriber notification is an additional step to ensure a beneficiary is receiving optimal medication therapy outcomes with little to no delay in their drug regimen. As a result of this provision, sponsors and network pharmacies will need to ensure that they update their databases on a more consistent basis. We intend to provide additional guidance on what constitutes "reasonable notification efforts" in the future, but we do not envision providing plans with a comprehensive database of physician contact information as this is not information that we keep track of, and therefore it is not feasible for plans to rely on us to completely and accurately maintain such a database.

Comment: Several commenters stated that notification via U.S. mail occurs after the fact and suggests an alternative of beneficiary notification at the site of service.

Response: We continue to work with the industry to work on automated methods whereby beneficiaries are notified at point of sale that a drug dispensed is non-formulary. Until such time as these notifications are automated, plan sponsors must send written notice of transition fills through the U.S. mail.

Comment: One commenter requested CMS to define "other coverage" related to the requirement to provide a transition period for "newly eligible Medicare enrollees from other coverage" questioning whether this means that newly eligible Medicare enrollees who do not have "other coverage" should not qualify for a transition period. The commenter requests that we clarify that "newly eligible Medicare enrollee" would not include anyone who had been eligible for Medicare as a result of a disabling condition and moves to being eligible for Medicare as a result of reaching the specified age (such as, 65).

Response: We agree and clarify that "newly eligible Medicare enrollee" would include anyone who had been eligible for Medicare as a result of a disabling condition and moves to being eligible for Medicare as a result of reaching the specified age (such as, 65), including enrollees who do not have "other coverage" but who may be paying out of pocket for drugs they are currently taking.

Comment: One commenter supported the transition proposal but requests that CMS further revise § 423.120(b)(3) to standardize the amount of the temporary supplies that PDP sponsors are required to provide in the LTC setting. Some PDP sponsors have interpreted this element of CMS' transition policy that temporary supplies "may be for up to" 31 days to enable them to authorize fills of less than 31 days, even when physicians have prescribed a 31-day fill. The commenter recommends that we revise its proposed regulation to require PDP sponsors to provide transition supplies of at least 31 days unless a lesser amount is actually prescribed by the physician.

Response: We agree and are clarifying the existing language to state that the temporary supply of nonformulary Part D drugs (including Part D drugs that are on a sponsor's formulary but require prior authorization or step therapy under a sponsor's utilization management rules) must be for up to 90 days in 31-day supply increments unless a lesser amount is actually prescribed by the physician. We believe this clarification is necessary to protect beneficiaries residing in LTC facilities from unnecessary delays in obtaining the full amount of a temporary fill or from uneven interpretation among plan sponsors.

Comment: Many commenters suggested that we articulate in regulation the extension of transition fills through the completion of any requested exception, even if that process takes longer than 30 days. Moreover, commenters suggested that we also require a transition fill whenever a member encounters formulary difficulties obtaining current prescriptions. A few commenters urged us to codify in regulation the requirement that Part D plans cover an emergency supply of nonformulary drugs outside of the initial 90-day transition period. One commenter suggested that the regulations should be strengthened to provide that without evidence of timely written notice to the affected enrollee, the enrollee should be entitled to continue to receive the relevant medication(s). Other commenters requested we codify current guidance encouraging Part D sponsors to incorporate processes in their transition plans that allow for transition supplies to be provided to current enrollees with level of care changes.

Response: We note that current policy directs Part D sponsors to provide for a transition extension on a case-by-case basis when enrollees have not been successfully transitioned to the sponsor's formulary requirements. We do not believe that it is appropriate to codify this "case-by-case" directive into the existing rule. Our guidance already addresses that sponsors need to review an enrollee's request for an extension and the circumstances requiring such a request on an individual basis.

We also disagree with the comments that the regulation should be strengthened to provide that without evidence of timely written notice, the enrollee should be entitled to continue to receive the relevant medication(s). We believe that this situation would be more appropriately be handled through the complaint process given the level of scrunity that would be required to verify whether evidence exists that notice was provided to the enrollee by the plan sponsor.

We also disagree with the comment requesting that we codify into regulation at this time our current guidance encouraging transition supplies to be provided to current enrollees with level of care changes. As we have not encountered large number of complaints, we will continue to examine this issue. If we decide to mandate transition in this area, we will do so through future rulemaking.

Finally, we will consider codifying our emergency supply policy for LTC enrollees in future rulemaking.

Comment: Some commenters urged us to adopt the GAO recommendation to make the ANOC sent prior to each open season more individualized and thus more valuable to plan enrollees.

Response: We appreciate commenters recommending a more individualized ANOC being sent out prior to each open season. We believe that this is outside the scope of this proposal, which is to strengthen beneficiary protections during the transition process.

12. Part D Sponsor Responsibility for Retroactive Claims Adjustment Reimbursements and Recoveries Under Part D (§ 423.464, § 423.466, and § 423.800)

In the October 22, 2009 proposed rule, under the authority of sections 1860D–23 and 1860D–24 of the Act, we proposed that sponsors make retroactive claim adjustments and take other payer contributions into account as part of the coordination of benefits. In making these proposed changes, we noted that some beneficiary changes (such as LIS status changes or midyear Part D enrollment changes), LTC pharmacy billing practices for dual-eligible beneficiaries, and the presence of secondary, tertiary, and even quartenary payers have contributed to a higher than expected volume of retroactive claims adjustments requiring Part D sponsor reimbursements and recoveries, as well as a greater than anticipated complexity of calculating these amounts. While we previously anticipated that beneficiaries would be owed reimbursements due to changes in LIS status, and that plan sponsors would be required to make such reimbursements under § 423.800(c), we did not believe our current regulations addressed the other entities that may sometimes need to be taken into account in reimbursement or recovery transactions. Moreover, we noted that no industry standard electronic process exists to explicitly handle underpayment recoveries or overpayment reimbursements created by these adjustments, and that the current Health Insurance Portability and Accountability Act (HIPAA) standard for coordination of benefits for pharmacy claims only partly supports these activities when the pharmacy initiates "reverse and rebill" transactions. As a result, Part D sponsors sometimes struggle with how to manage these retroactive adjustments and those sponsors that are refunding overpayments or seeking underpayment recovery are each doing it differently.

We also noted in the October 22, 2009 proposed rule that, since our current regulations do not address retroactive adjustments and the complexities associated with coordination of benefit activities that cannot be accomplished between the Part D sponsor and the pharmacy through reversal and rebilling, we have issued general guidance to direct sponsor coordination of benefit activities. As part of our implementation guidance on the automated process for the transfer of TrOOP-related data, we established a 45-day maximum time limit for the sponsor to take adjustment action, make a refund, and initiate recovery. We established this time limit after an informal survey and discussions with Part D sponsors and their processors.

We noted in the October 22, 2009 proposed rule (74 FR 54663) that many of the post-adjudication adjustments, such as those that are due to enrollment changes, are changes that affect beneficiary cost sharing, premiums and plan benefit phase. Establishing a reasonable time limit for all Part D adjustment, refund, and recovery activity is in the beneficiaries' best interests because it ensures that required changes are effectuated on a timely basis, thus correcting retroactive and prospective beneficiary premium and cost-sharing amounts. Moreover, it is in the best interest of others who have paid a claim on the beneficiary's behalf because it ensures that these amounts are resolved timely.

For these reasons, we proposed at § 423.464 and § 423.466 to codify our previous policy guidance by proposing that sponsors must make retroactive claim adjustments and take other payer contributions into account as part of the coordination of benefits. Further, we proposed adding a new timeliness standard at § 423.466 to require adjustment and issuance of refunds or recovery notices within 45 days of the sponsor's receipt of the information necessitating the adjustment.

As part of making these proposed changes, we noted that, to date, most Part D coordination of benefits activity has been performed at point-of-sale or soon after, so pharmacy reversal and rebilling of claims can be accomplished within the payers' timely filing windows. For Part D, this window must be a minimum of 90 days, but for other (non-Part D) providers of prescription drug coverage the filing window could be as short as 30 days. However, we acknowledged that with the volatility of LIS data and Part D enrollments creating a significant volume of retroactive adjustments, Part D sponsors are facing more claims adjustments than current pharmacy claim reversal and rebilling approaches can adequately address.

In addition, we acknowledged issues regarding proprietary pricing information and the chilling effect that disclosure of this information might have upon the ability of pharmacies to negotiate with payors. To ensure the confidentiality of pricing information, coordination of benefits on the initial claim is accomplished without reporting complete information on negotiated pricing. The amount then reported in the (Nx) transaction to the Part D plan is the amount of the beneficiary payment after the supplemental payment. As a result, a Part D sponsor attempting to determine refund or recovery amounts without having the pharmacy reverse and rebill the original claim can generally only impute the amount of any supplemental payment made by another payer by determining the difference between the Part D cost-sharing and the beneficiary amount paid after the supplemental payment. The only alternative is to ask the pharmacy to reverse and rebill the claim to all payers. However, such a procedure would be generally impractical after the industry standard 30-day window because many supplemental payers will not accept the late claim.

In the absence of legal authority to compel supplemental payer cooperation and to avoid pharmacy underpayment, imposing a requirement on sponsors to nonetheless calculate a precise reimbursement or recovery liability would require the creation of a new payer-to-payer transaction that would both enable reprocessing and address pharmacies' concerns about revealing their proprietary pricing. However, as we noted in the proposed rule (74 FR 54663), it is not clear that both goals can be achieved. Nor is it clear that even if this conflict could be resolved, that the cost of doing so would be justified by the benefits.

Therefore, while simple adjustments involving just the Part D sponsor and the pharmacy are relatively straightforward (and can and should be promptly transacted), those involving other payers are not. We solicited comments on alternative approaches to improving post-adjudication coordination of benefits necessitated by retroactive Medicare enrollment and low-income subsidy changes when multiple payers are involved, as well as our assessment that the costs of achieving precision in such transactions may outweigh the benefits.

Our specific proposals to modify § 423.464 included the following changes:

• Revising paragraph (a) to clarify that all Part D sponsors must comply with administrative processes and requirements established by CMS to ensure effective coordination between Part D plans and other providers of prescription drug coverage for retroactive claims adjustments, underpayment reimbursements and overpayment recoveries; and

• Adding a new paragraph (g)(7) to address the sponsors' responsibility to account for payments by SPAPs and other providers of prescription drug coverage in reconciling retroactive claims adjustments that create overpayments and underpayments, as well as to account for payments made, and for amounts being held for payment, by other individuals or entities. The new paragraph would also specify that Part D sponsors must have systems to track and report adjustment transactions and to demonstrate that—

(1) Adjustments involving payments by other plans and programs providing prescription drug coverage have been made,

(2) Reimbursements for excess cost-sharing and premiums for LIS eligible individuals have been processed in accordance with the requirements in § 423.800(c), and

(3) Recoveries of erroneous payments for enrollees have been sought as specified in § 423.464(f)(4).

Except as otherwise provided below, after considering the comments received in response to the proposed rule, this final rule adopts the proposed changes to the retroactive claims adjustment reimbursement and recovery provisions in § 423.464 and § 423.466.

Comment: Multiple commenters agreed that the costs of achieving precision in retroactive COB transactions outweigh the benefits of creating specialized electronic transactions for calculating payer-to-payer claims adjustments. A number of these commenters offered recommendations to CMS in response to our request for alternative approaches to improving post-adjudication coordination of benefits, including establishing a process to notify supplemental payers when an Nx transaction was not generated and the Part D sponsor is making a retroactive adjustment to the primary amount paid.

Response: We appreciate the commenters' concurrence with our assessment that the costs to create a specialized transaction for retroactive claims adjustments outweigh the benefits and their recommendations for improving post-point-of-sale adjudication coordination of benefits. Until such time as any cost effective alternative approaches are identified, we will not require the development of payer-to-payer coordination of benefit transactions for retroactive claims adjustments. Instead, we will work with the industry to develop work-around solutions, such as imputing amounts to be reimbursed based on best available information, and will take the commenters' recommended approaches into consideration during that effort.

In the interim, the existing coordination of benefit requirements require sponsors to coordinate not only with beneficiaries, but also with SPAPs, other plans or programs providing prescription drug coverage and beneficiaries and other individuals or entities that have made payment on the beneficiaries' behalf. These requirements include coordination of benefits at point-of-sale, as well as retroactive claims adjustments necessitated by not only beneficiary changes, such as retroactive LIS eligibility determinations, LIS status changes or mid-year Part D enrollment changes, but also other payer changes, beneficiary submission of paper claims, etc. In addition, as discussed elsewhere in this rule, sponsors must have systems to track and report adjustment transactions and to process adjustments and issue refunds or recovery notices within 45 days of the sponsor's receipt of information necessitating a retroactive claims adjustment.

As specified in subregulatory guidance in the Medicare Prescription Drug Benefit Manual chapters on Coordination of Benefits and Premium and Cost-Sharing Subsidies for Low-Income Individuals, Part D sponsors should also: work with other providers of prescription drug coverage to resolve payment issues; have a process in place to handle payment resolution that is not restricted by implementation of timely filing requirements; make retroactive adjustments and promptly refund monies owed to the correct party (including, but not limited to, the beneficiary); and generally limit requests for pharmacy reprocessing to those situations where the total payment to the pharmacy changes. Coordination of benefits guidance also includes the need to transfer TrOOP and gross covered drug cost balances to the new plan whenever a beneficiary transfers enrollment between Part D sponsors during the coverage year. As discussed elsewhere in this final rule, sponsors have a 45-day maximum time limit from receipt of changes in the reported transfer data to make an adjustment and issue a refund or initiate recovery.

Comment: One commenter suggested that CMS establish an exception that would permit a Part D sponsor to refund the beneficiary directly without accounting for other payers if the net claims adjustment is $10 or less and there is no N transaction reporting another payer amount paid on the claim.

Response: We disagree with this suggestion. Although individual claims adjustments may not exceed the suggested threshold, cumulative amounts due to other payers (such as SPAPs) could be substantial. Additionally, the other payers would be unaware that a claim had been retroactively adjusted and that a refund was issued to the beneficiary. As a result, the other payers would not know to seek recovery from the beneficiary. Therefore, we continue to believe that sponsors must comply with the coordination of benefits requirements without regard to the monetary amount of the adjustment.

Comment: One commenter asked that we clarify in § 423.464 that p*harmacies holding copayments are exempt from the coordination of benefits requirements since they do not meet the definition of a plan or program providing prescription drug coverage. The commenter noted that t*his clarification will ensure that pharmacies recognize they are not a provider of prescription drug coverage, and are only entitled to reimbursement if the member should receive reimbursement and the pharmacy has attested that it is holding the member's cost-sharing amounts due and has not billed the member. Several other commenters requested that specific language be added to the regulations at either § 423.800(c), or § 423.464(g) and § 423.466(a), to clarify that the requirements, including the 45-day time period for issuing refunds or initiating recoveries due to retroactive adjustments, apply not only when a supplemental payer is involved, but also when a pharmacy is owed for cost-sharing initially withheld by the sponsor for LIS beneficiary claims.

Response: We agree that pharmacies are not providers of prescription drug coverage and, therefore, are not covered under § 423.464(g). However, it was our intention to apply the 45-day time limit to all retroactive adjustment regardless of whether a pharmacy alone, a pharmacy and the beneficiary, or a pharmacy, the beneficiary and another payer are involved. As a result, we are finalizing § 423.464(g) as proposed. In response to the concerns raised by the commenters regarding the application of the 45-day timeframe to pharmacies, in this final rule we are also amending § 423.800 to add a new paragraph (e) to make it clear that the 45-day timeframe

applies to adjustments involving pharmacies and beneficiaries, including LTC pharmacies holding cost-sharing amounts due. Generally, sponsors will reimburse the beneficiary for adjustments made to retail claims, but for full benefit dual-eligible individuals, in the absence of other information indicating the cost-sharing has been waived, the sponsor will reimburse the LTC pharmacy.

Comment: Several commenters argued that the 45-day time period for issuing reimbursement or initiating recovery should be changed to 90 days because of the various research and coordination issues that may need to be resolved with other stakeholders in the industry.

Response: We disagree with these commenters. We believe a 45-day period is more than sufficient to resolve any coordination of benefits issues and refund overpayments or institute recovery of underpayments resulting from the retroactive claims adjustments. As we stated in the proposed rule, we considered a 90-day time limit, but concluded that this longer timeframe was not in the best interests of beneficiaries because it would delay the payment of refunds and notification of the need for payment recovery. Moreover, we noted that as part of the automated transfer of TrOOP-related data, we established a 45-day maximum time limit for sponsors to take adjustment action, make a refund and initiate recovery. We further explained that we established this time limit after an informal survey and discussions with Part D sponsors and their processors. For these reasons, we continue to believe that a 45-day time limit represents a reasonable compromise. Therefore, we are finalizing the requirement as proposed.

13. Time Limits for Coordination of Benefits (§ 423.466)

In the October 22, 2009 proposed rule (74 FR 54664), we proposed to revise § 423.466 by adding a new paragraph (b) that would establish a 3-year time limit on Part D coordination of benefits. In making this proposed change, we noted that currently, there is no statutory or regulatory time limit for Part D sponsor coordination of benefits with SPAPs, other providers of prescription drug coverage, or other payers. Current CMS guidance as set forth in the Coordination of Benefits (COB) chapter of the Medicare Prescription Drug Benefit Manual only directs Part D sponsors to establish at least a 90-day timely claims filing window and to make appropriate allowances for COB claims on a case-by-case basis. The COB chapter also directs sponsors, in retroactive enrollment situations, to coordinate benefits with other payers as required by the regulations at § 423.464(f), as well as to accept claims from the beneficiary without imposing time limits. This chapter further states that sponsors, even in those situations when retroactive enrollment is not an issue, are liable for claims received after the end of the coverage year as defined in § 423.308 and that, while contract provisions regarding timely claims filing may limit claims from network pharmacies, non-network pharmacies and beneficiaries must still have the opportunity to submit claims for reimbursement without the imposition of time limits by the Part D sponsor.

We also noted the benefits to be derived from this proposed change. In addition to limiting sponsors' financial liability, a specified time limit would strengthen the ability of SPAPs, other providers of prescription drug coverage and other payers, including beneficiaries, to obtain payment for covered Part D drugs within that time frame. Moreover, we would benefit from a COB time limit because it would enable us to conduct reopening efficiently and on a predictable schedule.

In considering whether to establish time limits on the submission of claims to Part D sponsors by beneficiaries and other payers of prescription drug coverage for proper coordination of benefits, we noted that the Medicare FFS time limit for filing claims, as specified in § 424.44, is 15 to 27 months depending on the date that the item or service was furnished and that under certain circumstances these time limits may be extended an additional 6 months. We also noted that the Deficit Reduction Act of 2005 (Pub. L. 109–171) (DRA) amended section 1902(a)(25) of the Act, to provide for a 3-year time limit for States to seek recovery of Medicaid claims payments when the State is not the primary payer. Although this DRA provision does not address SPAPs and, therefore, does not impose a time limit on the requirement for Part D sponsors to coordinate benefits with SPAPs, it does establish the time limit for State Medicaid programs to recover from Part D plans.

Having considered these filing limit precedents, we proposed to establish a 3-year filing limit for Part D coordination of benefits with SPAPs, other entities providing prescription drug coverage, and all other payers, including beneficiaries or other individuals or (non-network) entities paying, or holding amounts for payment, on the beneficiaries' behalf. Specifically, we proposed to revise new § 423.466 by adding a new paragraph (b) that would establish a 3-year time limit on Part D coordination of benefits. Part D sponsors would be required to coordinate benefits with SPAPs, other entities providing prescription drug coverage, and other (non-network) payers for a period not to exceed 3 years from the date on which the prescription for the covered Part D drug was filled. Adding this provision to the regulation would clarify timely filing responsibilities and deadlines for all beneficiaries and payers, as well as place a limit on Part D sponsors' claims payment liabilities and coordination of benefits responsibilities.

As noted in our response to the comments below, after considering the comments received in response to this proposal, we continue to believe a 3-year time limit on Part D coordination of benefits is reasonable, and in this final rule, we are adopting the provision as proposed.

Comment: Two commenters expressed support for the establishment of a clear timeframe for coordination of benefits, and two others expressed agreement with the proposed 3-year time limit. A number of other commenters suggested alternative time limits of 2 years, 18 months or 1 year. The rationale cited by commenters for a shorter time period was that it would more closely align the COB time limit with the regulatory deadline for submission of Part D cost data, thereby reducing the number of payment reconciliation reopenings and curtailing the costs associated with maintaining open claims databases.

Response: We disagree that we should shorten the proposed coordination of benefits time limit. Other payers need time to seek reimbursement and sponsors need a clear limit in order to resolve claims for which they are responsible. We believe that a 3-year limit would permit CMS to address both needs. A timeframe that aligned with the regulatory deadline for submission of PDE data would allow only 6 months for submission of claims incurred late in the coverage year, a timeframe that we believe Part D experience to-date has demonstrated would not allow sufficient time for claim identification and subrogation. As we noted in the proposed rule, the 3-year limit is also aligned with the DRA timeframe, providing a uniform period for coordination of benefits for all payers, rather than creating different timeframes based on payer type (for example, SPAPs or other entities providing prescription drug coverage). This alignment will, in our view, ease administration for all parties.

Therefore, in the final rule, we adopt the requirement for Part D sponsors to coordinate benefits with SPAPs, other entities providing prescription drug coverage, and other (non-network) payers for a period not to exceed 3 years from the date on which the prescription for the covered Part D drug was filled. By the effective date of this final rule, the timeframe for coordination will have ended for claims for prescriptions filled any time in 2006, as well as for prescriptions filled in the early months of 2007. For example, a Part D sponsor would be responsible for coordinating benefits on a claim for a covered Part D drug filled on March 3, 2008 until March 3, 2011.

It is important to note that this final rule establishes a time limit for Part D sponsor liability for coordination of benefits with other payers and does not affect the timeframes for Part D sponsors to pursue Medicare secondary payer (MSP) claims and to recover amounts paid by the sponsor as primary when an MSP payer is identified. Such timeframes are separately identified in 42 CFR part 411.

Comment: One commenter stated the application of the DRA's health claim reimbursement rules and standards to prescription drugs is inequitable, because Part D claims processing, unlike health claims processing, is predominantly real-time. As a result, a 3-year submission window is not necessary.

Response: We disagree. Although no interpretive guidance has been issued on this provision, the plain reading of section 1902(a)(25)(J) of the Act encompasses all Medicaid claims, including claims for prescription drugs. As a result, we believe the application of this standard for Part D is appropriate.

Comment: One commenter recommended that CMS impose time limits for the payment of COB claims once filed with the Part D sponsor.

Response: This suggestion is outside the scope of the proposed rule. We can consider whether such a time limit is warranted and address the issue as appropriate in future rulemaking. However, we note that once a COB claim has been submitted, we expect Part D sponsors will make good faith efforts to promptly coordinate benefits with the submitter of the claim, whether an SPAP, another entity providing prescription drug coverage, a beneficiary or someone acting on his or her behalf, or another payer. Any payer that does not believe a Part D sponsor is making good faith efforts to coordinate claims on a timely basis should report the complaint to CMS.

14. Use of Standardized Technology Under Part D (§ 423.120)

Under the authority of section 1860D–4(b)(2)(A) of the Act, we proposed to revise our regulations at § 423.120(c)(3) to require Part D sponsors to contractually mandate that their network pharmacies submit claims electronically to the Part D sponsor or its intermediary on behalf of the beneficiary whenever feasible unless the enrollee expressly requests that a particular claim not be submitted to the Part D sponsor or its intermediary.

As we noted in the October 22, 2009 proposed rule (74 FR 54665), the only way that an enrollee can be assured access to the negotiated price at the point of sale is through online adjudication of the prescription drug claim. Any other price available to the beneficiary at the point of sale cannot be deemed to be the negotiated price mandated under section 1860D–2(d) of the Act. Therefore, to ensure access to these negotiated prices, billing information on the NCPDP "Pharmacy ID Card Standard", which is the standard for identification cards for the Part D program, must be used by the pharmacies filling the beneficiaries' prescriptions to submit claims to the Part D sponsor (or its intermediary).

We noted that CMS guidance set forth in the Coordination of Benefits Chapter of the Prescription Drug Plan Manual (in section 50.4 entitled, "Processing Claims and Tracking TrOOP"), instructs plan sponsors to process all claims online real-time. The requirements of accurate TrOOP accumulations, Part D benefit administration of multiple coverage intervals, and coordination of benefits with other payers all necessitate online real-time adjudication of individual pharmacy claims. This guidance states further that we expect that Part D plan sponsors will establish policies and procedures appropriately restricting the use of paper claims to those situations in which on-line claims processing is not available to the beneficiary at the point of sale in order to promote accurate TrOOP accounting, as well as to minimize administrative costs to the Part D plans and the Medicare program and reduce opportunities for fraudulent duplicative claim reimbursements. We proposed to revise § 423.120(c)(3) to require Part D sponsors to contractually mandate that their network pharmacies submit claims electronically to the Part D sponsor or its intermediary on behalf of the beneficiary whenever feasible unless the enrollee expressly requests that a particular claim not be submitted to the Part D sponsor or its intermediary.

We proposed to codify this guidance in regulation because we have been made aware of an increasing number of instances in which network pharmacies are not submitting pharmacy claims to Part D Sponsors on behalf of Part D enrollees. Generally, we believe it is in the best interest of Part D enrollees to have their claims consistently processed through the Part D sponsor (or its intermediary). Not only does processing claims through the Part D sponsor ensure access to Part D negotiated prices, but it also ensures that proper concurrent drug utilization review (including safety checks) is performed. In addition, online, real-time processing facilitates accurate accounting for enrollees' true out-of-pocket (TrOOP) and total drug costs by the Part D sponsor so that each claim is processed in the appropriate phase of the benefit and accurate cost sharing assessed.

We also proposed to add a new paragraph (c)(2) to § 423.120 to codify our existing guidance that Part D sponsors utilize standard electronic transactions established by 45 CFR 162.1102 for processing Part D claims. We noted that we would issue guidance on the use of optional or conditional fields in the HIPAA standard transactions through the Call Letter and Prescription Drug Benefit Manual instructions. We noted further that we routinely work with NCPDP and industry representatives in arriving at recommendations for standardized use of such fields when necessary to improve administration of the Part D benefit.

Finally, noting that pharmacies cannot routinely distinguish Medicare Part D claims from other types of prescription drug coverage when the same routing information ("RxBIN and RxPCN") is used for all lines of business managed by a single processor, we also proposed to add a new paragraph (c)(4) in § 423.120 to require that sponsors and their intermediary processors establish and exclusively utilize unique RxBIN or "RxBIN/RxPCN combinations" to identify all Medicare Part D member claims, as well as to assign unique "RxID" identifiers to individual Part D beneficiaries. We solicited comments on the operational issues and timelines that would be involved in making these proposed technical changes to claims processing systems.

After reviewing the comments received in response to these proposals, we are adopting these provisions with some modification. Specifically, we revised § 423.120(c)(4) to specify that effective on January 1, 2012 sponsors assign and exclusively use unique Part D identifiers. Exclusive use of these

Prescription Drug Event Record Layout

HDR RECORD

FIELD NO.	FIELD NAME	NCPDP FIELD	POSITION	PICTURE	LENGTH	NCPDP, CMS OR PDFS DEFINED	DEFINITION / VALUES
1	RECORD ID		1 - 3	X(3)	3	PDFS	"HDR"
2	SUBMITTER ID		4 - 9	X(6)	6	CMS	Unique ID assigned by CMS.
3	FILE ID		10 - 19	X(10)	10	PDFS	Unique ID provided by Submitter. Same ID cannot be used within 12 months.
4	TRANS DATE		20 - 27	9(8)	8	PDFS	Date of file transmission to PDFS.
5	PROD TEST CERT IND		28 - 31	X(4)	4	PDFS	TEST, CERT or PROD
6	FILLER		32 - 512	X(481)	481		SPACES

BHD RECORD

FIELD NO.	FIELD NAME	NCPDP FIELD	POSITION	PICTURE	LENGTH	NCPDP, CMS OR PDFS DEFINED	DEFINITION / VALUES
1	RECORD ID		1 - 3	X(3)	3	PDFS	"BHD"
2	SEQUENCE NO		4 - 10	9(7)	7	PDFS	Must start with 0000001
3	CONTRACT NO		11 - 15	X(5)	5	CMS	Assigned by CMS
4	PBP ID		16 - 18	X(3)	3	CMS	Assigned by CMS
5	FILLER		19 - 512	X(494)	494		SPACES

DET RECORD

FIELD NO.	FIELD NAME	NCPDP FIELD	POSITION	PICTURE	LENGTH	NCPDP, CMS OR PDFS DEFINED	DEFINITION / VALUES
1	RECORD ID		1 - 3	X(3)	3	PDFS	"DET"
2	SEQUENCE NO		4 - 10	9(7)	7	PDFS	Must start with 0000001
3	CLAIM CONTROL NUMBER		11 - 50	X(40)	40	CMS	Optional Field
4	HEALTH INSURANCE CLAIM NUMBER (HICN)		51 - 70	X(20)	20	CMS	Medicare Health Insurance Claim Number or Railroad Retirement Board (RRB) number.
5	CARDHOLDER ID	302-C2	71 - 90	X(20)	20	NCPDP	Plan identification of the enrollee. Assigned by plan.
6	PATIENT DATE OF BIRTH (DOB)	304-C4	91 - 98	9(8)	8	NCPDP	CCYYMMDD Optional Field
7	PATIENT GENDER CODE	305-C5	99 - 99	9(1)	1	NCPDP	1 = M 2 = F Unspecified or unknown values are not accepted
8	DATE OF SERVICE (DOS)	401-D1	100 - 107	9(8)	8	NCPDP	CCYYMMDD
9	PAID DATE		108 - 115	9(8)	8	CMS	CCYYMMDD, The date the plan paid the pharmacy for the prescription drug. Mandatory for Fallback plans , Optional for all other plans
10	PRESCRIPTION SERVICE REFERENCE NO	402-D2	116 - 124	9(9)	9	NCPDP	The field length is 9 to accommodate proposed future NCPDP standard. Under 5.1 right justify and fill with 2 leading zeros. When plans compile PDEs from non-standard formats, the plans must assign a unique reference number if necessary. A reference number must be unique for any DOS and Service Provider ID combination.
11	FILLER		125 - 126	X(2)	2		SPACES

FIELD NO.	FIELD NAME	NCPDP FIELD	POSITION	PICTURE	LENGTH	NCPDP, CMS OR PDFS DEFINED	DEFINITION / VALUES
12	PRODUCT SERVICE ID	407-D7 or 489-TE	127 - 145	X(19)	19	NCPDP	DDPS accepts NDC only. Do not report HRI or UPC codes. Fill the first 11 positions, no spaces or hyphens, followed by 8 spaces. Format is MMMMMDDDDPP. If Compound Code (field 17) = 2 (Compound) and the NCPDP Compound Segment is used in claims processing, the Product Service ID (field 12) contains the NDC of the most expensive Part D covered drug from the Compound Product ID (489-TE) occurrences. If Compound Code (field 17) = 2 (Compound) and the Compound Segment is not used in claims processing, the Product Service ID (field 12) contains the NDC from the Product/Service ID (407-D7) from the NCPDP Claim Segment. DDPS will reject the following billing codes for compounded legend and/or scheduled drugs: 99999999999, 99999999992, 99999999993, 99999999994, 99999999995, and 99999999996.
13	SERVICE PROVIDER ID QUALIFIER	202-B2	146 - 147	X(2)	2	NCPDP	Mandatory for Standard Format The type of pharmacy provider identifier used in field 14. 01 = National Provider Identifier (NPI) 06 = UPIN 07 = NCPDP Number 08 = State License 11 – Federal Tax Number 99 – Other For Non-Standard formats any of the above values are acceptable. For Standard Data Format, valid values are 01 – NPI or 07 – NCPDP Provider ID
14	SERVICE PROVIDER ID	201-B1	148 - 162	X(15)	15	NCPDP	When Plans report Service Provider ID Qualifier = '99' - Other, populate Service Provider ID with the default value "PAPERCLAIM" defined for TrOOP Facilitation Contract. When Plans report Federal Tax Number (TIN), use the following format: ex: 999999999 (do not report embedded dashes)
15	FILL NUMBER	403-D3	163 - 164	9(2)	2	NCPDP	Values = 0 - 99. If unavailable, use 0.
16	DISPENSING STATUS	343-HD	165 -165	X(1)	1	NCPDP	Blank = Not Specified P = Partial Fill C = Completion of Partial Fill

FIELD NO.	FIELD NAME	NCPDP FIELD	POSITION	PICTURE	LENGTH	NCPDP, CMS OR PDFS DEFINED	DEFINITION / VALUES
17	COMPOUND CODE	406-D6	166 - 166	9(1)	1	NCPDP	0=Not specified 1=Not a Compound 2=Compound
18	DISPENSE AS WRITTEN (DAW) PRODUCT SELECTION CODE	408-D8	167 - 167	X(1)	1	NCPDP	0=No Product Selection Indicated 1=Substitution Not Allowed by Prescriber 2=Substitution Allowed - Patient Requested Product Dispensed 3=Substitution Allowed - Pharmacist Selected Product Dispensed 4=Substitution Allowed - Generic Drug Not in Stock 5=Substitution Allowed - Brand Drug Dispensed as Generic 6=Override 7=Substitution Not Allowed - Brand Drug Mandated by Law 8=Substitution Allowed Generic Drug Not Available in Marketplace 9=Other
19	QUANTITY DISPENSED	442-E7	168 - 177	9(7)V999	10	NCPDP	Number of Units, Grams, Milliliters, other. If compounded item, total of all ingredients will be supplied as Quantity Dispensed.
20	DAYS SUPPLY	405-D5	178 - 180	9(3)	3	NCPDP	0 – 999
21	PRESCRIBER ID QUALIFIER	466-EZ	181 - 182	X(2)	2	NCPDP	The type of prescriber identifier used in field 22. 01 = National Provider Identifier (NPI when implemented) 06 = UPIN 08 = State License Number 12 = Drug Enforcement Administration (DEA) number Mandatory for Standard Format. Optional when non-standard data format = ‘B’, ‘C’, ‘P’, or ‘X’

FIELD NO.	FIELD NAME	NCPDP FIELD	POSITION	PICTURE	LENGTH	NCPDP, CMS OR PDFS DEFINED	DEFINITION / VALUES
22	PRESCRIBER ID	411-DB	183 - 197	X(15)	15	NCPDP	Mandatory for Standard Format. Mandatory for non-standard data format when Prescriber ID Qualifier is present and valid. Optional when non-standard data format = 'B', 'C', 'P', or 'X' when Prescriber ID Qualifier is not present
23	DRUG COVERAGE STATUS CODE		198 - 198	X(1)	1	CMS	Coverage status of the drug under part D and/or the PBP. C = Covered E = Supplemental drugs (reported by Enhanced Alternative plans only) O = Over-the-counter drugs
24	ADJUSTMENT DELETION CODE		199 - 199	X(1)	1	CMS	A = Adjustment D = Deletion Blank = Original PDE
25	NON- STANDARD FORMAT CODE		200 - 200	X(1)	1	CMS	Format of claims originating in a non-standard format. B = Beneficiary submitted claim C = COB claim P = Paper claim from provider X = X12 837 Blank = NCPDP electronic format
26	PRICING EXCEPTION CODE		201 - 201	X(1)	1	CMS	M = Medicare as Secondary Payer O = Out-of-network pharmacy Blank = In-network pharmacy and Medicare Primary
27	CATASTROPHIC COVERAGE CODE		202 - 202	X(1)	1	CMS	A = Attachment Point met on this event C = Above Attachment Point Blank = Attachment Point Not Met
28	INGREDIENT COST PAID	506-F6	203 - 210	S9(6)V99	8	NCPDP	Amount the pharmacy is paid for the drug itself. Dispensing fees or other costs are not included in this amount.
29	DISPENSING FEE PAID	507-F7	211 - 218	S9(6)V99	8	NCPDP	Amount the pharmacy is paid for dispensing the medication. The fee may be negotiated with pharmacies at the plan or PBM level. Additional fees may be charged for compounding/mixing multiple drugs. Do not include administrative fees. Vaccine Admin. Fee reported in Field 40
30	TOTAL AMOUNT ATTRIBUTED TO SALES TAX		219 - 226	S9(6)V99	8	CMS	Depending on jurisdiction, Sales Tax may be calculated in different ways or reported in multiple NCPDP fields. Plans will report the total sales tax for the PDE irregardless of how the tax is calculated or reported at point-of-sale.

FIELD NO.	FIELD NAME	NCPDP FIELD	POSITION	PICTURE	LENGTH	NCPDP, CMS OR PDFS DEFINED	DEFINITION / VALUES
31	GROSS DRUG COST BELOW OUT- OF-POCKET THRESHOLD (GDCB)		227 - 234	S9(6)V99	8	CMS	When the Catastrophic Coverage Code = blank, this field equals the sum of Ingredient Cost Paid + Dispensing Fee Paid + Total Amount Attributed to Sales Tax+ Vaccine Admin Fee. When the Catastrophic Coverage Code = A this field equals the portion of Ingredient Cost Paid + Dispensing Fee Paid + Total Amount Attributed to Sales Tax+ Vaccine Admin Fee falling at or below the OOP threshold. The remaining portion is reported in GDCA.
32	GROSS DRUG COST ABOVE OUT-OF-POCKET THRESHOLD (GDCA)		235 - 242	S9(6)V99	8	CMS	When the Catastrophic Coverage Code = 'C', this field equals the sum of Ingredient Cost Paid + Dispensing Fee Paid + Total Amount Attributed to Sales Tax + Vaccine Admin. Fee above the OOP threshold. When the Catastrophic Coverage Code = 'A' this field equals the portion of Ingredient Cost Paid + Dispensing Fee Paid + Total Amount Attributed to Sales Tax + Vaccine Admin Fee falling above the OOP threshold. The remaining portion is reported in GDCB.
33	PATIENT PAY AMOUNT	505-F5	243 - 250	S9(6)V99	8	NCPDP	Payments made by the beneficiary or by family or friends at point of sale. These amounts count towards a beneficiary's TrOOP costs.
34	OTHER TROOP AMOUNT		251 - 258	S9(6)V99	8	CMS	Other health insurance payments by TrOOP-eligible other payers. This field records all third party payments that contribute to a beneficiary's TrOOP, i.e. all TrOOP eligible payments except LICS and Patient Pay Amount. Examples: payments made on behalf of a beneficiary by charities or qualified SPAPs.
35	LOW INCOME COST SHARING SUBSIDYAMOUNT (LICS)		259 - 266	S9(6)V99	8	CMS	Amount the plan reduced patient liability due to a beneficiary's LICS status. The MMA provides for Medicare payments to plans to subsidize the cost-sharing liability of qualifying low-income beneficiaries at the point of sale. This amount counts towards a beneficiary's TrOOP costs.

FIELD NO.	FIELD NAME	NCPDP FIELD	POSITION	PICTURE	LENGTH	NCPDP, CMS OR PDFS DEFINED	DEFINITION / VALUES
36	PATIENT LIABILITY REDUCTION DUE TO OTHER PAYER AMOUNT (PLRO)		267 - 274	S9(6)V99	8	CMS	Amounts by which patient liability is reduced due to payment by other payers that are not TrOOP-eligible and do not participate in Part D. Examples of non-TrOOP-eligible payers: group health plans, governmental programs (e.g. VA, TRICARE), Workers' Compensation, Auto/No-Fault/Liability Insurances.
37	COVERED D PLAN PAID AMOUNT (CPP)		275 - 282	S9(6)V99	8	CMS	The net Medicare covered amount which the plan has paid for a Part D covered drug under the Basic benefit. Amounts paid for supplemental drugs, supplemental cost-sharing and over-the-Counter drugs are excluded from this field.
38	NON COVERED PLAN PAID AMOUNT (NPP)		283 - 290	S9(6)V99	8	CMS	The amount of plan payment for enhanced alternative benefits (cost sharing fill-in and/or non-Part D drugs). This dollar amount is excluded from risk corridor calculations and TrOOP accumulation.
39	ESTIMATED REBATE AT POS		291 -298	S9(6)V99	8	CMS	The estimated amount of rebate that the plan sponsor has elected to apply to the negotiated price as a reduction in the drug price made available to the beneficiary at the point of sale. This estimate should reflect the rebate amount that the plan sponsor reasonably expects to receive from a pharmaceutical manufacturer or other entity.
40	VACCINE ADMINISTRATION FEE		299-306	S9(6)V99	8	CMS	The fee reported by a pharmacy, physician, or provider to cover the cost of administering a vaccine, excluding the ingredient cost and dispensing fee
41	PRESCRIPTION ORIGIN CODE	419-DJ	307-307	X(1)	1	NCPDP	'0'=Not Specified '1'=Written '2'=Telephone '3'=Electronic '4'=Facsimile <Blank>
42	FILLER		308-512	X(205)	205	CMS	SPACES

Notes:
For any field that references NCPDP values, please refer to the appropriate NCPDP specification to ensure compliance.
All dollar fields are mandatory. If the field is not applicable, report a default value of zeroes. Since the field is a signed field, plans must utilize the appropriate overpunch signs as specified in the *NCPDP Telecommunications Standard, Version 5.1.*

BTR RECORD

FIELD NO.	FIELD NAME	NCPDP FIELD	POSITION	PICTURE	LENGTH	NCPDP, CMS OR PDFS DEFINED	DEFINITION / VALUES
1	RECORD ID		1 - 3	X(3)	3	PDFS	"BTR"
2	SEQUENCE NO		4 - 10	9(7)	7	PDFS	Must start with 0000001
3	CONTRACT NO		11 - 15	X(5)	5	CMS	Must match BHD
4	PBP ID		16 - 18	X(3)	3	CMS	Must match BHD
5	DET RECORD TOTAL		19 - 25	9(7)	7	CMS	Total count of DET records
6	FILLER		26 -512	X(487)	487	CMS	SPACES

TLR RECORD

FIELD NO.	FIELD NAME	NCPDP FIELD	POSITION	PICTURE	LENGTH	NCPDP, CMS OR PDFS DEFINED	DEFINITION / VALUES
1	RECORD ID		1 - 3	X(3)	3	PDFS	"TLR"
2	SUBMITTER ID		4 - 9	X(6)	6	CMS	Must match HDR
3	FILE ID		10 - 19	X(10)	10	PDFS	Must match HDR
4	TLR BHD RECORD TOTAL		20 - 28	9(9)	9	CMS	Total count of BHD records
5	TLR DET RECORD TOTAL		29 - 37	9(9)	9	CMS	Total count of DET records
6	FILLER		38 -512	X(475)	475	CMS	SPACES

Note:
Maximum number of detail records per file is 3 million records. If one file contains multiple batches, maximum record count applies to the cumulative total across all batches.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Center for Medicare
Medicare Plan Payment Group

Date: March 23, 2011

To: All Part D Plan Sponsors

From: Cheri Rice, Acting Director, Medicare Plan Payment Group

Subject: Extension of the Submission Deadline for Benefit Year 2010 Prescription Drug Event Data

The Centers for Medicare & Medicaid Services is announcing the extension of the Prescription Drug Event (PDE) submission deadline for inclusion in the benefit year 2010 Part D payment reconciliation. The submission deadline has been has been extended for benefit year 2010 PDE data from May 31, 2011 to June 29, 2011, midnight ET.

As in previous years, CMS will continue to accept 2010 PDEs after the submission deadline, but any PDE data received after the deadline will not be included in the 2010 reconciliation. In addition, CMS will not accept 2010 Plan-to-Plan (P2P) PDEs after the June 29, 2011 deadline as P2P PDEs can alter the financial values of other Part D contracts after reconciliation has been completed.

Please keep in mind that correct payment for the Part D drug benefit and the accuracy of the Part D payment reconciliation depends on the accurate and timely submission of PDEs by Part D plans. The June 29, 2011 deadline is final and will not be extended again.

For any questions regarding this memorandum, please contact Tara Waters at Tara.Waters@cms.hhs.gov.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Center for Medicare

TO: All Medicare Advantage Organizations

FROM: Cheri Rice
Acting Director, Medicare Plan Payment Group

DATE: February 3, 2011

SUBJECT: CMS Response to Risk Adjustment Data Validation (RADV) Sampling and Payment Error-Calculation Methodology Questions

On Tuesday, December 21, 2010, CMS posted a description of the Agency's proposed draft RADV sampling and payment error calculation methodology on our website at https://www.cms.gov/HealthPlansGenInfo/ and invited public comment on this document. To date, we have received comments on a variety of topics, including a proposed FFS adjuster and RADV audit documentation standards. We are thoroughly evaluating all comments and anticipate making changes to our draft, based on input we received. We anticipate the final revised RADV sampling and payment error calculation methodology paper will be issued in the near future. CMS also plans to issuena question and answer document that summarizes the comments received on the RADV methodology and the Agency's response to those comments.

Please direct questions regarding this memorandum to the RADV email address: RADV@cms.hhs.gov

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S3-16-16
Baltimore, Maryland 21244-1850

Center for Beneficiary Choices

Date: April 2, 2007

To: Prescription Drug Plan Sponsors, Medicare Advantage Organizations, and Other Interested Parties

From: Abby L. Block
Director
Center for Beneficiary Choices

Subject: Notification of Changes in Medicare Part D Payment for Calendar Year 2008 (Part D Payment Notification)

This memo describes changes in the payment methodologies applied under Part D of the Act for Calendar Year (CY) 2008. The key changes in Part D payment methodologies for 2008 include: updated benefit parameters for the defined standard benefit and the Retiree Drug Subsidy (RDS); calculations of the national average monthly bid amount and the regional low-income benchmark premium amounts; normalization of the Part D risk adjustment model; and statutory changes in the risk corridors. This information applies to all Prescription Drug Plan (PDP) Sponsors, Medicare Advantage Organizations and others offering prescription drugs under Part D. Any changes to employer/union-only group waiver plan payment for 2008 will be issued in separate guidance. This memo is a key element of the information that CMS is providing to help organizations bid for the upcoming contract year.

Further Information

If you have specific questions about any of these changes, please contact Meghan Elrington at 410-786-8675 or Deondra Moseley at 410-786-4577.

2008 Part D Payment Notification
Table of Contents

I. Benefit Design

Section A. Medicare Part D Benefit Parameters: Annual Adjustments for Defined Standard Benefit in 2008

In accordance with section 1860D-2(b) of the Social Security Act (the Act), CMS must update the statutory parameters for the defined standard Part D prescription drug benefit each year. These parameters include the annual deductible, initial coverage limit, annual out-of-pocket threshold, and minimum copayments for costs above the annual out-of-pocket threshold. As required by statute, the parameters for the defined standard benefit are indexed to the percentage increase in average per capita total Part D drug expenses for Medicare beneficiaries. Accordingly, the actuarial value of the drug benefit increases along with any increase in Part D drug expenses, and the defined standard Part D benefit continues to cover a constant share of Part D drug expenses from year to year. All of the Part D benefit parameters are updated using one of two indexing methods specified by statute: (i) the annual percentage increase in average expenditures for Part D drugs per eligible beneficiary or the "annual percentage increase", and (ii) the annual percentage increase in the Consumer Price Index (CPI) (all items, U.S. city average).

The first indexing method, the "annual percentage increase", is used to update the following Part D benefit parameters:

(i) the deductible, initial coverage limit, and out-of-pocket threshold for the defined standard benefit,
(ii) minimum copayments for costs above the annual out-of-pocket threshold,
(iii) maximum copayments below the out-of-pocket threshold for certain low-income full subsidy eligible enrollees,
(iv) the deductible for partial low-income subsidy (LIS) eligible enrollees, and
(v) maximum copayments above the out-of-pocket threshold for partial LIS eligible enrollees.

The benefit parameters listed above will be increased by 4.64% for 2008 as summarized by Table 1 below. This increase reflects the 2007 annual percentage trend of 6.19% as well as a multiplicative update of -1.47% for prior year revisions. Please see Appendix 1 for additional information on the calculation of the annual percentage increase.

Per 42 CFR 423.886(b)(3), the cost threshold and cost limit for qualified retiree prescription drug plans are updated after 2006 in the same manner as the deductible and out-of-pocket threshold for the defined standard benefit. Thus, the "annual percentage increase" will be used to update these parameters as well. The cost threshold and cost limit for qualified retiree prescription drug plans will be increased by 4.64% from their 2007 values.

The second indexing method, the annual percentage increase in the CPI, is used to update the maximum copayments below the out-of-pocket threshold for full benefit dual eligible enrollees with incomes that do not exceed 100% of the Federal poverty line. These maximum copayments will be increased by 2.42% for 2008 as summarized in Table 1 below. This increase reflects the 2007 annual percentage trend in CPI of 2.17%, as well as a multiplicative update of 0.25% for prior year revisions. Please see Appendix 1 for additional information on the calculation of the annual percentage increase in the CPI.

Table 1. Updated Part D Benefit Parameters for Defined Standard Benefit, Low-Income Subsidy, and Retiree Drug Subsidy

Annual Percentage Increases			
	Annual percentage trend for 2007	Prior year revisions	Annual percentage increase for 2007
Applied to all parameters but (1)	6.19%	-1.47%	4.64%
CPI (all items, U.S. city average): Applied to (1)	2.17%	0.25%	2.42%

Part D Benefit Parameters	2007	2008
Standard Benefit Design Parameters		
Deductible	$265	$275
Initial Coverage Limit	$2,400	$2,510
Out-of-Pocket Threshold	$3,850	$4,050
Total Covered Part D Drug Spend at OOP Threshold (2)	$5,451.25	$5,726.25
Minimum Cost-sharing in Catastrophic Coverage Portion of Benefit		
Generic/Preferred Multi-Source Drug	$2.15	$2.25
Other	$5.35	$5.60
Part D Full Benefit Dual Eligible Parameters		
Copayments for Institutionalized Beneficiaries	$0.00	$0.00
Maximum Copayments for Non-Institutionalized Beneficiaries		
Up to or at 100% FPL		
Up to Out-of-Pocket Threshold (1)		
Generic/Preferred Multi-Source Drug (3)	$1.00	$1.05
Other (3)	$3.10	$3.10
Above Out-of-Pocket Threshold	$0.00	$0.00
Over 100% FPL		
Up to Out-of-Pocket Threshold		
Generic/Preferred Multi-Source Drug	$2.15	$2.25
Other	$5.35	$5.60
Above Out-of Pocket Threshold	$0.00	$0.00
Part D Non-Full Benefit Dual Eligible Full Subsidy Parameters		
Resources ≤ $6,120 (individuals) or ≤ $9,190 (couples) (4)		
Maximum Copayments up to Out-of-Pocket Threshold		
Generic/Preferred Multi-Source Drug	$2.15	$2.25
Other	$5.35	$5.60
Maximum Copayments above Out-of-Pocket Threshold	$0.00	$0.00
Resources bet $6,120-$10,210 (ind) or $9,190-$20,410 (couples) (4)		
Deductible (3)	$53.00	$56.00
Coinsurance up to Out-of-Pocket Threshold	15%	15%
Maximum Copayments above Out-of-Pocket Threshold		
Generic/Preferred Multi-Source Drug	$2.15	$2.25
Other	$5.35	$5.60
Part D Non-Full Benefit Dual Eligible Partial Subsidy Parameters		
Deductible (3)	$53.00	$56.00
Coinsurance up to Out-of-Pocket Threshold	15%	15%
Maximum Copayments above Out-of-Pocket Threshold		
Generic/Preferred Multi-Source Drug	$2.15	$2.25
Other	$5.35	$5.60
Retiree Drug Subsidy Amounts		
Cost Threshold	$265	$275
Cost Limit	$5,350	$5,600

(1) CPI adjustment applies to copayments for non-institutionalized beneficiaries up to or at 100% FPL.
(2) Amount of total drug spending required to attain out-of-pocket threshold in the defined standard benefit if beneficiary does not have prescription drug coverage through a group health plan, insurance, government-funded health program or similar third party arrangement.
(3) The increases to the LIS deductible, generic/preferred multi-source drugs and other drugs copayments are applied to the unrounded 2007 values of $53.43, $1.02 and $3.05, respectively.
(4) The actual amount of resources allowable will be updated for contract year 2008.

Section B. Reporting Drug Costs When Contracting with a Pharmacy Benefit Manager (PBM)

On July 20, 2006, CMS issued the memo "Modified Q&A Addressing Drug Costs Reported on Prescription Drug Events (PDEs)", which addressed how Part D sponsors should report drug costs to CMS. In this memo, CMS stated that a Part D Sponsor that uses a PBM may use either the lock-in amount or the pass-through amount as the basis for calculating beneficiary cost-sharing and gross covered drug costs throughout the benefit, as well as reporting drug costs on EOBs and PDE records.

In addition, we stated our intent to issue a Notice of Proposed Rulemaking proposing that the pass through model be the only acceptable methodology for 2008 and beyond. CMS is currently preparing this Notice of Proposed Rulemaking and we are committed to providing the public with sufficient time to comment on this proposed policy. However, we are aware that given the time required for public comment and to issue the final rule, Part D sponsors will not have sufficient time after the release of the final rule to prepare their 2008 bids in accordance with the policies established in this rule. Therefore, CMS intends to propose a single approach to determining beneficiary cost-sharing and gross covered drug costs, and for reporting drug costs to CMS, for 2009 instead of 2008 as indicated in the July 20th memo.

Therefore, for plan year 2008 as in 2006 and 2007, Part D sponsors that use a PBM may apply either the pass through or lock-in pricing approach when calculating cost-sharing and reporting drug costs. Part D sponsors must choose only one approach and cannot switch between them for purposes of calculating cost-sharing and reporting drug costs. Thus, the chosen pricing approach must be used consistently as a basis for: (i) calculating beneficiary cost-sharing; (ii) accumulating gross covered drug costs; (iii) calculating TrOOP; (iv) reporting drug costs on the Prescription Drug Event (PDE) records; and (v) developing bids submitted to CMS.

To ensure transparency in bid development, all plans will be required to submit an actuarial attestation, through HPMS and hardcopy, which identifies the pricing approach (lock-in or pass through) that was used in the development of each 2008 bid. Additional information regarding this attestation will be issued in future guidance.

II. Bidding

Section A. Calculation of the National Average Monthly Bid Amount

Beginning in 2007, section 1860D-13(a)(4)(B) of the Act directs CMS to calculate the national average monthly bid amount each year as a weighted average of the standardized bid amounts for each prescription drug plan (PDP) and Medicare Advantage Prescription Drug Plan (MA-PD) described in section 1851(a)(2)(A)(i) of the Act. It is weighted based on each plan's prior enrollment as a percentage of all Part D eligible individuals enrolled in these plans. Bids submitted by MSA plans, PFFS plans, SNP plans, PACE plans, Cost plans, and Fallback plans are not included in this calculation.

When calculating the national average monthly bid amount for contract year 2006, CMS assigned equal weighting to PDP sponsors, under section 1860D-13(a)(4)(B)(ii), because CMS

did not have prior enrollment for these Part D plans. MA-PD plans were assigned a weight based on their prior MA enrollments and new MA-PD plans were assigned zero weight.

In 2007, CMS began a transition from the 2006 method of calculating the national average monthly bid amount to the weighted average method based on actual plan enrollments under the "Medicare Demonstration to Limit Annual Changes in Part D Premiums Due to Beneficiary Choice of Low-Cost Plans". Under the demonstration, the national average monthly bid amount for 2007 is a composite of (i) a weighted average calculated using the 2006 weighting methodology and (ii) a weighted average calculated based on actual plan enrollments. In 2007, 80% of the national average monthly bid amount was based on the 2006 averaging methodology and 20% was based on the enrollment-weighted average. When the demonstration program cited above ends, the national average monthly bid amount will be a weighted average based on prior enrollment.

To continue the transition from the 2006 method of calculating the national average monthly bid amount to the enrollment-weighted average method, CMS is amending this demonstration to extend it for 2008. In 2008, 40% of the national average monthly bid amount will be based on the 2006 averaging methodology and 60% will be based on the enrollment-weighted average. The 2008 national average monthly bid amount and the reference month for the plan enrollment used to determine the enrollment-weighted average will be provided in future guidance after the June bid submission deadline.

Section B. Calculation of the Low-Income Benchmark Premium Amount

Section 1860D-14(b)(2) of the Act directs CMS to calculate annually the low-income benchmark premium amount for each PDP region. The low-income benchmark premium amount for each PDP region is determined by calculating a weighted average of the monthly beneficiary premiums for PDPs offering basic prescription drug coverage in the PDP region, the portion of the monthly beneficiary premium attributable to basic prescription drug coverage for PDPs offering enhanced alternative coverage in the PDP region, and the MA monthly prescription drug beneficiary premium for MA-PD plans in the PDP region, with the weighting based on plan enrollment. PACE, private fee-for-service plans, MSA plans, and section 1876 cost plans are not included in this calculation.

In determining the 2006 low-income benchmark premium amounts, PDPs were weighted equally as CMS did not have prior enrollment data for these Part D plans, and MA-PD plans were assigned a weight based on prior enrollment as of March 31, 2005. New MA-PD plans were assigned a zero weight.

In 2007, under the "Medicare Demonstration to Transition Enrollment of Low Income Subsidy Beneficiaries," CMS calculated the regional low-income benchmark premium amounts using the same weighting methodology applied in 2006, i.e., all PDP bids were weighted equally, and MA-PD bids received weights based on plan enrollments in the reference month (June 2006).

CMS is amending the "Medicare Demonstration to Transition Enrollment of Low Income Subsidy Beneficiaries" so that it is extended to 2008. Starting in 2008, CMS will conduct a

transition from the 2006 methodology for calculating the regional low-income benchmark premium amounts to the methodology set forth at 42 CFR 423.780(b)(2), which requires calculation of a weighted-average based on actual plan enrollments. During the transition, the regional low-income benchmark premium amounts will be a composite of two different calculations: (1) a weighted average calculated using the 2006 weighting methodology, and (2) a weighted average calculated based on actual plan enrollments for both PDPs and MA-PD plans. In 2008, 50% of the regional low-income benchmark amount will be based on the 2006 weighting methodology and 50% will be based on the enrollment-weighted average. When the demonstration program cited above ends, the regional low-income benchmark premium amounts will be a weighted average based on prior enrollment in accordance with the methodology set forth at 42 CFR 423.780(b)(2).

Under the "Medicare Demonstration to Transition Enrollment of Low-Income Subsidy Beneficiaries," in 2007 Part D plans are required to charge full subsidy eligible beneficiaries a monthly beneficiary premium equal to the applicable low-income benchmark premium amount, if the plan's monthly beneficiary premium attributable to basic prescription drug coverage exceeds the low-income benchmark premium amount by $2 or less (the "*de minimis* amount"). CMS is amending the demonstration and extending the *de minimis* policy to 2008. The *de minimis* amount for 2008 will be $1.

III. Risk Adjustment

Section A. Normalization of the Part D Risk Adjustment Model.

When we calibrate a risk adjustment model, we establish model coefficients that will result in the average beneficiary risk score being equal to 1.0 in the calibration year. Over time, risk scores rise due to population and coding changes. The result is that, over time, the average beneficiary risk in future years is greater than 1.0. This phenomenon has occurred with Part D and the average Part D beneficiary risk score now exceeds 1.0. Adjusting model coefficients so that the average beneficiary risk score will equal 1.0 in future years is called normalization.

In order for CMS to pay a plan for the appropriate risk of its enrollees, Part D sponsors bid their revenue needs based on their expected population and then adjust, or standardize, their bid using the expected average risk score of their projected enrollees; the standardized bid is the revenue needed by that plan to provide coverage to the average (1.0) beneficiary. When CMS calculates payment, the plan enrollees' actual risk scores are used to adjust the direct subsidy paid to each plan; in this way, plan payment is adjusted for the expected relative costliness of their enrollees.

In the absence of normalization, rising Part D risk scores will lead to reduced standardized bids and, as a result, in a lower national average monthly bid amount and a lower base beneficiary premium. The formula for the Part D direct subsidy is:

*Direct subsidy = standardized bid * beneficiary risk score – beneficiary premium*

Ultimately, non-normalized risk scores result in lower beneficiary premiums that are balanced out by increased direct subsidy payments. As seen in the formula for the direct subsidy payment (above), lower beneficiary premiums result in higher direct subsidy payments.

To calculate a normalization factor that would set the average risk score for all potential Part D plan enrollees to 1.0 for 2008 plan payments, we calculated an annual trend factor in the risk scores and applied an adjustment, using this trend factor, to project risk scores for 2008. This Part D normalization factor is 1.065 for 2008. This downward adjustment, which helps ensure that the average risk score across all Part D plans equals 1.0, will not affect total plan revenue. It will, however, affect the calculation of the beneficiary premium and the direct subsidy and thereby the share of the bid paid for by the beneficiary (through the plan beneficiary premium) and by the Federal government (through the direct subsidy). Further guidance on how CMS will apply this Part D normalization factor will be provided in the 2008 Part D bid instructions.

Section B. Standard Set of ICD-9 Diagnosis Codes for Risk Adjustment

Each year, CMS publishes on its website a list of the valid ICD-9-CM codes for the following fiscal year, based on the recommendations of the ICD-9-CM Coordination and Maintenance Committee. All final decisions on valid codes are made by the Director of the National Center for Health Statistics (NCHS) and the Administrator of CMS. NCHS, a component of the Centers for Disease Control, has the lead on ICD-9-CM diagnosis issues. The published code sets can be found at http://www.cdc.gov/nchs/icd9.htm. More information on the process for updating valid ICD-9 codes can be found at http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes/01_overview.asp#TopOfPage.

In 2009, we are moving to a standard set of codes against which to validate the diagnoses received from plans into our Risk Adjustment System (RAS). The goal of this transition to a standard set of codes for a payment year is to synchronize the list of codes RAS accepts and stores (acceptable codes) with the list of valid codes. Currently, there are more acceptable codes than valid codes because RAS is "flexible" (e.g., still accepts and stores an old ICD-9 code that has been superseded by a later NCHS code, and does not send an error message to the plan). Having a standard set of codes for each year will make it easier for CMS and plans to manage risk adjustment processing, editing, and error reporting.

As described in Table II below, starting with 2009 payment, the list of acceptable ICD-9-CM codes for the CMS-HCC, ESRD, and RxHCC risk adjustment models for risk adjustment for any given payment year will comprise the list of published NCHS/CMS codes (valid codes) for the three fiscal years prior to and including the payment year. The list of currently acceptable codes can be found on our website at http://www.cms.hhs.gov/MedicareAdvtgSpecRateStats/06_Risk_adjustment.asp#TopOfPage.

CMS will issue guidance as soon as possible with further detail on the transition to a standard set of codes for payment year 2009.

Table II. Phase-in Schedule for New Lists of Diagnosis Codes for Risk Adjustment

Year of Payment	Date of Service	Source of codes
2007	1/06 – 12/06	The list of codes published on our website at http://www.cms.hhs.gov/MedicareAdvtgSpecRateStats/06_Risk_adjustment.asp#TopOfPage (which lists acceptable codes by year)
2008	1/07 – 12/07	The list of codes published on our website at http://www.cms.hhs.gov/MedicareAdvtgSpecRateStats/06_Risk_adjustment.asp#TopOfPage (which lists acceptable codes by year)
2009	1/08 – 12/08	Valid diagnoses in Fiscal Years 2006, 2007, 2008
2010	1/09 – 12/09	Valid diagnoses in Fiscal Years 2007, 2008, 2009
2011	1/10 – 12/10	Valid diagnoses in Fiscal Years 2008, 2009, 2010

IV. Payment Reconciliation

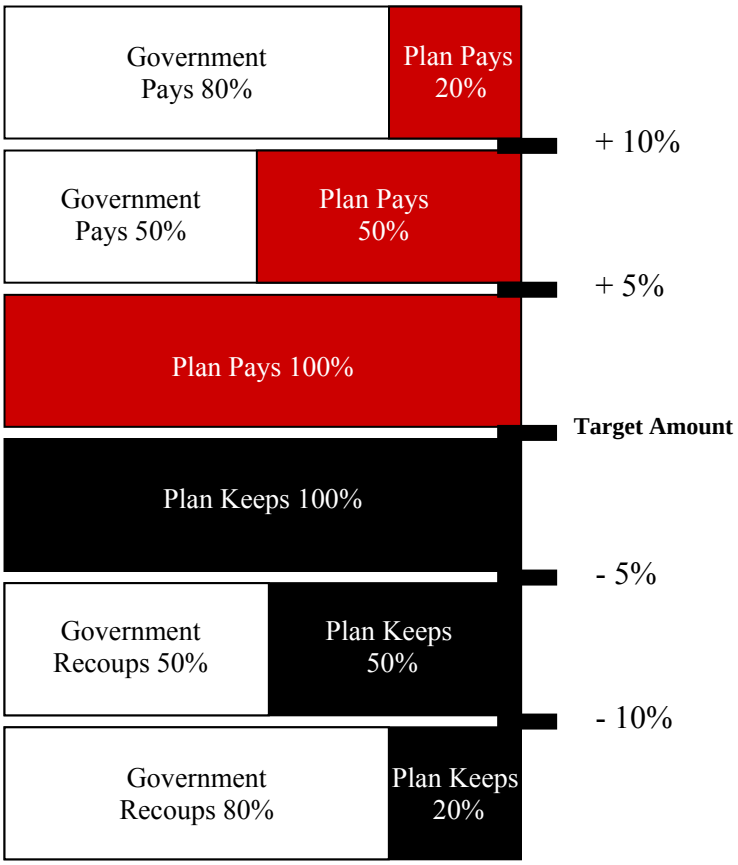
Section A. Part D Risk Sharing for 2008 through 2011

Pursuant to section 1860D-15(e) of the Act and the regulations at 42 CFR 423.336, the following changes will be made to the risk sharing arrangements for contract years 2008 through 2011:

- The first threshold risk percentage changes from 2.5% to 5% of the target amount;
- The second threshold risk percentage changes from 5% to 10% of the target amount;
- The payment adjustments for the first corridor change from 75% to 50% and the second corridor remains at 80%; and
- The conditions for higher percentages (a.k.a. 60/60 rule) under Section 1860D-15(e)(2)(B)(iii) of the Act and the regulations at 42 CFR 423.336(b)(2)(iii) will no longer be applicable.

Figure 1 below describes the risk corridors for 2008 through 2011.

Figure 1. Part D Risk Corridors for 2008-2011



V. Appendix 1

Medicare Part D Benefit Parameters for the Defined Standard Benefit: Annual Adjustments for 2008

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) directs CMS to update the statutory parameters for the defined standard Part D drug benefit each year. These parameters include the standard deductible, initial coverage limit, and catastrophic coverage threshold, and minimum copayments for costs above the annual out-of-pocket threshold. In addition, CMS is statutorily required to update the parameters for the low income subsidy benefit and the cost threshold and cost limit for qualified retiree prescription drug plans eligible for the Retiree Drug Subsidy. Included in this notice are (i) the methodologies for updating these parameters, (ii) the updated parameter amounts for the Part D defined standard benefit and low-income subsidy benefit for 2008, and (iii) the updated cost threshold and cost limit for qualified retiree prescription drug plans.

As required by statute, the parameters for the defined standard benefit formula are indexed to the percentage increase in average per capita total Part D drug expenses for Medicare beneficiaries. Accordingly, the actuarial value of the drug benefit increases along with any increase in drug expenses, and the defined standard Part D benefit continues to cover a constant share of drug expenses from year to year.

All of the Part D benefit parameters are updated using one of two indexing methods specified by statute: (i) the annual percentage increase in average expenditures for Part D drugs per eligible beneficiary, and (ii) the annual percentage increase in the Consumer Price Index (CPI) (all items, U.S. city average).

I. Annual Percentage Increase in Average Expenditures for Part D Drugs Per Eligible Beneficiary

Section 1860D-2(b)(6) of the Social Security Act defines the "annual percentage increase" as "the annual percentage increase in average per capita aggregate expenditures for covered Part D drugs in the United States for Part D eligible individuals, as determined by the Secretary for the 12-month period ending in July of the previous year using such methods as the Secretary shall specify." The following parameters are updated using the "annual percentage increase":

Deductible: From $265 in 2007 and rounded to the nearest multiple of $5.

Initial Coverage Limit: From $2,400 in 2007 and rounded to the nearest multiple of $10.

Out-of-Pocket Threshold: From $3,850 in 2007 and rounded to the nearest multiple of $50.

Minimum Cost-Sharing in the Catastrophic Coverage Portion of the Benefit: From $2.15 per generic or preferred drug that is a multi-source drug, and $5.35 for all other drugs in 2007, and rounded to the nearest multiple of $0.05.

Maximum Copayments below the Out-of-Pocket Threshold for certain Low Income Full Subsidy Eligible Enrollees: From $2.15 per generic or preferred drug that is a multi-source drug, and $5.35 for all other drugs in 2007, and rounded to the nearest multiple of $0.05.

Deductible for Low Income (Partial) Subsidy Eligible Enrollees: From $53[1] in 2007 and rounded to the nearest $1.

Maximum Copayments above the Out-of-Pocket Threshold for Low Income (Partial) Subsidy Eligible Enrollees: From $2.15 per generic or preferred drug that is a multi-source drug, and $5.35 for all other drugs in 2007, and rounded to the nearest multiple of $0.05.

II. Annual Percentage Increase in Consumer Price Index, All Urban Consumers (all items, U.S. city average)

Section 1860D-14(a)(4) of the Social Security Act specifies that the annual percentage increase in the CPI, All Urban Consumers (all items, U.S. city average) as of September of the previous year is used to update the maximum copayments below the out-of-pocket threshold for full benefit dual eligible enrollees with incomes that do not exceed 100% of the Federal poverty line. These copayments are increased from $1 per generic or preferred drug that is a multi-source drug, and $3.10 for all other drugs in 2007[2], and rounded to the nearest multiple of $0.05 and $0.10, respectively.

III. Calculation Methodology

Annual Percentage Increase

The first time CMS will have Part D program data that can be used in the calculation of the annual percentage increase, as defined in section 1860D-2(b)(6) of the Social Security Act, will be in 2008 for the 2009 contract year benefit parameters. Therefore, until sufficient Part D program data becomes available, the National Health Expenditure (NHE) prescription drug per capita estimates will be used. The annual percentage trend for the 2008 benefit formula is based on the estimated NHE prescription drug per capita costs as follows:

[1] Consistent with the statutory requirements of 1860D-14(a)(4)(B) of the Social Security Act, the update for the deductible for low income (partial) subsidy eligible enrollees is applied to the unrounded 2007 value of $53.43.

[2] Consistent with the statutory requirements of 1860D-14(a)(4)(A) of the Social Security Act, the copayments are increased from the unrounded 2007 values of $1.02 per generic or preferred drug that is a multi-source drug, and $3.05 for all other drugs.

$$\frac{\textit{August } 2006 - \textit{July } 2007}{\textit{August } 2005 - \textit{July } 2006} = \frac{\frac{5}{12}(CY\ 2006) + \frac{7}{12}(CY\ 2007)}{\frac{5}{12}(CY\ 2005) + \frac{7}{12}(CY\ 2006)} = \frac{\frac{5}{12}(\$714) + \frac{7}{12}(\$761)}{\frac{5}{12}(\$676) + \frac{7}{12}(\$714)} = 1.0619$$

(Source: Prescription Drug Spending, National Health Accounts, 1960-2015; National Health Statistics Group; February, 2007; Table #11 at http://www.cms.hhs.gov/NationalHealthExpendData/downloads/proj2006.pdf)

The 2008 benefit parameters reflect the 2007 annual percentage trend as well as a revision to the prior estimate for the 2006 annual percentage increase. The 2007 parameter update reflected an annual percentage increase of 6.86%. Based on the updated NHE prescription drug per capita costs, the 2007 increase is now estimated to be 5.29%. Accordingly, the 2008 benefit parameters reflect a multiplicative update of -1.47% (1.0529/1.0686 – 1) for prior year revisions. In summary, the 2007 parameters outlined in section I are updated by 4.64% for 2008 as summarized by Table III-1.

Table III-1. Annual Percentage Increase

Annual percentage trend for July 2007	6.19%
Prior year revisions	-1.47%
Annual percentage increase for 2007	4.64%

Note: Percentages are multiplicative, not additive. Values are carried to additional decimal places and may not agree to the rounded values presented above.

Annual Percentage Increase in Consumer Price Index, All Urban Consumers (all items, U.S. city average)

The annual percentage increase in the CPI as of September of the previous year referenced in section 1860D-14(a)(4)(A)(ii) is interpreted to mean that, for contract year 2008, the September 2007 CPI should be used in the calculation of the index. To ensure that plan sponsors and CMS have sufficient time to incorporate the cost-sharing requirements into benefit, marketing material and systems development, the methodology to calculate this update includes an estimate of the September 2007 CPI based on the projected amount included in the President's FY2008 Budget. The September 2006 value is from the Bureau of Labor Statistics. The annual percentage trend in CPI for contract year 2008 is calculated as follows:

$$\frac{\text{Projected September 2007 CPI}}{\text{Actual September 2006 CPI}}\ \textit{or}\ \frac{207.3}{202.9} = 1.0217$$

(Source: President's FY2008 Budget and Bureau of Labor Statistics, Department of Labor)

The 2008 benefit parameters reflect the 2007 annual percentage trend in the CPI, as well as a revision to the prior estimate for the 2006 annual percentage increase. The 2007 parameter update reflected an annual percentage increase in CPI of 1.81%. Based on the actual reported CPI for September 2006, the September 2006 CPI increase is now estimated to be 2.06%. Thus, the 2008 update reflects a multiplicative 0.25% (1.0206/1.0181 – 1) correction for prior year revisions. In summary, the cost sharing items outlined in section II are updated by 2.42% for 2008 as summarized by Table III-2.

Table III-2. Cumulative Annual Percentage Increase in CPI

Annual percentage trend for September 2007	2.17%
Prior year revisions	0.25%
Annual percentage increase for 2007	2.42%

Note: Percentages are multiplicative, not additive. Values are carried to additional decimal places and may not agree to the rounded values presented above.

IV. Part D Payment Demonstration Adjustment

The fixed capitated option of the Part D Payment Demonstration includes a catastrophic benefit that begins at the total drug expense corresponding to the out-of-pocket threshold in the Defined Standard Benefit. For 2008, this amount is increased from $5,451.25 in 2007 to $5,726.50 Specifically, this is the minimum amount of total covered Part D drug expenditures that will have occurred when the beneficiary reaches the out-of-pocket threshold of $4,050 in 2008 in the defined standard benefit. This expense level is determined arithmetically as a function of the 2008 out-of-pocket threshold (as opposed to being indexed directly).

V. Retiree Drug Subsidy Amounts

As outlined in §423.886(b)(3) of the regulations implementing the Part D benefit, the cost threshold and cost limit for qualified retiree prescription drug plans that end in years after 2006 are adjusted in the same manner as the annual Part D deductible and out-of-pocket threshold are adjusted under §423.104(d)(1)(ii) and (d)(5)(iii)(B), respectively. Specifically, they are adjusted by the "annual percentage increase" as defined previously in this document and the cost threshold is rounded the nearest multiple of $5 and the cost limit is rounded to the nearest multiple of $50. The cost threshold and cost limit are defined as $250 and $5,000, respectively, for plans that end in 2006, and, as $265 and $5,350, respectively, for plans that end in 2007. For 2008, the cost threshold is increased to $275, and the cost limit is increased to $5,600.