

Drug Card Pre-Application Conference

Responses to questions posed at the Drug Card Pre-Application Conference & email

NOTE: Due to the extraordinary attendance at the conference, interest in this program, and resulting large number of questions received by us, we are answering questions on a rolling basis. If you do not see the answer to your question at this time, please check back frequently for updates. Also, some of the questions were similar to others, in which case we answered only one version of the question. Therefore, please carefully read through all of the questions and answers.

All questions received by us by December 31, 2003 will have answers posted by January 7, 2004.

Last Updated: December 29, 2003

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Solicitation, Application Process & Timing (Endorsement)

1. Can a prescription benefit manager (PBM) provide a discount card to Medicare recipients without being part of a managed care organization?
 - A. PBM may operate its own drug card program as long as it meets all qualifications for Medicare approval. No partnership with a managed care organization is required for Medicare approval.

2. In order to be a provider of discount cards does a PBM have to be presently providing prescription cards to managed care organization?
 - A. No

3. Can an endorsed sponsor have multiple programs to accommodate private label customers? If not, do each of these customers need to submit a separate application for endorsement listing our organization as a subcontractor to meet the program requirements?
 - A. An Applicant may submit applications to operate multiple approved programs; each with its own exclusive Medicare enrollment. The Applicant could then include private label customers' names and logos on the approved card's information and outreach materials, provided CMS approved such materials. However, in each case, the Applicant's name would be required to be displayed on all materials on which the Medicare name and/or logo appears since CMS is approving only the entities that submit the applications for approval, not the entities with which an Applicant subcontracts. Alternatively, private label customers wishing to offer an approved drug card without identifying the subcontractor managing the pharmacy benefit may each submit an application of their own, and identify the subcontractor managing the pharmacy benefit. In such instances, assuming a successful application, CMS will provide Medicare approval for the private label customer, whose drug card can be marketed with the Medicare name and logo, but without identifying the subcontractor.

4. Can a company submit more than one application? For example, assume we want to offer two discount card products, each at different costs to the Medicare member. Do we include both of these in one application, or do we submit two different applications? Can product variants (for example offering different network sizes, annual fees, lists of discounted drugs, etc.) be submitted under the same application?
 - A. There is no limit to the number of drug card programs for which an organization may submit an application for Medicare endorsement. We encourage Applicants to submit only one application describing all the discount cards they may offer. However, Organizations may elect, for their administrative convenience, to submit a separate application for each program for which they are seeking approval.

5. Will organizations that participate in the Discount Card be at an advantage when the new Medicare drug benefit becomes effective in 2006?

- A. According to the authorizing legislation for both the Medicare-approved discount card drug program and the Part D (Medicare drug benefit), CMS will not consider operation of an approved discount card as a qualification for participation as a prescription drug program under Part D. However, card sponsors offering an approved drug card whose performance results in significant customer satisfaction may find that that reputation provides a significant advantage in competing for enrollees once the Part D programs are open for enrollment.
6. If we want to sponsor more than one plan, can we submit another plan after the application is in?
- A. CMS will accept no applications for Medicare approval after January 30, 2004. However, entities that have already submitted an application prior to that date may submit an additional application (or an amendment to the submitted application) on or prior to January 30, 2004.
7. If the applicant is a 50-50 joint venture and uses a 100%-owned subsidiary of one of its owners (i.e., an affiliate) to meet an applicant requirement, must the applicant have a contract with the affiliate?
- A. In the scenario you describe, since a subsidiary is a separate business entity (e.g., is incorporated, has its own board of directors), the Applicant must provide evidence of a contract between the subsidiary and the Applicant if the subsidiary is to provide services related to the operation of the Applicant's approved drug card program.
8. Should the Notice of Intent be provided at the organization level or the plan level?
- A. The notice of intent should be provided by the organization seeking to offer the approved discount card program. With respect to Medicare managed care organizations, the notice should be provided by the managed care organization, not the managed care plan. Managed care organizations wishing to offer both an exclusive Medicare managed care plan drug card as well as general drug card available to all beneficiaries residing in the card program's service area need submit only one notice of intent to apply. Note that Medicare managed care organizations wishing to offer these two types of drug cards must submit two separate applications, one using the general solicitation and another using the Medicare managed care solicitation.
9. Do you anticipate there being any flexibility in the January 30, 2004 application deadline?
- A. To meet the six-month implementation deadline established by the Medicare-approved drug card program's authorizing statute, CMS has adopted an aggressive application review process. The January 30, 2004 deadline is crucial to ensuring that both card sponsors and CMS will be prepared to make this program fully operational (i.e., discounts and transitional assistance available to beneficiaries) by June 1, 2004.

10. To whom does the notice of intent get sent?

- A. Both the notice of intent and the CMS Connectivity Request are to be sent to Kim August. Please see our December 23, 2003 revisions to the solicitations for more details.

11. How many subcontracts may an Applicant use to meet the drug card program qualifications?

- A. There is no limit on the number of entities with which an Applicant may subcontract to meet the qualifications for Medicare approval of their discount drug card program. However, please note that in the case of the Covered Lives requirement, one subcontractor must meet the 1 million lives qualification by itself. For example, An Applicant may not use two subcontractors, each with 500,000 covered lives to meet the qualification. Similarly, an Applicant using a contractor to meet the three years experience requirement must use entities that by themselves each have three years experience. For example, an Applicant combining three entities with one-year experience each would not meet the experience qualification.

12. To be an endorsed sponsor for Medicare Part D in 2006, does the sponsor need to participate in the discount drug program in 2004 and 2005.

- A. No.

13. How do Medicare managed care organizations file a notice intent to apply with CMS?

- A. Medicare managed care organizations are to follow the same notice of intent to apply filing procedures as all other Applicants. Please refer to Section 2.1 of the updated version (December 23, 2003) of the Medicare managed care organization solicitation for clarified information on the filing of the notice of intent to apply.

14. Do those of us applying for special approval have to get out letters of intent in at the same time as everyone else?

- A. All organizations that may apply for Medicare approval (regardless of the type of program for which they are seeking approval – managed care, special approval, etc.]) must submit on or before January 7, 2004 a notice of intent to submit an application (including the CMS Connectivity Request) to CMS. Applicants are asked to meet this deadline so that they can ensure that they can meet the connectivity qualifications of the program according to CMS' announced approval schedule. Please note that a notice of intent does not obligate an organization to submit an application to CMS.

15. Do contracts for rebates or discounts with pharmaceutical manufacturers need to be reviewed or approved by CMS. Do templates of rebate contracts need to be submitted to CMS?

- A. CMS requires sponsor applicants to provide contracts between the sponsor and subcontractor (if any) that negotiates pharmaceutical manufacturer rebates. CMS

does not expect sponsors to provide manufacturer rebate contracts. Rather, sponsor applicants must provide a discussion about these contracts, as required by the application requirements in Section 3.2.2. of the general solicitation, including the sponsor must attest that such contract(s) exists and with what manufacturer(s).

Organizational Structure & Experience

1. Can an approved card sponsor continue to operate its current (non-Medicare-approved) discount drug card for their Medigap members for no fee while operating a Medicare-approved drug discount card?
 - A. Approved card sponsors may continue to offer their non-Medicare-approved drug cards.

Contracts

1. As a card sponsor, can you establish additional subcontracting relationships throughout the term of the discount card program (e.g., organizations)? If so, does this require submission of an updated application to CMS?
 - A. Card sponsors may establish additional subcontracting relationships during the term of their contract. Although this situation does not obligate the card sponsor to submit a new or amended application to CMS, the card sponsor is required to provide CMS with a notice of any change to its program that might affect its qualification for endorsement. Card sponsors are to provide such notice as soon as it occurs. With respect to a new subcontractor, when such subcontractor is responsible for an area that affects the sponsor's qualification for Medicare approval, CMS would expect to receive a description of the change (including how it will impact the card sponsor's program) as well as a copy of the executed contract.

16. Can a card sponsor close down before January 2006?
 - A. Approved card sponsors will be required to sign a contract with CMS for a term beginning on May 3, 2004 and ending on the effective date of enrollment for the Part D program in 2006. A card sponsor may not terminate that contract unless it can demonstrate that CMS is not performing its obligations under the program or unless CMS mutually agrees to terminate the contract.

17. If a card sponsor uses a subcontractor who has subcontractors, does the card sponsor need to provide with the application (a) a single contract with the primary subcontractor, or (b) contracts with both primary and secondary subcontractors.
 - A. Applicants need to provide only the contracts with primary, secondary or any other subcontractors for areas related to covered lives, years of experience, pharmacy network, discount and rebate negotiation, enrollment and transitional assistance eligibility, transitional assistance administration, grievance process operation, information and outreach materials development, and call center operation.

Eligibility, Enrollment & Reconsiderations **(Enrollment and Eligibility)**

1. CMS described group enrollment for Medicare managed care plans, where a member can opt out of a card that the managed care plan offers. Would it be possible to get a similar provision for Medigap carriers?

A. Medigap plans may not group enroll under the drug card program. While we understand the predicament described, the statute contemplates beneficiaries making an active choice in: 1) selecting the card best serving their needs, 2) actively deciding to enroll in the card for discounts, and 3) actively deciding to apply for transitional assistance. Different from all other potential applicants, the statute contemplates special arrangements for Medicare coordinated care plans and Medicare cost contractors, if they decide to offer an exclusive card. Specifically, among other things, the statute requires that a beneficiary only join that plan's card. Therefore, the choice of another card is not an option for the beneficiary. In this circumstance we believe that group enrollment would not undermine the statutory intent of choice among cards, therefore we allow it, with the understanding that the beneficiary may decline. Medigap plans are not precluded from assisting their members in enrolling in a card they offer, provided that beneficiaries are informed that they have an option to join another card of their choice. CMS has provided for enrollment methods for the discount card (not including transitional assistance, which requires a signed form) that include telephone and Internet possibilities. It is our expectation that this flexibility will enable sponsor organizations to develop cost effective enrollment processes for their anticipated volume.

18. Will the income for purposes of determining eligibility for transitional assistance include social security income? Will the number of household members affect this amount? Is this amount total for the household or just the members on Medicare?

A. The income threshold includes social security income. Income belonging to the applicant or, if the applicant is married, to both the applicant and spouse (whether the spouse receives Medicare or not) will be counted. No other household members' income will be counted.

19. Will disabled adults, under age 65, on Medicare be eligible for prescription drug discounts?

A. Yes. The program is open to all eligible Medicare beneficiaries. All drug card applicants must meet the same eligibility criteria, namely, that they are eligible for or are enrolled in Medicare Part A or enrolled in Part B and are not receiving outpatient prescription drugs under their state's Medicaid program at the time of application for enrollment in the drug card.

20. Will all Medicare eligible recipients be eligible for the discount card or just those in a certain income bracket?

- A. All Medicare beneficiaries may apply for a discount card. Income is only a consideration for the Transitional Assistance portion of the program.
21. If a beneficiary enrolls in different programs in 2004 and 2005, how will the card sponsor who provided services for the member in 2004 be notified of the beneficiary's 2005 election?
- A. Elections made during the Annual Election Period (November 15, 2004 – December 31, 2004) will return an automatic disenrollment notice to the sponsor through the CMS enrollment exclusivity system.
22. What steps will CMS take when it discovers that a member has enrolled in more than one program? Please describe the notification CMS will make to the member and the program sponsors.
- A. Individuals may not be enrolled in more than one drug card sponsor at a time. Because all enrollments must be entered into the CMS enrollment exclusivity system, we expect that this scenario will not arise.
23. With respect to the annual enrollment fee that is to be collected by the program sponsor. Is CMS envisioning any specific process? (e.g. at enrollment, monthly, quarterly, etc.?)
- A. We envision the annual enrollment fee being charged once annually. We have provided flexibility to sponsor organizations in the collection of this fee in that each organization may decide to either collect the fee with each enrollment, or bill each enrolled individual for such fee after enrollment. Remember, individuals who apply for Transitional Assistance must not be required to pay any enrollment fee. If the individual is determined eligible for Transitional Assistance, CMS will pay this fee to the sponsor on the beneficiary's behalf. If the individual is determined ineligible for Transitional Assistance s/he may elect to enroll in just the discount card (and pay the fee).
24. Will you make an enrollment form available in Spanish?
- A. Yes, we will provide a translated application shortly after the English version is made available.
25. How will the beneficiaries apply for the discount cards?
- A. The basic concept of the enrollment process is described in the regulation and the solicitation documents. Beneficiaries will complete an enrollment form, or other CMS approved method, and submit it to the discount card sponsor to whom they wish to belong. The sponsor will respond to each beneficiary with the appropriate determination and information.
26. The regulation says a sponsor cannot enroll a TA applicant in its drug card prior to an eligibility determination for TA, yet exclusive sponsors are

permitted to group enroll its members, with application for TA deferred to later. Don't these rules conflict?

- A. We do not believe these rules conflict. The managed care group enrollment process includes that the required notification sent to all individuals prior to such enrollment will include information about transitional assistance, providing an opportunity to apply for it, as well as the opportunity to decline enrollment in the discount card. The statute creates special rules for members of managed care plans with exclusive drug cards and restricts such members to enrolling in only the exclusive cards. Other individuals (who are not in managed care plans offering exclusive cards) may decide that they wish to choose another discount card (for example, one with a lower enrollment fee) if they are not determined eligible for TA. Further, exclusive card sponsors may group enroll only for the drug card. If a beneficiary applies for transitional assistance than the same steps apply for sponsors of exclusive cards as for other sponsors, namely the beneficiary must provide a signed attestation of their income and other related eligibility requirements.

27. Can the dually eligible beneficiaries who participate in the Medicare Savings Programs -- (Qualified Medicare Beneficiaries (QMB), Specified Low-Income Medicare Beneficiaries (SLMB) and Qualifying Individuals (QI) -- be group enrolled for TA?

- A. No. They have to actively apply. However, if they do apply for TA -- QMBs, SLMBs and QIs are deemed to meet the income portion of the eligibility requirements.

28. Can a company charge a different enrollment fee for a Transitional Assistance plan than the fee charged for a regular discount card plan?

- A. No. The Medicare approved discount card program includes Transitional Assistance (TA); these are not separate plans. An individual who receives TA is an enrollee of the discount card. There is an annual enrollment fee for the program of up to \$30 charged by the sponsor, as it determines, to each individual for 2004 and 2005. Sponsors may not collect any enrollment fee from individuals applying for or enrolled in TA. The annual fee for discount card enrollees with TA will be paid by CMS.

29. Can a card sponsor charge an annual enrollment fee of \$30 for TA eligible beneficiaries, but at the same time waive the fee for "regular" discount card enrollees?

- A. No. This would not be permitted, as any annual enrollment fee must be charged uniformly to all enrollees of a discount card program, within each state.

30. Has any thought been given to allowing those who apply for TA to get the discount card automatically if they are not eligible for TA?

- A. Yes, CMS weighed this option carefully. While such a process may seem a convenience to certain beneficiaries, for others it may impose an annual enrollment fee that the beneficiary would be required to pay. Further, due to the limits on when

an individual may change cards, such a process could also inadvertently limit choice. To ensure that all individuals are aware of their options, the notice that is sent to those who applied for TA but were found ineligible informs them that they may choose to enroll in the discount card.

31. CMS said that if a member submits an enrollment on the last day of a month, with the enrollment process taking possibly several days after that to confirm eligibility and send an ID card, etc. to the enrollee, the sponsor would not be required to give retroactive discounts or TA payments. Is this accurate?

A. Yes

32. Will a faxed signature be acceptable for Transitional Assistance enrollments?

A. Yes. Beneficiaries applying for Transitional Assistance must complete and sign an enrollment form. Sponsors may accept this enrollment form in hard copy or by facsimile.

33. Will model language be provided for beneficiary reconsideration rights?

A. Yes. CMS will provide model notification letters that include information to provide beneficiaries with their reconsideration rights.

34. Can a sponsor extend the periods described for sponsor disenrollment of a beneficiary who does not pay the annual enrollment fee, such as extend the 10 days following notification of delinquency to 30 or more days?

A. Yes. The 10 days described in the solicitation is a minimum standard so a sponsor could not offer less. The period of time must be applied uniformly to all card program enrollees.

35. What are sponsors required to document when taking enrollments over the telephone or via the Internet?

A. CMS expects sponsors interested in utilizing enrollment formats other than paper enrollment forms to develop processes that incorporate appropriate privacy, data protection and security measures. CMS security policies are available on the web at <http://www.cms.hhs.gov/it/security>.

An example of an acceptable process might be an individual's authorization to use a credit card to pay an annual enrollment fee as a method by which the sponsor authenticates the identity of the individual applying.

For enrollment via telephone, sponsors must document the elements included in the model enrollment form. Sponsors should also provide a process to identify the caller, which could again be an authorization to charge an enrollment fee to a credit card.

36. Do the notices of eligibility or ineligibility have to be sent in writing (hard-copy)?

A. Yes. Models of notices will be provided.

37. Does the notice of ineligibility have to include the reason why an individual was found ineligible?

A. Yes.

38. Can individuals found ineligible apply for reconsideration without documenting a change in the data used when they were found ineligible?

A. When a beneficiary applies for the discount card program (with or without TA), and is found ineligible either because of answers to questions attested to on the enrollment form, or from the CMS systems verification process, he or she is entitled to apply for reconsideration of the eligibility result. The reconsideration process will involve the beneficiary's explaining why he or she disagrees with the result, including the submission of documentary evidence where applicable.

39. How will an individual having TRICARE or other coverage be determined?

A. These questions, and others, will be on the enrollment form and the beneficiary will attest to the validity of the answers provided.

40. Is a beneficiary with M+C HMO coverage for outpatient drugs (not employer group health plans) eligible for transitional assistance?

A. Yes. The legislation provides explicitly for that.

Transitional Assistance

1. Will SLMB/QMB individuals be required to fill out an application for transitional assistance if they are affiliated with an exclusive plan sponsor, or will they be deemed eligible (given that they should meet all of the requirements of eligibility – i.e., they can't be disqualified on the basis of having other drug coverage since there is an exception for Medicare Advantage members)?

A. All transitional assistance enrollees must complete an enrollment form. Individuals that are SLMB/QMB or QI are deemed to meet the income requirement for transitional assistance only. All other eligibility factors apply.

41. Please confirm whether or not individuals with employer-sponsored M+C or MediGap coverage would qualify for transitional assistance.

A. Yes. To be eligible, an individual may not have group health plan or individual coverage other than an M+C or Medigap plan. Please note, if the individual has both M+C and some other employer-sponsored health insurance offering coverage for prescription drugs, s/he would not be eligible.

42. A sponsor decides to require the \$30 enrollment fee up front. A beneficiary then applies for, and receives, transitional assistance. I'm assuming the MCO must refund the enrollment fee - is this a correct assumption? How long does the MCO have to refund the fee?

A. A sponsor may only charge the enrollment fee upfront to those beneficiaries who are enrolling in the discount card only. Sponsors must not collect the fee from beneficiaries applying for transitional assistance. In the case where a beneficiary applies for and enrolls in the discount card only, paying the applicable fee, and then applies for transitional assistance at a future date, the sponsor must refund the fee paid by the beneficiary as it will collect the fee from CMS for transitional assistance enrollees. We have not established a time requirement for the processing of this refund, but expect sponsors to react promptly to this requirement. If our experience with the program necessitates the creation of a timeframe, we will do so and provide such guidance to sponsors.

43. If a beneficiary is enrolled in a non-exclusive card, will any unused TA follow the beneficiary into an exclusive card if the beneficiary joins a plan offering an exclusive card? How is this tracked?

A. Yes, the transitional assistance will roll over any time a beneficiary changes cards during the annual enrollment period or a special enrollment period. The MCO offering the exclusive card in your scenario would be aware of the beneficiary's new enrollment in the plan and would be expected to provide to the beneficiary information about the exclusive card and how to enroll. At the time the beneficiary enrolls, the remaining balance on the card (which is provided to the enrollment system by the present sponsor at the time of disenrollment) would be rolled over to the exclusive card.

Marketing Materials & Review Process **(Information and Outreach)**

1. Can a plan sponsor market two or more discount card programs with different application fees and program features?
 - A. A sponsor can offer two programs with different enrollment fees and program features within the same service area.

44. Are there requirements of the sponsors to print membership cards that are consistent in look, or have CMS logo, or have consistent field layouts so the pharmacies recognize the cards and easily input the required fields
 - A. The information and outreach guidelines will have specific requirements for membership card and the Medicare Mark. Card sponsors will be required to follow the NCPDP standards in developing their membership cards. Further guidance will be provided in the guidelines.

45. What are the requirements or expectations for communicating the transitional assistance balance remaining to the member at the point-of-sale? Do we need to amend our retail pharmacy contracts to obtain this result? Can the balance be made available electronically such as website or interactive voice system?
 - A. Card Sponsors will be responsible for ensuring that contracted pharmacies are able to provide the balance of transitional assistance at the point of sale. Therefore Card Sponsors should specify in their pharmacy contracts that the balance of transitional assistance is a service that must be provided to the beneficiary at the pharmacy. The balance of transitional assistance must also be available through the Card Sponsor's customer service phone number.

46. Will we receive materials/guidelines to distribute with discount card applications to help seniors screen for transitional assistance so we can limit the number of transitional assistance applications
 - A. The information and outreach guidelines will provide guidance on how to communicate transitional assistance and the requirements. CMS has developed model materials that will assist beneficiaries in understanding transitional assistance. This information will be communicated in the model Member Handbook and Annual Notice of Change. CMS has also developed standardized enrollment forms and eligibility determination letters that provide information on transitional assistance. Card Sponsors will also be responsible for providing this information in their summary of program features.

47. As a qualified Medicare approved drug discount card provider, will we have access to Medicare enrollees' names, address and phone numbers to mail our program literature and call them to solicit their enrollment in our program?

A. CMS will not provide names and address to sponsors for their advertising campaigns.

Payment and Financials

1. What is the process for reimbursing the M+COs for TA members? How will the claims system work?

- A. The M+COs will be paid the same way as the non-M+CO sponsors; through the Payment Management System. This method will allow daily payment. Other payment options involving the CMS Managed Care Payment system would have limited payments to monthly. We are not using a claims payment system.

48. If an individual misrepresents their eligibility for TA and CMS confirms this, but it is later determined that the individual is not eligible, who bears the liability for the funds expended on behalf of that individual?

- A. CMS is only going to verify eligibility once; upon receipt of an enrollment transaction from a sponsor. If CMS learns that the individual has misrepresented eligibility, the individual is liable for the funds expended on his/her behalf.

49. Will CMS systems accept a negative balance related to member's subsidies?

- A. Sponsors are required to submit the remaining subsidy balance monthly. When the member has exhausted their subsidy and the balance reaches zero, this monthly reporting stops. Deductions from the subsidy balance are to be based on finalized claims, so there should not be a negative balance to be reported. CMS systems will reject negative amounts. As we stated in the preamble to the final rule, "Endorsed sponsors must have a process for managing payment against an individual's transitional assistance cap to ensure that not more than the amount of transitional assistance available is provided to the individual."

50. Will CMS be sending beneficiaries statements of payments for TA funds (similar to statements that are sent for current {Part A payments})?

- A. CMS will not be sending the TA beneficiaries any statements regarding payments made on their behalf.

51. If a beneficiary gains TA on reconsideration, will the TA be pro-rated in 2005?

- A. The proration schedule is contained in the regulation; the member loses \$150 per quarter that he is not enrolled with a drug card sponsor. If the beneficiary is found to be eligible for TA after reconsideration, he is considered to have been enrolled as of the date of his initial application and is entitled to the subsidy amount allowable for that date.

Price Comparison Website

1. If prices can vary by pharmacy contract, what price goes on the price compare?
 - A. The price will reflect the maximum contracted negotiated price (including the dispensing fees) associated with the participating pharmacy for each drug offered through each respective drug card sponsor's program. This price will reflect the maximum price that a Medicare beneficiary would incur at the point of sale.

52. Will the slides from the conference on Price Comparison be shared on-line?
 - A. Yes. The slides have been incorporated into the day 2 slide presentation, and they are available on the web at www.cms.hhs.gov/discountdrugs.

53. How often will a sponsor be able to submit price changes to CMS' Price Comparison website and how quickly will they be posted?
 - A. Data for Price Comparison may be updated on a weekly basis. All card sponsors will submit their electronic drug pricing data files directly to CMS' contractor for Price Comparison, DestinationRx, Inc. All Data must be submitted by Midnight Pacific Time on Wednesday of each week. DestinationRx, Inc. will process and display the submitted data by 12:01 AM Eastern Time on Monday of each week.

Reporting and Performance Monitoring

1. Will CMS further define the reporting requirements (such as the format and frequency)?

- A. Yes, as stated in the December 19th presentation on monitoring and reporting, we will provide this information via the CMS website at a later date.

54. How are you expecting sponsors to report rebates/discounts? Aggregate vs. average across all drugs and beneficiaries?

- A. This is described in Attachment 6 of the general solicitation. Further clarification, if needed, will be made available via our website.

55. What specific details must the grievance log consist of?

- A. The details are outlined in Attachment 6 of the general solicitation, please refer to it. Any further clarifications, as needed, will be made via our website.

Systems, including that related to Eligibility & Enrollment, as well as Transaction Requirements, Infrastructure Requirements, Testing Plan, and "Go Live" Requirements (IT)

1. During the presentation at the pre-application conference, it was stated that a systems survey was posted on the CMS website, but I cannot find the survey.

- A. The survey is titled the CMS Connectivity Questionnaire, which is now due January 7th with a sponsor's intent to bid. The CMS Connectivity Questionnaire is located at www.cms.hhs.gov/discountdrugs under the related links categories for the solicitation. Please note the document is available as a MS Word document, which is found using the zipped link, or in PDF format.

56. Will Medicare cover the cost of the T1 lines for special cases?

- A. CMS's intent is to pay for one T1 line per sponsor if that sponsor does not currently have such connectivity to the CMS Data Center.

57. Can multiple subcontractors of a sponsor be electronically connected to CMS for eligibility/enrollment?

- A. CMS's intent is to pay for one T1 per sponsor. We are expecting one set of feeds per sponsor.

58. When will the system-training handout be available electronically?

- A. We expect to issue the file formats and the finalized business requirement supporting our system development activities by January 16. Test cases will be issued in mid February.

59. If a beneficiary is enrolled in a State Pharmacy Assistance Program, may they also receive benefits under the Discount card? If they qualify for the \$600 assistance and sign up for a Discount card, will they lose their benefits under the State program?

- A. Yes, beneficiaries may be enrolled under both. If a beneficiary qualifies for TA, it may be beneficial for them to participate in both so they receive \$600 in federal TA. CMS cannot say what the State discount program's enrollment rules may be in the future, but from our viewpoint, enrollment in both is permissible.

60. If a Medicare beneficiary who chooses to enroll in the Medicare-approved drug discount card program already was participating in a discount card program offered by a pharmaceutical company or other private entity (i.e., a card that is not Medicare-endorsed and pre-dated the Medicare discount card program), can the beneficiary continue to use the non-Medicare-endorsed card, as well as the Medicare-endorsed card?

- A. Yes. Enrollment in a Medicare-endorsed card would not preclude enrollment in any non-Medicare-endorsed card. It would however, preclude simultaneous enrollment in an endorsed Medicare card.

61. On what basis will the \$62 million in transitional coordination of benefits (COB) funding be distributed? Can the \$62 million be used for outreach, education, printing, mailing and so forth? Can the funds be used for systems changes in an SPAP contractor's point-of-service system?

- A. The grant money to fund COB activities is part of the legislative provisions for the Part D benefit, not the drug card. CMS is analyzing that piece of the legislation and will provide guidance in the future.

States

1. Can State Medicaid agencies require/mandate that card eligible recipients such as QMBs, SLMBs, QIs and other dual eligibles sign up for the card? Would it make a difference if the state allows them to disenroll voluntarily? Would it make a difference if the state paid their enrollment fee?
 - A. State Medicaid programs are not permitted to establish additional eligibility requirements other than those provided for under Federal Medicaid law unless these conditions complement, rather than conflict with, Federal law and the State provides a rational purpose in support of imposing the additional conditions. If a State wishes to require that its Medicaid beneficiaries who are eligible for the Medicare-endorsed drug discount card program enroll in the program, we will review the State's proposal to see whether it meets these requirements.

Medicare Managed Care: Endorsement / Application and Endorsement

1. Are the application or start up dates different for endorsed card sponsors vs. exclusive card sponsors?
 - A. No. The dates will be the same, with the exception of M+C organizations that simultaneously apply to offer a new coordinated care plan or plans and an exclusive card program to members of such plan(s), and service area expansions under coordinated care plans, as provided under 42 CFR § 403.804(a)(2).
2. Will the discount program solicitation responses be sent at the same time as the ACR filing scheduled for 2/2/04, or will the applications be filed separately?
 - A. They will be filed separately. Applications are due into CMS January 30, 2004. ACRPs will also be due January 30, 2004. This due date for ACRPs is a few days earlier than initially indicated, as the DIMA rates will be also be released earlier than initially anticipated by CMS (on January 16, 2004), and ACRPs are due two weeks after CMS releases the new rates.
3. Should the Letter of Intent be provided at the organization level or the plan level?
 - A. Letters of intent should be provided at the organization level.
4. All members of our plan are provided "value added" discount plans for being members of the BCBS plan. This applies to members under, as well as over 65 years of age. One of the "value added" benefits is a prescription drug discount plan. Will our members over age 65 still be able to use this discount feature for their prescription drugs?
 - A. The discount card program will not affect your ability to continue offering a non-endorsed discount card program to your plan enrollees. If your organization applies for Medicare endorsement, however, it will have to demonstrate that it meets the requirements contained in either the general solicitation or the Medicare managed care solicitation (if it wishes to offer an exclusive card program). At its option, a plan may simultaneously offer its members both an endorsed discount card program and a non-endorsed discount card program.
5. Will transitional assistance be available to Medicare cost plan members as it is for M+C enrollees?
 - A. Yes. Transitional assistance will be available to eligible enrollees enrolled in discount card programs sponsored by Medicare cost plans.
6. There are several Blue Plans that operate in service areas that are smaller than states. Would such plans be precluded from developing their own endorsed discount card program?
 - A. An entity offering a non-exclusive endorsed drug discount card program must offer the program to all eligible Medicare beneficiaries in a state included in the program's service area. However, an exclusive card sponsor could limit the service area for its exclusive card program to the service area for its Medicare managed care plan(s) offering the exclusive card program, which may include a portion of a state.

7. Some organizations that hold an M+C contract also serve members who are Medicare-eligible, but who are not M+C enrollees (i.e., members for whom the plan does coordination of benefits). If a plan wants to offer an exclusive card, could it offer the exclusive card to all its Medicare-eligible members (i.e., those in M+C and those in its other plans)?
 - A. An exclusive card sponsor may only offer its exclusive card program to enrollees in its Medicare managed care plans.
8. If an M+C organization offers 2 programs; 1 for plan members only (exclusive) and another for non-plan members (non-exclusive) is this permitted?
 - A. Yes. The organization would have to respond to both the general solicitation (for the non-exclusive card program) and the Medicare managed care solicitation (for the exclusive card program) to obtain CMS approval of both programs.

Managed Care: ACR/Benefits

1. Assuming an exclusive sponsor elects to apply TA to cost-sharing for drugs provided under its managed care plan drug benefit, is there a 5%/10% co-insurance required? For example, if there is a \$5 co-pay under the plan, is the beneficiary responsible for 25 (5%) or 50 (10%) cents?
 - A. Coinsurance is not required in this case. The full cost sharing due from a beneficiary under the Medicare drug benefit may be paid with TA funds, at the enrollee's discretion.

2. Will CMS modify the 2004 ACR [to accommodate M+COs who participate in the drug card program]?
 - A. Yes. We have done so. See Instructions for the 2004 DIMA ACRP Season for further details.

3. I work with an M+C organization that provides a prescription drug benefit for its M+C members which is subject to a maximum benefit threshold (i.e., once the member's prescription drug expenses reach a certain dollar level, the benefit is exhausted). After the member exhausts this benefit, he or she still has access to the M+C organization's negotiated discounts with network pharmacies. The M+C organization also enrolls members who elect not to purchase the prescription drug benefit. These members also have access to the M+C organization's negotiated discounts with network pharmacies, although the discounts are not the same as for M+C members who have exhausted their benefits. My question is what effect, if any, does the discount card law have on the M+C organization's ability to make these discounts available to their M+C members. Do they have to offer an endorsed card?
 - A. The endorsed discount card program is strictly voluntary. Medicare managed care organizations will not be required to offer an endorsed discount card and, at their option, can continue offering a non-endorsed discount program to their Medicare managed care plan members.

Medicare Managed Care: Cost Plans

1. What is a “Medicare cost reimbursement contractor” referred to on page 5 of the Overview under Medicare Managed Care Plans Offering Exclusive Card Programs?
 - A. We are referring to organizations offering reasonable cost reimbursement plans under Section 1876(h) of the Social Security Act.

2. Can administrative costs during the transition period be considered in the 2006 ACR?
 - A. No.

3. Will there be any changes to the cost reports for Medicare cost plans [who presumably opt for exclusive endorsement]?
 - A. No.

Medicare Managed Care: Waiver Issues

1. Will something waived for one MCO also be waived for all other MCOs automatically (that is, once CMS establishes that a provision is "waivable" by awarding a waiver to one organization -- does that decision apply uniformly across-the-board to all other MCOs?)
 - A. The waivers or modifications of requirements that are included in our regulations will apply to all Medicare managed care organizations wishing to apply for endorsement of an exclusive card sponsor. This includes waivers or modifications of the following requirements: (1) pharmacy access; (2) service area; (3) covered lives; and (4) beneficiaries' use of transitional assistance only for covered discount card drugs obtained through the endorsed card program. However, the proposed waivers and modifications in the solicitation -- as well as any additional waivers or modifications of requirements that Medicare managed care organizations may apply for as part of their application package -- will not necessarily apply across the board. Because our regulations at section 403.814(b)(3)(v) permit us to approve waivers of additional requirements as appropriate on a case-by-case basis only, we will approve a waiver or modification of endorsement requirements if an applicant: (1) applies for waiver or modification of said requirements; and (2) meets the necessary requirements for a waiver or modification of said endorsement requirements (e.g., does not currently obtain manufacturer rebates as a condition of approval for a manufacturer rebates waiver). If two similarly situated Medicare managed care organizations make the same waiver or modification request, we will treat the two applicants the same and similarly approve or deny the request for both.

Managed Care: Miscellaneous

1. If a Medicare Advantage plan has both an exclusive program for its members and a non-exclusive program for non-members in the state, can they co-mingle marketing materials-that is provide marketing materials for both programs to prospects at the same time?
 - A. If a Medicare managed care organization offers an exclusive card program to members of one of its plans, the plan members may not enroll in any other card program, including a non-exclusive card program offered by the Medicare managed care organization. In addition, individuals not enrolled in the Medicare managed care plan(s) offering the exclusive card program may not enroll in the exclusive card program. Therefore, it is not clear to us why a Medicare managed care program would wish to commingle marketing materials for its exclusive and non-exclusive programs, with the possible exception of information contained in mass media forums such as television or the organization's web site. However, our rules do not prohibit a Medicare managed care organization from commingling marketing materials for its exclusive and non-exclusive programs; obviously if this could be confusing to beneficiaries for whom only the exclusive card program is available, the Medicare managed care organization should take this under consideration in determining whether to commingle such materials. When acting as a card sponsor, these materials should not include any marketing of non-endorsed features.
2. Does CMS intend to conduct any audits of the discount card program as part of their regular biennial audits conducted by Regional Office staff?
 - A. CMS continues to develop the endorsed sponsor oversight program. While CMS will clearly be involved in managing this process, we envision a prominent role for data and contractors, including Medicare program safeguard contractors, in the oversight of the discount drug program. There may be opportunities for combination of Medicare managed care and drug card on-site oversight activities which could reduce duplication of effort in some areas (e.g., reviewing grievances).
3. The interim rule referenced other exceptions to the Uniform Premium Rule, but were not listed. Can CMS provide Plans with this information?
 - A. Non-uniformity resulting from implementation of the Medicare Drug Discount Card Program will not be taken into account in applying the uniform premium and uniform benefits requirements in section 1854(c) and 1854(f)(1)(D) of the Act. The interim rule discusses the most likely scenarios involving non-uniformity that fall under this exception. However, we recognize that Medicare managed care organizations may structure their endorsed drug discount card programs or related benefits under their Medicare managed card plans or in a manner resulting in other types of non-uniformity. Applicants concerned about whether any non-uniformity resulting from their approach to implementation of their endorsed drug discount card programs should submit questions to CMS specifically describing their scenarios.

Other

1. How many of the 4.7 million people you estimate would be transitional assistance enrollees are in M+C?
 - A. There are 7.3 million beneficiaries estimated to enroll in the drug card in 2004, with an estimated 4.7 million qualifying for transitional assistance and an estimated 2.6 million qualifying for the discount card only. Of the estimated 4.7 million transitional assistance enrollees, about 1.2 million are estimated to be in M+C. Of the estimated 2.6 million discount card only enrollees, the vast majority is assumed to be in Medicare fee-for-service. The major reason why the vast majority of the 2.6 million are assumed to be in traditional Medicare is that enrollment in the drug discount card only component is assumed to occur predominantly among beneficiaries without drug coverage, and many beneficiaries in M+C have drug coverage.