Medicare-Approved Prescription Drug Discount Card and Transitional Assistance Program

Solicitation for Applications for Medicare Managed Care Organizations
December 16, 2003

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1.0 INTRODUCTION

The Centers for Medicare and Medicaid Services is seeking applications from Medicare managed care organizations offering an exclusive card program (as described in the Medicare Prescription Drug Discount Card and Transitional Assistance Program Interim Final Rule [Federal Register, December 15, 2003]) who are interested in entering into a Medicare approval contract. Medicare managed care organizations eligible to offer an exclusive card program are Part C organizations offering a plan described at section 1851(a)(2)(A) of the Social Security Act and reasonable cost reimbursement plans under Section 1876(h) of the Act. Applications are to be submitted according to a process described under "Applicant Instructions" in Section 2.0.

1.1 Background

Statutory Authority

The Medicare Prescription Drug Discount Card and Transitional Assistance Program (hereafter referred to as the "Medicare Drug Discount Card Program") was established by section 101 subpart 4 of Pub.L. 108-173, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and is codified in section 1860D-31 of the Social Security Act (the Act).

September 2002 Program Superceded

As stated in the interim final rule for this program, the final rule published September 4, 2002 (67 FR 56618) and the solicitation published in conjunction with that final rule have already been withdrawn. This solicitation is in no way connected to the September 4, 2002 final rule.

1.2 Special Qualifications for Card Programs Operated by or Contracting with Medicare Managed Care Organizations

Overview

Entities already under contract with CMS to operate a Part C coordinated care plan described at section 1851(a)(2)(A) of the Act or a reasonable cost reimbursement plan under section 1876(h) of the Act (known as "Medicare managed care plans," with the entities offering such plans known as "Medicare managed care organizations") may seek to operate as an approved discount card exclusively for members of one or more their Medicare managed care plans (known as "exclusive card programs," with the organizations offering these exclusive card programs known as "exclusive card sponsors."). Medicare managed care organizations already have an established relationship with CMS and an existing set of Medicare beneficiaries enrolled in their Medicare managed care plans. In addition, their Medicare managed care plans may include an outpatient drug benefit offering with pharmacy networks. Therefore, it is appropriate that we alter for exclusive card sponsors certain discount drug card sponsor qualifications to ensure that members of Medicare managed care plans offered by organizations sponsoring exclusive card programs can benefit from integration of the benefits offered under the exclusive card program and their Medicare managed care plan. In addition, altering card sponsor requirements that are duplicative of or conflict with requirements under the Medicare managed care program will promote greater efficiency under both programs. Medicare managed care organizations seeking an approval of a drug card whose enrollment is limited to members of one or more of its Medicare managed care plans are required to complete this abbreviated application for approval rather than the standard Medicare Discount Card Application used by all other entities seeking an approval. Medicare managed card organizations seeking an approval for a drug card program whose enrollment will not be limited to members of one or more of its managed care plans should respond to the Solicitation for Application for Non-Medicare Managed Care Organizations.

Congress has waived or modified standard drug program requirements in several areas for exclusive card sponsors. In addition, CMS has waived or modified additional standard drug program requirements for exclusive card sponsors under its authority under Section 1860D-31(h)(9)(B)(iii) of the Act, which authorizes waiver or modification of approved sponsor requirements if those requirements are duplicative of or conflict with requirements applicable to Medicare managed care organizations under Part C or Section 1876 of the Medicare statute, or if waiver of the requirements would improve coordination of the benefits under the Medicare Prescription Drug Discount Card Program and Medicare managed care plans. Specifically, the following requirements are waived or modified for exclusive card sponsors: (1) the requirements in 42 CFR 403.806(f)(1) and (2) that approved sponsors offer their approved card programs to all discount card eligible individuals residing in their service area and that their service area encompass all portions of a State; (2) the pharmacy access standard under Section 1860D-31(e)(1)(B) of the Act; (3) the covered lives requirement in 42 CFR 403.806(a)(3); and (4) the requirement in 42 CFR 403.808(d)(1) that transitional assistance be applied only toward costs incurred for covered discount card drugs obtained through the Medicare drug discount card program.

As discussed in further detail, we will consider waiving or modifying the following requirements upon request:

- Formulary – If the exclusive card sponsor uses a formulary to administer any outpatient drug benefit or discount card program offered to members of its Medicare managed care plans that offer the exclusive card program and such formulary that differs from the formulary requirements under 42 CFR 403.806(d)
- Obtaining manufacturer rebates – If the exclusive card sponsor offers a drug benefit to members of its Medicare managed care plans that offer an exclusive card program and such drug benefit does not currently obtain manufacturer rebates on prescription drugs as required in 42 CFR 403.806(d)
- Reporting – If the exclusive card sponsor must report any information that is duplicative of the reporting requirements under Part C or Section 1876(h) of the Act or unnecessary in light of waiving for the exclusive card sponsor other card sponsor requirements as required in 42 CFR 403.806(i).
- Reporting on formulary drug pricing data as required in 42 CFR 806(i).
- Applicant experience – 3 years of private sector experience in the United States in pharmacy benefit management as required in 42 CFR 806(a)(2).

Section 3.0 further discusses these waivers and modifications. If the Applicant wishes for CMS to waive/modify any of these requirements, it should request the waiver or modification, and provide an explanation in support of its request, in its application. Applicants may also request that CMS waive or modify other requirements for approval. To do so, the Applicant must demonstrate that the requirements at issue are duplicative of, or conflict with, requirements applicable to Medicare managed care organizations, or that they interfere with the coordination of benefits offered under their drug card with benefits provided under the Medicare managed care program. NOTE: Our regulations provide that the provisions in 42 CFR 403.812 and 403.813 may not be waived.

In addition, given the unique characteristics of and requirements under the Medicare managed care program, the approach we are taking in the standard Medicare Discount Card Application is not always warranted for Medicare managed care organizations that wish to operate an exclusive card program. In order to account for these differences, we have also modified some of the procedures for demonstrating compliance with certain drug card sponsor requirements. For example, although exclusive card sponsors must meet the business stability and financial integrity requirement in 42 CFR 403.806(b), we permit exclusive card sponsors to demonstrate their compliance with this requirement through continued compliance with 42 CFR 422.400 (in the case of Part C organizations) or 42 CFR 417.120 and 417.122 (in the case of Medicare cost plans). In addition, we modify the procedural requirements concerning the call center and the grievance/customer complaints processes.

1.3 Objectives

The Drug Card Program is intended as a transitional program to provide immediate assistance with prescription drug costs to Medicare beneficiaries during CY 2004 and CY 2005 and through a transitional period in 2006 while preparations are made for the implementation of a full

Medicare drug benefit in 2006. Medicare generally does not cover the cost of outpatient drugs. The Medicare Drug Discount Card Program is designed to provide Medicare beneficiaries – and particularly those without drug coverage – access to discounts on outpatient prescription drugs through enrollment in card programs offered by sponsors approved by Medicare. Certain enrollees may also qualify, based on low income and lack of other drug coverage, for up to $600 of annual transitional assistance that they may apply directly to the cost of their drugs obtained using their discount drug cards.

The objectives of the Drug Card Program are to:

- Provide eligible Medicare beneficiaries access to discounts on their purchases of prescription drugs.

- Provide eligible low-income beneficiaries an annual prescription drug cost assistance (referred to as "transitional assistance") of up to $600.

- Provide access to the discounts and subsidies through approved qualified private sector prescription drug discount card programs based on structure and experience, customer service, pharmacy network adequacy, ability to garner and pass through prescription drug manufacturer rebates, discounts, or other price concessions and available pharmacy discounts.

- Promote beneficiary awareness of the Medicare Drug Discount Card Program through CMS's approval and ongoing beneficiary educational activities as well as card sponsors' use of the Medicare name. The increased visibility of the approved drug discount cards will lead to greater enrollment by beneficiaries. This, combined with the exclusive enrollment feature of the program, will provide card sponsors the necessary leverage to negotiate competitive discounts and drug manufacturer rebates, discounts, and other price concessions which can be used to reduce prescription drug prices for enrolled beneficiaries.

1.4 Program Overview

1.4.1 Summary of Card Program Responsibilities

Key aspects of each Medicare managed care approved discount card shall include the ability to:

- Enroll all current or new members of Medicare managed care plans offering exclusive card programs, but give members an opportunity to actively decline enrollment , if desired.

- Process beneficiaries' enrollment applications for the drug discount card and transitional assistance, and administer the payment of such assistance.

- Administer transitional assistance funds, including ensuring that such funds are applied only to covered discount card drugs and, at the option of the Medicare managed care organization, to deductibles, coinsurance, and copays associated with covered discount card drugs covered under any drug benefit a Medicare managed care plan may provide; applying appropriate coinsurance levels; and making available an enrollee's transitional assistance balance at the point of sale.

- Offer a contracted pharmacy network, providing access similar to the access already available under a Medicare managed care plan's current retail pharmacy network.

- Charge an annual enrollment fee of no more than $30 per year in 2004 and 2005 per discount card enrollee. CMS will pay the enrollment fee on behalf of enrollees with transitional assistance.

- Provide customer service to beneficiaries, including enrollment assistance, toll-free telephone customer service help, and education about the drug card services similar to the customer service already provided under the Medicare managed care plan's customer service.

- Provide access to prescription drug-related items and services offered by the program for no additional fee, such as drug interaction monitoring and allergy alerts through detection systems linking pharmacies in the entire network.

- Protect the privacy of beneficiaries and beneficiary-specific health information.

- Limit enrollment in its Medicare-approved discount card program to eligible members of its Medicare managed care plan offering the program.

- Develop educational materials and conduct information and outreach activities consistent with CMS standards for completeness, appropriateness, and understandability.

1.4.2 Summary of CMS Responsibilities

Approval Process

CMS has determined the qualifications entities must meet to receive Medicare approval for their prescription drug discount cards. CMS will review the applications for approval submitted in response to this solicitation. CMS will determine which entities qualify for approval and enter into agreements with appropriate card sponsors.

Drug Card Program Oversight

CMS plans to develop a Medicare Drug Discount Card program monitoring system to ensure compliance with program requirements. We plan to focus on several operational areas critical to beneficiary satisfaction with their drug card and to protecting the financial integrity of the transitional assistance portion of the program. Specifically, we plan to focus on enrollment and

disenrollment, information and outreach, access to pharmacies and discounts, customer service, confidentiality of enrollee information, and proper payment of transitional assistance. *(NOTE: CMS will monitor approved drug card sponsors to ensure that they maintain the confidentiality of enrollee information required for approval. In addition, approved drug card sponsors, as covered entities under the Privacy Rule, are subject to investigation and penalties for findings of Privacy Rule violations as determined by the Department of Health and Human Services Office for Civil Rights and the Department of Justice.)*

Our monitoring efforts will be based on an analysis of data we collect from drug card sponsors, CMS contractors, external government entities and our own systems. Such data will include pricing information, card sponsor grievance logs, marketing review information, customer service performance data, and customer complaints. For a list of the card sponsor reporting requirements, please see Section 3.6.

CMS will develop and operate a complaints tracking system to monitor and manage complaints brought to our attention that are not satisfactorily resolved through card sponsors' grievance process. We plan to conduct mystery shopping and beneficiary satisfaction surveys. Finally, CMS plans to engage a program safeguard contractor to conduct random audits of card sponsors' transitional assistance enrollment and payment records.

Any information gathered will be analyzed to detect possible trends that indicate less than satisfactory performance, significant departures from the marketed card program offering, or fraud or other violations of State and Federal laws.

CMS will make determinations about the need for corrective action, intermediate sanctions, civil monetary penalties, or contract termination, consistent with the requirements of 42 C.F.R. §403.820. The Office of the Inspector General also has the authority to levy civil monetary penalties in certain situations, consistent with 42 CFR 403.820. Finally, we will also make all necessary referrals to the Department of Health and Human Services Office of the Inspector General, or to Federal and State authorities where violations of laws under the jurisdictions of these agencies is in question.

Education and Outreach

CMS is committed to educating Medicare beneficiaries about the Drug Discount Card Program, at the time the approvals are announced and as part of ongoing education efforts thereafter. CMS anticipates that there will be national media attention when the Medicare-approved discount card programs are announced in the Spring of 2004. We will make available general program information and a subset of comparison information for each non-Medicare managed care drug card program 30 days before the initial enrollment date. The general information will address the availability of the Medicare drug discount card program and general program features (e.g., limitation of enrollment to only one drug card at a time, initial enrollment date, the use of formularies containing the drugs on which discounts are available). CMS will also disseminate information about the availability of transitional assistance and the eligibility requirements for such assistance. We will disseminate specific comparison information about non-Medicare managed care drug card programs to promote informed consumer choice,

including enrollment fee, customer service hours, contact information, drug card web site, and special notices (e.g., if a sponsor has a special approval for administering their program to American Indians/Alaska Natives, residents of long term care facilities, and/or residents of the territories). We will provide only limited information about Medicare managed care drug card programs – specifically, whether a Medicare managed care plan offers a Medicare-approved discount card program – and refer beneficiaries to Medicare managed care plans for further information about Medicare managed care drug card programs. This information will be made available through the Medicare web site (www.medicare.gov) and through the toll-free information line (1-800-MEDICARE).

CMS plans to educate beneficiary and consumer groups, health care providers, States, and other interested groups about the Medicare drug discount card program. CMS may also engage in other activities that publicize or otherwise educate beneficiaries about the program.

CMS will provide, through the Prescription Drug and Other Assistance Program section of www.medicare.gov, a price comparison web site that will include negotiated prices in actual dollars, which will include dispensing fee information, for the purpose of comparing across non-Medicare managed care approved card programs. If, as permitted below, a Medicare managed care contractor requests a waiver of reporting price formulary drug pricing data through a price comparison web site and we grant such a request, price information will not be provided for exclusive Medicare managed care approved card program(s).

Information and Outreach Guidelines and Review

CMS has developed a contractor to provide technical assistance in the development of the information and outreach guidelines. The guidelines are posted on the CMS website as a separate document from this solicitation. Included in the information and outreach guidelines are standards for the use of a Medicare approval emblem. To use the emblem on their cards, card sponsors will need to abide by these standards.

CMS is responsible for the review of information and outreach materials associated with this program. In addition, CMS is responsible for ensuring coordination of this process with the current Medicare managed care marketing review process.

Enrollment Processing/Transitional Assistance Eligibility

CMS has developed a system to review an individual's eligibility for the Medicare drug discount card program and the transitional assistance. For individuals applying for the drug card, we will verify an individual's eligibility by confirming the individual's status as a Medicare beneficiary and his or her status in regard to receiving outpatient prescription drug assistance through title XIX or an 1115 waiver. We will assess the latter through files provided to us by the State Medicaid programs for this purpose.

We will also review the declared income of individuals applying for transitional assistance to ensure that it does not exceed 135% of the poverty line for their declared family size. This system consists of income and retirement benefit information provided by the Internal Revenue

Service and the Social Security Administration, and possibly other data sources that we may choose to include. With regard to income and other benefits, we will take into consideration Social Security benefits, Railroad Retirement benefits, Veteran's benefits, Supplemental Security Income benefits and Adjusted Gross Income as defined by the IRS.

To review income, we will use data sources that identify, for most individuals, the types of income we will count. An individual denied access to transitional assistance or the discount card may request that we reconsider our decision and provide us with information or an explanation regarding his or her prescription health insurance, income, family size, or Medicare status. We will contract with an independent review entity to conduct the reconsideration process.

We have also developed a database to track enrollment decisions by each individual and to ensure enrollment exclusivity. This system will track enrollments and disenrollments from card programs and will block new enrollments during any given enrollment year unless the enrollment occurs during the Annual Coordinated Election Period or a special election period is indicated. This system will also track whether an individual is enrolled in a Medicare managed care plan offering an exclusive card program.

Transitional Assistance Administration

CMS will maintain as part of its enrollment and eligibility system, a process for determining when a beneficiary is effectively enrolled and eligible for transitional assistance, the prorated assistance amount for the year (if applicable), and the monthly balance.

CMS will establish accounts for each card sponsor utilizing the Department of Health and Human Services (DHHS) Payment Management System (PMS). CMS will transmit to the PMS a withdrawal limit for each card sponsor based on projected enrollment initially and then adjusted periodically based on the number of enrolled beneficiaries determined eligible for transitional assistance, as provided by CMS' Medicare Beneficiary Database (MBD) Drug Card enrollment system. Card sponsors will receive reimbursement for transitional assistance funds and enrollment fees by submitting daily electronic requests to the PMS. Those funds will be made available through the Federal Reserve to card sponsors' bank accounts.

1.5 Period of Approval Agreement

CMS plans to approve all exclusive card programs that meet the qualifications in Section 3.0, and to permit successful applicants to market and label their programs as "Medicare-approved." Announcements of the Medicare-approved discount card programs will begin in Spring 2004. The effective period for approval will be from May 3, 2004 through December 31, 2005, with card sponsors required to continue to make available to beneficiaries still enrolled on December 31, 2005 drug discounts and any remaining transitional assistance until each enrollee's effective date of enrollment in a Part D drug plan or the last day of the open enrollment period for Part D. Card sponsors will not be permitted to accept new enrollments after December 31, 2005. There will be no renewal of the approval under section 1860D-31 of the Social Security Act after the initial period of approval.

After the initial application period, we will continue to accept applications for the approved card on a flow basis only when included as part of an application for a new Medicare managed care contract. No new applications will be accepted during contract year 2005 as part of CMS' preparation for the transition to Medicare Advantage.

1.6 Eligible Applicants

The Applicant must currently operate as a Medicare managed care organization under a contract with CMS. CMS's contract will be with only one non-governmental legal entity. The Medicare managed care organization must act as the sponsor and our contract will be with the Medicare managed care organization.

Although we will amend only one entity's contract per approved discount card program, the Applicant may meet the qualifications in Section 3.0 by using its own capabilities or by combining its capabilities with other entities through contracts or other legal arrangement.

2.0 APPLICANT INSTRUCTIONS

2.1 Application, Intent to Respond, and Application Inquiries

The Medicare managed care organization seeking an agreement with CMS to offer a Medicare-approved discount card program may submit an application for approval for one or more exclusive drug discount cards into which members of one or more of its Medicare managed care plans may exclusively enroll. For example, a Medicare managed care organizations could offer exclusive card program A to members of its Medicare managed care plan A, exclusive card program B to members of its Medicare managed care plan B, and non-exclusive card C to all eligible Medicare beneficiaries except members of Medicare managed care plans offering exclusive drug discount cards (including members of Medicare managed care plans A and B). Medicare managed care plans that wish to offer a non-exclusive card program must submit a separate application using the General Solicitation.

We encourage applicants to submit only one application describing all the exclusive cards they may offer under their Medicare managed care offerings. However, for their own administrative convenience, Applicants may elect to submit a separate application for each drug discount card they intend to offer.

To assist CMS in planning for the review of applications and to assure that potential applicants are notified of any additional guidance posted on the web, and for future correspondence, potential applicants should notify CMS of their intention to apply by January 7, 2004. Applicants should send notice of their intent to apply (including the completed CMS Connectivity Request by mail, electronic mail, or fax to:

Kim August
Centers for Medicare & Medicaid Services (CMS)

Center for Beneficiary Choices
7500 Security Boulevard, Mail Stop C4-23-07
Baltimore, Maryland 21244-1850
Fax: 410-786-8933
E-Mail: kaugust@cms.hhs.gov

Applicants seeking the approval of multiple drug discount cards should submit only one notice of intent to apply. This intent to apply should indicate the applicant's primary contact and include the contact's:

- Direct telephone number;
- Fax number;
- E-mail address; and
- Mailing address

Inquiries about the application, including questions for the pre-application conference and the intent to respond should be in writing and sent to: DrugCard@cms.hhs.gov.

Please note that entities that submit notices of intent to apply are not obligated to submit an application for approval to CMS. However, CMS will not consider an application for approval from an entity that has not submitted a timely notice of intent to apply. CMS has adopted this policy because only Applicants who submit a timely Connectivity Request (as part of the notice of intent) can eventually demonstrate their ability to exchange data with CMS in time to begin enrollment activities on May 3, 2004.

2.2 Approach to Application, Qualifications, and Evaluation

An applicant must submit sufficiently comprehensive information to support the application. Using the prompts under the "Application Requirements" headings in Section 3.0, the applicant shall provide a description of the proposed program, demonstrating how it meets the qualifications described under the "Qualifications" headings in Section 3.0, and otherwise how the program will work. Also, an individual with legal authority to bind the Applicant shall sign and submit the certification found in Section 5.0.

CMS reserves the right to request clarifications or corrections to a submitted application.

Applicants are advised that the information in their applications will be referenced in their Part C or cost plan contract addendum.

This solicitation does not commit CMS to pay any cost for the preparation and submission of an application.

CMS reserves the right to amend or cancel this solicitation.

Applicant responses to the prompts in Section 3.0 of the application will provide the information necessary for CMS to determine, on the basis of a pass/fail evaluation, whether the proposed

discount card program meets the qualifications outlined below. Only those discount card programs that meet all stated qualifications described in Section 3.0 will be approved. In addition, applicants must participate in telecommunications and systems testing processes as described on the CMS web site. The testing processes include demonstrating the ability to accurately submit and receive test files provided by CMS. An applicant will be required to successfully complete end-to-end system testing with CMS for transferring data before they can initiate their program. Although Medicare managed care organizations have existing connectivity to CMS, their ability to communicate with the eligibility and enrollment system must be established for this program.

Incomplete applications will not be considered.

2.3 Application Format

In preparing your application in response to the prompts in Section 3.0 of this solicitation, please repeat each question as stated, followed by your response. Provide complete answers, and detail the opportunities and value your discount card program offers to Medicare beneficiaries, in a clear, concise manner. If you have additional information you would like to provide, please include this information as an appendix to your application, and cross-reference its relation to the information requested.

In preparing your signed certification, please print out the certification provided in Section 4.0 of this solicitation and submit an original document signed by an individual with the legal authority to bind the Applicant.

To assure that each CMS review panelist receives the application in the manner intended by the applicant (e.g., collated, tabulated, colorized), applicants should deliver one (1) original and ten (10) copies of the written application with one (1) diskette or CD copy of the application in Microsoft Office format to the following address by 5:00 P.M. EST, January 30, 2004:

Centers for Medicare & Medicaid Services (CMS)
Center for Beneficiary Choices
Attn: Kim August
7500 Security Boulevard
Mail Stop C4-23-07
Baltimore, Maryland 21244-1850

CMS will not review applications submitted after the 5:00 P.M. deadline on January 30, 2004.

All copies and the original application should be in 3-ring binders. Tab indexing should be used to identify all major sections of the application. Page size should be 8 1/2 by 11 inches and the pages should be numbered. Type size should not be less than 12 point with a space and a half between lines.

2.4 Important Dates

Application Review Process

Date	Milestone
December 16, 2003	Posting of solicitation on CMS web site. Public Use Files available upon request.
December 16, 2003	Questions due to CMS for Pre-Application Conference.
December 18-19, 2003	Pre-Application Conference.
January 7, 2004	Notification of intent to apply. Submit telecommunications connectivity request to CMS.
TBA	Transaction test files made available by CMS.
January 12, 2004	Telecommunications testing begins.

Implementation Process

Anticipated Date	Milestone
January 30, 2004	Applications due. Information and outreach materials due.
Late January – mid March 2004	Review of applications.
End of March 2004	Finalize and sign approval agreements.
mid-March 2004	CMS completes review of information and outreach materials.
Late March 2004	Announce approvals. Completed transaction system check-list due to CMS. End-to-end testing begins.
April 1, 2004	Drug Card sponsors' information and outreach may begin. Only approved materials may be used.
April 30, 2004	CMS launches price comparison web site.
May 3, 2004	Card sponsors' enrollment may begin.
June 1, 2004	Card sponsors begin offering discounts; enrollments become effective; transitional assistance becomes available.

NOTE: The earliest date card sponsors may begin enrolling beneficiaries in their drug cards is May 3, 2004. All of the dates stated in this solicitation assume that card sponsors are preparing to meet that milestone. However, Applicants should be aware that they will be required to have submitted to CMS completed contracts with their subcontractors and have had their information and outreach materials approved by CMS before they will be permitted to begin enrollment activities. The date each card sponsor may begin

enrollment activities will be determined by the date by which each completes these two tasks.

2.5 Withdrawal of an Application

An applicant may withdraw an application at any time before an agreement becomes effective, by submitting a written notification for its withdrawal to the CMS contact noted above.

2.6 Amendments to an Application

Applicants are encouraged to provide sufficient documentation of qualification for approval at the time applications are due to CMS. However, CMS may award approvals on the basis of Applicants' representations of arrangements (e.g. contracts with pharmaceutical manufacturers, network pharmacy contracts). In those situations, approved sponsors will be required to submit all required documentation to CMS before sponsors will be permitted to begin information and outreach and enrollment activities under the discount card program.

2.7 Protection of Commercial Information

Only information within a submitted application (or attachments thereto) that constitutes a trade secret, privileged or confidential information, (as such terms are interpreted under the Freedom of Information Act and applicable case law), and is clearly labeled as such by the Applicant, will be protected from release by CMS under 5 U.S.C. § 552(b)(4). Information not labeled as trade secret, privileged, or confidential will not be withheld from release under 5 U.S.C. § 552(b)(4).

2.8 Certification Instructions

Pursuant to the Certification Statement in Section 4.0, changes to the information furnished in this application must be reported to:

Centers for Medicare & Medicaid Services (CMS)
Center for Beneficiary Choices
Attention: Kim August
7500 Security Boulevard, Mail Stop C4-23-07
Baltimore, Maryland 21244-1850

2.9 Pre-application Conference

CMS will hold a pre-application conference on December 18-19, 2003 for all interested applicants. Applicants must pre-register for both sessions on-line at www.cms.hhs.gov under the drug card initiative) by 12 Noon on December 16, 2003. The purpose of this conference is to give applicants the opportunity to ask questions about this solicitation. The conference will include a break-out session for Medicare managed care organizations that wish to offer an exclusive card program. The conference will also include a session for applicants' information systems staff during which CMS staff will make presentations on systems requirements related to the drug card program. There will also be a session to address the special approval for

applicants interested in operating exclusive card programs, as well as discount card programs that serve I/T/U pharmacies, LTC facilities, and the U.S. territories. Questions submitted through DrugCard@cms.hhs.gov to CMS by 12 Noon on December 16, 2003 will have priority for oral response by CMS during the conference. Questions submitted after this date and from the floor will be addressed orally as time permits. CMS will post a summary of the questions and CMS responses on the CMS Web site at www.cms.hhs.gov.

2.10 Requests for Waived or Modified Qualifications

As noted above in the Overview (Section 1.2.), CMS will consider requests for waivers of Drug Card Program qualifications. The chart below indicates the qualifications we understand Medicare managed care contractors may find to conflict with or be duplicative of the requirements applicable to Medicare managed care organizations, or to interfere with the coordination of benefits offered under a Medicare+Choice or Medicare cost plan. Applicants should review the chart, including CMS' rationale for how there might be proper basis for granting applying Applicants a waiver from such qualifications. If the Applicant believes the rationale for waiving a qualification applies to it, the Applicant may request a waiver of the identified qualification by stating "yes" in the far right column of the chart. For those qualifications for which the Applicant has requested a waiver, the Applicant should respond to the Application Requirements stated in this solicitation. For those qualifications for which the Applicant has not requested a waiver, the solicitation directs the Applicant to respond to the corresponding Application Requirement of the Solicitation for Applications for non-Medicare Managed Care Contractors (the General Solicitation) posted on the CMS Web site.

POTENTIAL SUBJECTS OF APPLICANT WAIVER/MODIFICATION REQUESTS

Potential Waivers	Rationale	Applicant Requests Waiver/ Modification: Yes / No
ITEM 1: Formulary: A Medicare managed care contactor may request a waiver/modification of the requirements to offer one drug in each pre-determined category or to offer at least one generic drug in at least 55% of those categories if the contractor wishes to use under its approved discount card an existing formulary used under its plan(s)' drug benefit or drug discount program, and such formulary does not meet these requirements. The formulary under the approved discount card must be equivalent to the formulary under the drug benefit or drug discount program (excepting any drugs that do not meet the "covered discount card drug" definition in statute).	**Coordination between Medicare managed care plans and the discount card.** Medicare managed care contractors that offer discount cards and drug benefits may already have formularies in place. The formulary used under a contractor's approved discount cards should coordinate with the formulary used under its existing drug benefits or drug discount program to ensure optimal benefits coordination for Medicare managed care plan enrollees. * An Applicant may not request waiver of the formulary requirements under this rationale if (1) the Applicant's formulary under its drug benefit or drug discount program meets the formulary requirements set forth in 42 CFR 403.806(d), or (2) the Applicant does not currently use a formulary under any drug benefit or drug	

Potential Waivers	Rationale	Applicant Requests Waiver/ Modification: Yes / No
	discount program offering.	
ITEM 2: Manufacturer Rebates: A Medicare managed care contractor may request waiver/modification of requirements relating to obtaining manufacturer rebates on prescription drugs.	**Coordination between Medicare managed care plans and the discount card.** If an Applicant currently offers a drug benefit under its plan(s), it may have existing contractual arrangements for discounted drug prices that do not include manufacturer rebates. It would be disruptive to these arrangements and would also potentially harm coordination and continuity of care were CMS to require that these existing contractual arrangements be renegotiated to include manufacturer rebates. An Applicant may not request a waiver of the manufacturer rebate requirement if the Applicant, either itself or through its subcontractor(s), has negotiated manufacturer rebates.	
ITEM 3: Reporting: A Medicare managed care contractors may request waiver of certain reporting requirements when such requirements are duplicative of existing reporting obligations for operating its Medicare managed care plan(s).	**Duplicative of Medicare managed care contractor requirements.** Given the breadth and depth of reporting requirements currently required of Medicare managed care contractors by CMS, the reporting requirements under the drug card program may represent a substantial duplication of the Applicant's existing Medicare managed care reporting obligations.	
ITEM 4: Price Compare: A Medicare managed care contractor may request waiver of the requirement to report pricing data on their formulary drugs to CMS for the purpose of display on CMS' price comparison web site. However, Medicare managed care contractors will be required to submit such data, like all other drug card sponsors, for CMS' use in monitoring drug card program.	**Conflicts with Medicare managed care contractor enrollment policies.** Enrollment in exclusive drug cards offered by Medicare managed care contractors will be limited to enrollees of the contractors' Medicare managed care plans. As a result, enrollees in these cards will not have had the opportunity to select a drug card based at least in part on drug prices offered under the drug card. Therefore posting the drug prices of Medicare managed care plan exclusive drug cards on the price comparison web site serves no practical purpose and conflicts with the enrollment limitations placed on exclusive drug card offered by Medicare managed care contractors,	
ITEM 5: Years of Experience: A Medicare managed care contractor may request waiver of the requirement to demonstrate that they, or an entity with which they contract, have a minimum of three years experience in pharmacy benefit management.	**Duplicative of Medicare managed care contractor requirements.** CMS adopted this qualification to ensure that it would only approve card programs operated by stable business entities. Medicare managed care contractors have established contracts with CMS. To obtain these contracts, Medicare managed care organizations have already had to demonstrate sufficient capability to operate successfully a	

Potential Waivers	Rationale	Applicant Requests Waiver/ Modification: Yes / No
	managed care plan. Moreover, Medicare managed care contractors must be licensed by the States in which they operate, providing further evidence of their stability. Therefore, this qualification may be considered duplicative of Medicare managed care program requirements.	
ITEM 6: Eligibility/Enrollment Systems: A Medicare managed care contractor may request waiver of the requirement to demonstrate the capability to exchange beneficiary/transitional assistance eligibility data with CMS or describe their procedures for accepting and processing disenrollment requests.	**Duplicative of Medicare managed care contractor requirements.** Medicare managed care contractors already exchange eligibility data with CMS and have procedures for disenrollment in place; provision of this information would be duplicative.	

3.0 SUMMARY OF QUALIFICATIONS

3.1 Card Sponsor Organization, Structure, and Experience

3.1.1 Type of Applicant

Qualification:

- Applicant currently operates as a Medicare managed care organization under a Part C or under a reasonable cost reimbursement contract with CMS.

Application Requirements:

- Identify the legal entity (same as Applicant) that would enter into agreement with CMS for approval of its prescription drug discount card program.

- Identify all entities with which the Applicant is under contract or other legal arrangement to meet all the card program qualifications. Identify the responsibility of these entities in meeting the qualifications.

3.1.2 Years of Experience

Qualifications

Request for Waiver: Applicants who requested a waiver of this qualification by completing the chart in Section 2.10 must complete this section. Applicants who did not request a waiver should

provide a response to the Application Requirements stated in Section 3.1.2 of the General Solicitation.

3.2 Formulary and Discounts to Beneficiaries

3.2.1 Formulary

Request for Waiver: Applicants who requested a waiver of this qualification by completing the chart in Section 2.10 must complete this section. Applicants who did not request a waiver should provide a response to Section 3.2.1 of the General Solicitation.

Qualifications:

- Applicant currently offers its commercial health plan and/or Medicare managed care plan members access to negotiated prices on prescription drugs through a formulary.

- Beginning June 1, 2004, Applicant provides its drug card enrollees access to the formulary to which commercial and/or Medicare managed care plan members currently have access.

- The list of discounted drugs included in the Applicant's formulary must be offered through the Applicant's contracted retail pharmacy network. Offering these drugs through mail order does not count toward meeting this qualification.

Application Requirements:

- Attest that you will provide negotiated prices on all covered discount card drugs on your formulary.

- Indicate which, if any, of the attached list of drugs commonly used by Medicare beneficiaries, according to results from the 2000 Medicare Current Beneficiary Survey (Attachment 1) your card will include.

- While Applicants are not required to offer discounts on all drugs, please discuss how your program may accommodate the needs of certain populations or address certain issues including:

    - Offering discounts on drugs needed by special populations, including those who are HIV positive, those with mental illnesses, those who require the use of alkylating agents to treat certain forms of cancer, and those who have received organ/tissue transplants requiring immunosuppressives.

    - Offering discounts on appropriate selections and dosage forms of drugs within each class or subclass as needed (for example, long-acting versus short-acting).

- State how your program guarantees that Medicare beneficiaries will receive (at point of sale) the lower of the discounted price available through the program or the usual and customary price.

- Explain how you will monitor and enforce your drug card's negotiated price.

3.2.2 Pricing/Rebates, Discounts, and Other Price Concessions

Qualifications:

Request for Waiver: Applicants who requested a waiver of this qualification by responding "yes" to Item 2 in the chart in Section 2.10 must complete this section. Applicants who did not request a waiver should provide a response to the Application Requirements stated in Section 3.2.2 of the General Solicitation.

- Applicant offers discount card enrollees access to "negotiated prices" calculated by combining a percentage of rebates, discounts, and other price concessions obtained from sources including manufacturers, wholesalers, and pharmacies, as well as any dispensing fee.

- Applicant charges enrollees at the point of sale the lower of the card program's negotiated price or the pharmacy's usual and customary price (the price that a pharmacy would charge a customer who does not have any form of prescription drug coverage).

- Applicant certifies that a contract exists with each network pharmacy ensuring that rebates, discounts, or other price concessions are passed through to the Medicare beneficiaries in the form of lower prices.

- Applicant requires network pharmacies to inform enrollees at the time of purchase of any differential between the negotiated price of the drug being dispensed and the price of the lowest-priced generic alternative available (not limited to those generics on the discount card program's formulary) that is therapeutically equivalent and bioequivalent and available at the pharmacy. For prescriptions provided via mail order, this information must be provided at the time of delivery of the drug.

- Prices may vary based on pharmacy contract and enrollee characteristics, such as transitional assistance eligibility.

- Applicant agrees that, for the duration of the drug card program(except during the week of November 15, 2004), any increase in the negotiated price for a covered drug will not exceed an amount proportionate to the change in the drug's average wholesale price (AWP), and/or an amount proportionate to the material change in the Applicant's cost structure, including a material change in any discounts, rebates, or other price concessions it receives from a pharmaceutical manufacturer or pharmacy.

Application Requirements:

- Describe the rebates (other than manufacturer rebates), discounts, and/or price concessions secured by contract. Indicate the amount of rebates (other than manufacturer rebates) and/or discounts to be passed through to beneficiaries directly at the point of sale. Your description must include the following information:

    - Estimate the aggregate level of rebates (other than manufacturer rebates)/discounts/other price concessions to be secured and the estimated total share that will be passed though to Medicare beneficiaries in the form of lower prices at the point of sale.

    - Describe how actual rebates (other than manufacturer rebates)/discounts/other price concessions will be tracked to determine whether they reach the level of anticipated share.

    - Explain how the process of passing through rebates (other than manufacturer rebates), discounts, and any other price concessions at the point of sale will work.

    - Indicate that a contract exists with each network pharmacy that ensures that rebates or discounts are passed through to the drug card program enrollees in the form of lower prices.

    - If negotiated prices will vary systematically by type of enrollee (e.g., low income enrollees or those with a particular disease or condition), please provide each of the above separately for each category of enrollee by which negotiated prices will vary under the program.

- Indicate that for the duration of the drug card program (except during the week of November 15, 2004, any increase in the negotiated price for a covered drug will not exceed an amount proportionate to the change in the drug's average wholesale price (AWP), and/or an amount proportionate to the material change in your organization's cost structure, including a material change in any discounts, rebates, or other price concessions it receives from a pharmaceutical manufacturer or pharmacy.

3.3 Service Area and Access to Pharmacies

3.3.2 Service Area

Qualification:

- A Medicare managed care plan drug card's service area must be identical to the service area under the affiliated Medicare managed care plan.

Application Requirement:

- Describe the service areas (by State and county) of the Medicare managed care plans (H number and plan number(s)) for which you will be offering your discount card program.

3.3.2 Pharmacy Network

Qualifications:

- If the Applicant currently offers a prescription drug benefit under its Medicare managed care plan, the Applicant must provide access to negotiated prices through a pharmacy network that is at least equivalent to the pharmacy network it currently uses to dispense prescription drugs to its Medicare managed care plan members.

- If the Applicant does not currently offer a prescription drug benefit under its Medicare managed care plan, the Applicant provides access to negotiated prices through a network of pharmacies that meets Medicare managed care provider access requirements at 42 CFR 422.112 (in the case of Part C organizations) and 417.416(e) (in the case of Medicare cost plans).

- NOTE: Applicants may offer a mail order option in addition to their contracted pharmacy network. (Mail order option only is precluded.) CMS expects drug cards offering mail order services to provide beneficiaries with access to a licensed pharmacist to answer questions, should there be inquiries that require clinical attention.

Application Requirements:

- If you currently offer a drug benefit as part of a Medicare managed care plan under which you are requesting to offer a Medicare-approved discount card program, indicate your intention to ensure that the pharmacy network available to discount card enrollees will be at least equivalent to your current pharmacy network under the Medicare managed care plan drug benefit.

- If you do not currently offer a drug benefit as part of a Medicare managed care plan under which you are requesting to offer a Medicare-approved discount card program, describe the pharmacy network that will be available to discount card enrollees for the purchase of covered discount card drugs.

- Describe the nature of your network pharmacy contracts. Describe your organization's policies and procedures for ensuring that these contracts are in compliance with all Federal and State laws. Describe specific contracting provisions that allow the drug card to meet the requirements under this program, including:

    - Making available the balance of transitional assistance at the point of sale;
    - Providing negotiated prices;
    - Providing the enrollee with the differential in price between the drug being purchased and the lowest priced therapeutically equivalent and bioequivalent generic drug available at the pharmacy; and
    - Applying the correct coinsurance amount.

- If your discount card includes mail order:

    - Provide the mail order pharmacy name, address, phone number, business hours, and senior management point of contact.

    - Provide a description of the service and its operations, including states in which pharmacy is licensed, how beneficiary education on generic substitutions is conducted, and the availability of a pharmacist to answer enrollee questions**.**

    - Indicate how you will monitor/conduct audits of mail order pharmacy services.

    - State when you expect your mail order service will be available to enrolled beneficiaries.

3.4 Other Drug-Related Items and Services Under the Approval and Items and Services Outside the Scope of the Approval

Qualifications:

- Applicant may provide under the approval, at its discretion, non-required additional services related to a covered discount card drug or a discount on over-the-counter drugs under the approval for no extra charge to enrollees (e.g., durable medical equipment related to a covered drug). These services would be in addition to the basic program requirements.

- Applicant agrees to ensure that enrollees are not charged an additional fee for either required services or additional services provided under the approval.

Application Requirement:

- List and describe any items or services related to covered discount card drugs beyond those required to qualify for approval, that you will offer enrollees for free. Also list and describe whether and how you will offer discounts on non-prescription drugs. Indicate that you (and any other entity involved in operating your drug card) will not charge any membership fee (other than the enrollment fee) for any services offered by your approved card.

3.3 Card Program Administration and Customer Service

3.3.1 Beneficiary Eligibility/Enrollment/Enrollment Fee

NOTE: Applicants should refer to Attachment 2 for an illustration of the Drug Card Enrollment Process

Qualifications:

- Applicant limits enrollment in its drug card to current or new members of the Medicare managed care plans offering such exclusive card program who do not receive drug coverage through a Medicaid plan, including Medicaid demonstration programs under 1115 waivers (including Pharmacy Plus waivers).

- Applicant limits enrollment in its drug card to those Medicare managed care plan members who reside within the Applicant's service area.

- Applicant charges each enrollee (or State) an annual enrollment fee of no more than $30 for 2004 and 2005. Applicant must charge a uniform enrollment fee within each Medicare managed care plan that offers the discount card. The enrollment fee may neither change nor be pro-rated during the year. No enrollment fee may be charged in 2006. Applicant may subsidize the enrollment fee (or offer the drug card for no fee) for drug card eligible Medicare managed care plan members and, if it chooses to do so, must include the drug card program as an additional benefit under its Adjusted Community Rate (ACR) filing. Should the Applicant charge a fee for its exclusive card program, the benefit would be considered an optional supplemental benefit.

- Applicant accepts for enrollment all eligible Medicare managed care plan members who apply.

- Applicant accepts payment of enrollment fees from States that offer such payments on behalf of Medicare beneficiaries who are not determined eligible for transitional assistance.

- Applicant accepts enrollments in the following manner:

    - For individuals applying for the drug card and transitional assistance, Applicant collects an enrollment form. This form may be made available on-line as a printable or downloadable form, but it must be signed and dated and returned to the Applicant via mail or facsimile
    - For individuals applying only for the drug card, Applicant accepts an enrollment form via mail or facsimile, but may, and is encouraged to, accept drug discount card enrollment requests via telephone and Internet.

- Medicare managed care organizations may use abbreviated enrollment forms where applicable, especially where the Medicare managed care organization already has some of the required information about the beneficiary. CMS will provide model standard enrollment forms, as well as model abbreviated enrollment forms. Applicant may use the model forms or may design its own forms, provided that such forms contain at least the same elements as the CMS standard forms and are reviewed and approved by CMS prior to use (whether from those eligible beneficiaries who are members of, or enrolling for the first time in, the Medicare managed care plan) Applicant may ask beneficiaries to respond to questions beyond those stated in the CMS standard form. However, the beneficiaries must be informed that responding to those questions is optional and that their decision to answer the optional questions will not affect their qualification for enrollment in the drug card.

- Beneficiaries enrolled in a Medicare managed care plan in which an approved drug discount card is offered by a Medicare managed care organization that is also an exclusive card sponsor may only enroll in the approved drug card program offered by that Medicare managed care organization for that Medicare managed care plan.

- A beneficiary is entitled to a Special Election Period when he or she enrolls in or disenrolls from a Medicare managed care plan, irrespective of whether the Medicare managed care plan offers an approved drug card program only to its Medicare managed care plan members.

- Applicants make enrollments in their drug card effective on the first of the month following the Applicant's receipt of a complete enrollment form from a beneficiary who is determined eligible. Applicant makes enrollments received during the Annual Coordinated Election Period (November 15, 2004 through December 31, 2004) effective the following January 1, 2005. Group enrollment (described below) is effective on the first of the month the Applicant reports as the first month of the program.

- Applicant may "group enroll" all eligible members of one or more of its Medicare managed care plan(s) into the approved drug card program offered to members of such plans without collecting an enrollment form (or submissions through other means) from these individuals. However, prior to group enrollment, Applicant must disclose to its Medicare managed care enrollees its intent to group enroll them and provide them the opportunity to actively decline the enrollment. Applicant should inform its managed care enrollees that if they decline enrollment in the Applicant's drug card program, they will be ineligible to enroll in another drug card program as long as they remain enrolled in the Applicant's managed care plan. Applicant must explain the annual enrollment fee, if any, provide information on the availability of transitional assistance with instructions on how to apply for it, and make an enrollment form for transitional assistance available to all members. Applicant may not group enroll for transitional assistance; a signed standard enrollment form is required for transitional assistance enrollment.

- Applicant contacts beneficiaries by telephone when an incomplete enrollment application is submitted. Applicant returns unsigned transitional assistance enrollment forms to applying beneficiary for signature.

- Applicant keeps enrolled in its discount card those beneficiaries who do not enroll in a new Medicare managed care plan during the Annual Coordinated Election Period and automatically charges these beneficiaries any applicable annual enrollment fee for the second year of drug card enrollment.

- Applicants may require payment of the enrollment fee, if any, at the time they receive the enrollment form (or Internet or telephone request), except for transitional assistance beneficiary applicants. Applicants may not collect a fee from transitional assistance enrollees.

- Applicant returns promptly any enrollment fee collected by an applying beneficiary later determined ineligible for enrollment in the Applicant's approved drug card (e.g., beneficiary receives drug coverage through a Medicaid plan).

- Applicant submits in batch enrollment/eligibility transactions to CMS according to the instructions provided. Enrollment/eligibility transactions for drug card only and transitional assistance must be batched separately. CMS will provide responses to each submitted transaction.

- Applicant sends enrollment materials – including materials describing the drug card program and an identification card (or, if Medicare managed care plan ID card provides access to the discounts, Applicant notifies enrollees that this is the case) – within 5 business days of group enrollment or of receipt of reply from CMS for all accepted enrollment/eligibility transactions. Applicant informs transitional assistance enrollees of the date the $600 becomes available for use and ensures enrollees understand the rules for accessing such assistance.

- Applicant reviews each enrollment form (or information received through other means) it receives for completeness, including signature (where necessary), and screens each form to ensure answers to standard, required data elements meet the criteria for enrollment in the program. Any enrollment form that indicates, through the answers to standard elements attested to (under penalty of perjury) by the beneficiary, that the beneficiary is ineligible for enrollment will be identified by the Applicant. Written notice must be sent to the beneficiary within five business days of the Applicant's identification of ineligibility due to data submitted on the form. This notice must describe the reason for being identified as ineligible and include instructions on accessing the reconsideration process.

- Applicant notifies beneficiaries disenrolling from the Medicare managed care plan that they will lose access to the exclusive card program. Applicant also notifies such disenrolling members that they are eligible for a Special Election Period and the length of such Period.

- Applicant may involuntarily disenroll from its drug card program a beneficiary who does not pay any required annual enrollment fee. Applicant must notify enrollees within 20 calendar days of the date the annual fee was due that delinquency will result in termination from its drug card program. If the enrollee fails to pay the delinquent amount within 10 days of this notice, the Applicant may disenroll the enrollee from its discount card program by submitting transaction to CMS and notifying the enrollee that his/her membership in the discount card program has ended. The effective date of disenrollment is the last day of the month in which the fee was due. Applicant must inform the enrollee that he or she cannot enroll in any other approved drug card program as long as he or she remains enrolled in the Medicare managed care plan in question. Applicant must also inform the enrollee that the next possible enrollment date, if applicable, is the Annual Coordinated Election Period that begins November 15, 2004 and continues through December 31, 2004.

Application Requirements:

- Indicate your intention to limit enrollment in your drug card to current and enrolling members of one or more of your Medicare managed care plans.

- Indicate your intention to enroll all current and enrolling Medicare managed care plan members eligible for this program.

- State the annual enrollment fees (if any) you intend to charge your drug card enrollees. If different fees are charged in each of your Medicare managed care plans, identify the fees by Medicare managed care plan.

- Indicate that you will promptly refund enrollment fees paid by beneficiaries applying for enrollment in your discount card who are determined ineligible for enrollment in a drug card program and by beneficiaries who are determined to be eligible for transitional assistance after they have been enrolled in your discount card.

- Indicate that you will not charge enrollment fees to beneficiaries who remain enrolled in your drug card during 2006.

- Indicate that your drug card can be ready to enroll beneficiaries on May 3, 2004 and provide discounts and access to transitional assistance by June 1, 2004**.**

- Indicate whether you intend to group enroll your Medicare managed care members in your proposed discount card program and, if so, describe your group enrollment process.

- For situations other than group enrollments, describe your process for enrolling Medicare managed care plan members in your proposed discount card program, including the means by which you intend to perform the enrollment function (e.g., paper, fax, telephone, Internet for non-transitional assistance Applicants; paper and fax only for transitional assistance Applicants), your processes for verifying program eligibility with CMS, communicating eligibility determinations back to the applying beneficiary within five days of receipt of the application, and making enrollments effective on the first of the month following your receipt of a complete enrollment form that is determined eligible.

- Indicate that you will collect only the data elements described in the CMS standard enrollment form shown in the model enrollment form posted on the CMS website.

- Describe your organization's capability to communicate mainframe to mainframe to exchange beneficiary eligibility data with CMS. Describe your organization's ability to separate drug card and transitional assistance transactions before submitting batch transactions. Describe the processing environment that will be used to manage required transactions and data.

- Describe your procedures for accepting and processing disenrollment requests from beneficiaries, including communicating such request to CMS. This description must include a discussion of your procedures for handling beneficiary requests for a Special Election Period and reporting of any remaining transitional assistance.

- Describe your procedures for notifying beneficiaries that they will lose access to the exclusive card program when they disenroll from the Medicare managed care plan.

- Describe your procedures for informing beneficiaries of the Special Election Period when they disenroll from the Medicare managed care plan.

- Describe your procedures for involuntarily disenrolling beneficiaries who fail to pay their annual enrollment fee.

3.5.2 Transitional Assistance Eligibility Determination

Qualifications:

- Applicant submits transactions to CMS for a transitional assistance eligibility determination for each complete enrollment form (that includes transitional assistance) it receives. Beneficiaries already enrolled as drug card members (without transitional assistance) may apply for transitional assistance at a later date by completing the transitional assistance enrollment form and submitting it to their current drug card sponsor.

- To be eligible for Transitional Assistance, each beneficiary must be eligible for the drug card, must reside in one of the 50 States or the District of Columbia, and must not have:
    - An annual income more than 135% of the poverty line (adjusted for applicant's family size, i.e., individual or couple) (NOTE: Beneficiaries enrolled in Medicaid as a Qualified Medicare Beneficiary (QMB), Specified Low-Income Medicare Beneficiary (SLMB), or Qualified Individual (QI) are deemed to meet the income requirements for transitional assistance.);
    - Medicaid (including under an 1115 demonstration program) that includes outpatient prescription drug assistance;
    - Other health insurance coverage that includes prescription drugs (such as an employer-sponsored or retiree group health plan or a privately paid for individual health insurance policy). Note: If other coverage is through a Medicare managed care plan or Medigap plan (even if an employer pays for the premium of the Medicare managed care plan or Medigap plan), it does not apply;
    - TRICARE; or
    - Federal Employee Health Benefits Program (FEHBP) (whether for current or retired employees).

  This data is collected on the transitional assistance enrollment form.

- Applicant reviews each enrollment form (or information received through other means) for completeness, including signature (where necessary), and screens each form to ensure that answers to standard, required data elements meet the criteria for enrollment in the program. Any enrollment form that indicates, through the answers to standard elements attested to by the beneficiary, that the beneficiary is ineligible for enrollment will be identified by the Applicant. Written notice must be sent to the beneficiary within 5 business days of the Applicant's identification of ineligibility due to data submitted on the form. This notice must

describe the reason identified for ineligibility and include instructions on accessing the reconsideration process.

- For enrollments not screened-out as above, Applicant transmits all required data obtained from information supplied by beneficiaries on the standard transitional assistance enrollment form to CMS according to the systems described on the CMS web site. CMS informs card sponsors whether the beneficiary is eligible for transitional assistance and if each beneficiary was enrolled in the transitional assistance program. Transitional assistance amounts will be prorated based on the date the beneficiary's complete enrollment form is received by the Applicant during the second year of the discount card program (2005).

- Beneficiaries determined eligible for transitional assistance are entitled to continue to receive such assistance for the duration of the drug card program, regardless of any changes in beneficiaries' status. Applicant must send enrollment materials (including a member handbook and ID card) to each accepted enrollee within 5 business days of receipt of CMS reply.

- For Medicare beneficiaries whom CMS determines to be ineligible for transitional assistance, Applicant notifies the beneficiary of this determination and his/her right to, and the process for, a reconsideration of the determination as well as the opportunity to select the discount card only (if eligible). This notification must be in writing and sent within 5 business days of the Applicant's receipt of the CMS eligibility determination reply.

- Applicant does not enroll in their drug discount card beneficiaries applying for transitional assistance if CMS determines that the beneficiaries are eligible for transitional assistance.

- Applicants determine the appropriate coinsurance levels for each transitional assistance enrollee based on the income information he or she provides on the standard enrollment form. For beneficiaries whose income is at or below 100% of the poverty line, the coinsurance level is 5% of the price of the covered drug. For beneficiaries whose income is above 100% and at or below 135% of the poverty line, the coinsurance level is 10% of the price of the covered drug.

Application Requirements:

- Describe your process for collecting and reviewing information from Medicare beneficiaries applying for transitional assistance. Indicate that your organization will send a written notice (stating the basis for ineligibility and the right to reconsideration) to ineligible beneficiaries within five business days of your identification of ineligibility due to data submitted on the enrollment form.

- Describe how you will handle incomplete enrollment forms or submissions.

- Indicate that you will forward to CMS applications of those beneficiaries who indicate that their income is not more than 135% of the poverty line (adjusted for applicant's family size); they are enrolled in Medicaid but not receiving prescription medicine assistance or are

medically needy and not receiving prescription medicine assistance; and they do not have group health insurance coverage or a private health insurance policy including drug coverage, TRICARE enrollment, or enrollment in a Federal Employee Health Benefits Program plan.

- Indicate that you will not enroll beneficiaries in your card program who are applying for transitional assistance until CMS has determined that they are eligible for such assistance.

- Describe your process for sending and receiving transitional assistance eligibility determination information to and from CMS.

- Describe your process for notifying beneficiaries that they are ineligible for transitional assistance.

- Describe your process for determining and applying the appropriate coinsurance level for each transitional assistance-eligible enrollee.

3.5.3 Reconsideration of Eligibility Determination

Qualifications

- Beneficiaries determined not eligible for the drug card and/or transitional assistance may request reconsideration of eligibility determination.

- Applicant provides timely written notice (that is, notice within 5 business days of the Applicant's identification of ineligibility due to data submitted on the form) to beneficiaries who are determined to be ineligible for the drug card and/or transitional assistance. The notice must describe the reason identified for ineligibility and contain information on the beneficiary's right to a reconsideration of the determination and instructions on accessing the reconsideration process. Finally, the notice must inform the beneficiary of his or her option of enrolling in the approved program without access to transitional assistance.

- The reconsideration process will be conducted by an independent entity through a contract administered by CMS and will include a review of the beneficiary's enrollment form and any other documentation required to successfully review each individual case.

- The Applicant must communicate with the reconsideration contractor and respond in a timely manner to requests for information, such as copies of enrollment forms.

- The eligibility decision from the reconsideration process is final. If the denial is reversed, the enrollment will be effective beginning with the 1st of the month following the positive eligibility determination from reconsideration, AND, if eligible for transitional assistance, the amount of available transitional assistance dollars (in year 2005) relates directly to the month in which the sponsor received the original, complete enrollment form for transitional assistance. The reconsideration contractor will notify the beneficiary by written notice, and CMS by submitting a transaction to enroll as appropriate.

- Applicant will be notified by CMS of individuals determined eligible for the drug discount card and/or transitional assistance.

- If the denial is upheld, the reconsideration contractor will notify the beneficiary in writing of its decision.

Application Requirements

- Describe your procedures for notifying beneficiaries of a determination that they are ineligible for transitional assistance and/or the discount card program and advising them of their reconsideration rights. Such notice must be provided within 5 business days of your organization's receipt of the CMS eligibility determination reply.

- Describe your procedures for communicating with and responding to the independent review entity (IRE) conducting transitional assistance or discount card eligibility reconsiderations.

3.5.4 CMS Reimbursement of Transitional Assistance

Qualifications:

- Applicant registers with the DHHS Payment Management System (PMS) via the web site http://dpmlink.dpm.psc.gov.

- Applicant submits EIN information (Attachment 3) to CMS upon award of Medicare approval for its drug discount card. CMS establishes an account and a withdrawal limit in PMS for Applicant.

- Applicants submit payment requests associated with their transitional assistance members as needed through the PMS. Based on this information, the PMS will authorize the Federal Reserve to make the appropriate deposit into Applicant's bank account.

- Applicant reports to CMS' enrollment and eligibility system each month the following beneficiary-level subsidy expenditure data for their transitional assistance-eligible enrollees:

    - Applicant's enrollment and eligibility system identification number;
    - Each transitional assistance enrollee's HIC number, name, sex, date of birth; and
    - Amount spent from each transitional assistance enrollee's subsidy for that month. Such amount shall represent only claims which have been adjudicated for payment and not claims that are pending or denied.

- Applicant provides a certified electronic file or hard copy report to CMS each month of the monthly transitional assistance expenditures and monthly cash payments from the PMS. The Applicant's Chief Financial Officer will provide certification.

- Applicant files a Federal Cash Transaction Report (PSC-272) in which the Applicant's Chief Financial Officer certifies the Applicant's transitional assistance expenditures with PMS quarterly

Application Requirements:

- Indicate that your organization will register with PMS.

- Describe how your organization will interact with the PMS daily to request payment for your enrollees' transitional assistance expenditures.

- Indicate your intention to submit to CMS' enrollment and eligibility system monthly beneficiary-level transitional assistance expenditures for your transitional assistance-eligible enrollees. Indicate that the data will include:

    - Your organization's identification number;
    - Each transitional assistance enrollee's HIC number, name, sex, date of birth; and
    - Amount spent from each transitional assistance enrollee's subsidy balance for that month.

- Indicate your intention to provide a certified electronic file or hard copy report to CMS each month of the monthly transitional assistance expenditures and monthly cash payments from the PMS. The Applicant's Chief Financial officer will provide certification.

- Indicate your intention to file a quarterly Federal Cash Transaction Report (PSC-272) with PMS, in which your organization's Chief Financial Officer certifies your organization's transitional assistance expenditures.

3.5.5 Card Sponsor Payment and Tracking of Transitional Assistance

Qualifications:

- Applicant establishes internal controls, accounting procedures and a financial accounting system to manage and report the transitional assistance funds.

- Applicant makes available to enrollees with transitional assistance, for the purchase of covered discount card drugs and, at the option of the Medicare managed care organization, for the payment of deductibles, copayments, and coinsurance for any covered discount card drug under any drug benefit it may provide to beneficiaries as part of its Medicare managed care plan, the amount of transitional assistance indicated by CMS. In most cases, the amount is expected to be $600 annually in 2004 and 2005, but in some cases in CY 2005 an enrollee's transitional amount may be prorated, and will thus be less than $600 in a given enrollment year. No additional transitional assistance will be made available to eligible enrollees during 2006. However, an enrollee may use any transitional assistance balance remaining at the end of 2004 or 2005 to purchase covered drugs during the following year (i.e., 2005 and 2006).

- Applicant ensures that transitional assistance funds are applied only to covered discount card drugs and, at the option of the Medicare managed care organization, costs incurred by the transitional assistance enrollee for covered discount card drugs obtained through any Medicare managed care prescription drug benefit it provides; specifically, Applicant may allow transitional assistance enrollees to utilize transitional assistance to assist in paying copayments, coinsurance, or deductibles for covered discount card drugs under any Medicare managed care drug benefit it provides. For covered discount card drugs obtained under the exclusive card program, Applicant must apply such funds regardless of whether the particular drug being purchased is offered for a negotiated price by the sponsor. If no negotiated price is offered, the pharmacy's usual and customary price shall prevail. The usual and customary price is the price that the pharmacy would charge a customer who does not have any form of prescription drug coverage. Transitional assistance funds may not be used to purchase over the counter drugs or to purchase or pay the cost-sharing for any drugs excluded from the definition of "covered discount card drug" as stated in 42 CFR § 403.802.

- Applicant does not require its transitional assistance enrollees to use the transitional assistance to which they are entitled prior to drawing down any drug benefit offered to beneficiaries by their Medicare managed care plan.

- Applicant ensures that when transitional assistance funds are used, enrollees receive the lower of the negotiated price (if any) or the usual and customary price.

- Applicant makes available electronically or by telephone at point-of-sale information concerning the amount of transitional assistance used and available for each transitional assistance enrollee.

- Applicant reimburses directly: 1) pharmacies for transactions where the balance of transitional assistance reported was in excess of the amount available, and 2) enrollees who become transitional assistance eligible after their initial enrollment for any enrollment fee they had paid prior to the determination, and 3) States in instances where they have paid enrollment fees on behalf of beneficiaries determined eligible for transitional assistance after their initial enrollment.

- Applicant operates both a real-time transitional assistance claims adjudication system and, for those claims involving coordination of benefits issues, an off-line claims processing system.

- Applicant tracks transitional assistance spending for each enrollee with such assistance, including roll-over amounts, if any, from the previous calendar year(s).

- Applicant develops and implements procedures to protect against the misuse of transitional assistance in the event of the theft or loss of an enrollee's identification card.

- Applicant adopts a system for determining final transitional assistance balances to be reported to CMS at the time a card enrollee disenrolls from Applicant's drug card program. CMS will not adjust the final balance at a later date to account for outstanding claims at the

time the Applicant reported the final balance, nor will CMS provide additional reimbursement to the Applicant to make up the difference. If the Applicant's systems for determining a final transitional assistance balance potentially creates a financial liability for enrollees, Applicant informs enrollees of such circumstances and the special responsibilities enrollees may have in such circumstances.

- Applicant continues to make remaining amounts of transitional assistance funds (which have been rolled over from previous years) available to eligible enrollees during the transition period (starting December 31, 2005 and ending when the beneficiary enrollees in a Part D plan or when the Part D initial enrollment period expires, whichever comes first).

- Applicant accepts payment of enrollment fee from CMS for transitional assistance enrollees.

- Applicant applies coinsurance requirements, such that when transitional assistance is used, enrollees with incomes greater than 100 percent and not greater than 135 percent of the poverty line (or others on their behalf) pay no more than 90 percent of the charge for the drug from their transitional assistance, and transitional assistance enrollees whose income is not greater than 100% of the poverty line pay no more than 95% of the charge for the drug from their transitional assistance.

Application Requirements:

- Describe the systems you will develop and implement to track and manage transitional assistance on behalf of transitional assistance-eligible beneficiaries. Discuss the information and claims adjudication systems you will develop to manage this effort. Specifically:

    - Describe how your organization will operate a real-time transactional assistance claims adjudication system. Discuss how this system will interact with network pharmacies to ensure accurate application of transitional assistance to the cost of covered drugs. Include in this discussion the accurate calculation of applicable coinsurance amounts. Should you elect to permit transitional assistance enrollees to apply transitional assistance toward such cost-sharing, also describe the accurate application of transitional assistance to any copayments, coinsurance, or deductibles for any covered discount card drug obtained under any Medicare managed care drug benefit your organization provides.

    - Describe how your staff will update and monitor this system to ensure accurate tracking of the transitional assistance spending. The discussion of this system should reflect your intention to allow enrollees to roll over any remaining balance at the end of one calendar year to their account for the next calendar year. This includes making the remaining 2005 transitional assistance balance available to enrollees during their transition period in 2006 (that is, the period between January 1, 2006 and the effective date of the beneficiary's enrollment in a Part D prescription drug plan or the last day of the period in which the beneficiary may enroll under Part D, whichever occurs first).

- Describe the internal controls, procedures, and financial system your organization will use to make transitional assistance account balance information available at the point of sale for all eligible beneficiaries with transitional assistance. Indicate whether the information will be available electronically, by telephone, or both.

- Describe the systems/ procedures your organization will adopt to ensure that accurate final transitional assistance balances are reported to CMS at the time a card enrollee disenrolls from your drug card program. If such systems potentially create a financial liability for enrollees, describe your procedures for informing enrollees of such circumstances and the special responsibilities enrollees may have in such circumstances.

- Indicate that your organization will reimburse: 1) pharmacies for transactions where the balance of transitional assistance reported was in excess of the amount available, and 2) enrollees who became transitional assistance eligible after their initial enrollment for any enrollment fee they had paid prior to the determination, and 3) States in instances where they have paid enrollment fees on behalf of beneficiaries determined eligible for transitional assistance after their initial enrollment.

- Indicate circumstances under which off-line claims adjudication (e.g., transactions involving pharmacies without real-time communication capabilities, institutional pharmacies) will be necessary. Describe your system for processing these claims, including the requirements for pharmacies and/or enrollees to submit claims and your timeframe for adjudicating the claim, providing a response to the pharmacy and/or enrollee, and making the appropriate adjustment to the enrollee's account balance.

- Attest that you will not require transitional assistance members of your Medicare managed care plan(s) to use the transitional assistance to which they are entitled prior to drawing down any drug benefit offered to Medicare managed care plan members.

3.5.6 Call Center

Qualification:

- Applicant maintains a toll-free customer service call center that is open during usual business hours and provides customer telephone service in compliance with usual business practices.

- Applicant uses CMS' FTS2001 telecommunications contract for its toll-free numbers, services, and circuits, allowing beneficiaries calling the 1-800-MEDICARE information line to be transferred directly to the Applicant's customer service representatives.

Application Requirements:

- Describe the hours of operation and business practices of your toll-free customer service call center. Please indicate if you will use the same call center/call center staff currently employed by your Medicare managed care program.

- Explain in detail how your customer service function would respond to the following types of concerns that a beneficiary may experience:

    - Questions or requests from transitional assistance-eligible enrollees concerning the current balance of their transitional assistance remaining.

    - Questions concerning differences between the Medicare drug discount card program, other (non-approved) discount card programs, and prescription drug insurance.

    - Discount card inquiries, prior to enrollment.

    - Problems in the enrollment process.

    - Questions concerning negotiated prices and formulary offerings.

    - Questions concerning the negotiated price for a particular drug at a specific pharmacy.

    - Questions concerning pharmacy access and mail order, if applicable, including changes in the pharmacy network.

    - Questions with a clinical component, including requests for counseling on relevant costs of equivalent medications or the availability of generic drugs.

    - Questions concerning lost or stolen identification cards.

    - Questions concerning denial of use of the card by a network pharmacy.

    - Mail order pharmacy questions, issues, and concerns (if applicable).

    - Questions from pharmacists concerning the Applicant's drug card program.

- Describe your card sponsor's additional mechanisms (if any) for communicating with enrollees or pharmacies (fax, e-mail).

- Indicate your intention to work directly with CMS and its telecommunications vendors to develop the direct transfer capabilities between the 1-800-MEDICARE information line and your customer service representatives.

3.5.7 Reduction of Medication Errors

Qualifications:

- Applicant operates a system to reduce the likelihood of medication errors and adverse drug interactions and to improve medication use.

- Applicant's system is supported by scientific and clinical literature.

Application Requirement:

- If your system is an existing program, describe your past achievement in reducing medication errors and adverse drug interactions and in improving medication use.

3.5.8 Grievance/Customer Complaints

Qualifications:

- Applicant expands its existing Medicare managed care grievance process to include its drug card program in order to track and address in a timely manner enrollees' complaints about any aspect of the card sponsor's operations.

- A grievance is any enrollee's complaint or dispute expressing dissatisfaction with the manner in which he or she has received services under a drug card. The subjects of a grievance may include:

    - The timeliness, appropriateness, access to, and/or setting of services provided by the card sponsor;

    - Concerns about waiting times, demeanor of pharmacy or customer service staff; or

    - A dispute concerning the card sponsor's refusal to offer discounts on particular prescription drugs, failure to accept transitional assistance as payment for prescription drugs, or charging of higher coinsurance payments than permitted under the Medicare drug discount card program.

Application Requirements:

- Indicate that your organization will expand its existing Medicare managed care grievance process to include your drug card program.

3.5.9 Information and Outreach

Qualifications:

- Applicant provides information and conducts outreach to Medicare beneficiaries to include a detailed description of the following:

    - Applicant's drug card that includes information on how to become enrolled in a program, how to qualify for the transitional assistance, and how transitional assistance works;

- Negotiated prices offered for covered discount card drugs.
- The permissible services Applicant provides for no additional fee, such as drug interaction counseling or allergy alerts;
- The availability of a grievance process and how it works;
- Toll-free numbers available to Applicant's drug card enrollees;
- A list of contracted pharmacies and prescription drugs offered for a negotiated price, and a guarantee that contracted pharmacies will provide the lower of the negotiated price or the "usual and customary" price.
- Enrollment fees (if any);
- A notice that drugs and prices may change or vary and a description of how the enrollee can obtain information regarding those changes and variations;
- A clear description of the service area in which Applicant's drug card is available;
- Applicant's procedures for managing transitional assistance against an enrollee's cap or transitional assistance balance transfer to a newly elected approved program as well as any potential enrollee liabilities related to such procedures; and
- A privacy notice for protected health information.

- Applicant provides beneficiaries with information and outreach materials that comply with CMS information and outreach guidelines. Such guidelines will be posted on the CMS web site at www.cms.hhs.gov as a separate document from this solicitation. Applicant provides the materials to beneficiaries in customer-appropriate printed material prior to and after enrollment.

- Applicant provides all information and outreach materials to CMS for review prior to conducting outreach to Medicare beneficiaries. When acting in the capacity of a Medicare managed care plan and co-mingling plan materials with card sponsor information and outreach materials, Medicare managed care organizations are required to obtain approval from CMS. These materials require approval from the appropriate CMS Regional Office and the contractor that will review drug card program information and outreach materials.

Application Requirements:

- Indicate your intention to follow the information and outreach guidelines, which will be provided by CMS on its web site (www.cms.hhs.gov). Any information and outreach materials submitted for CMS review and approval along with your application materials should be consistent with the guidelines from CMS.

- Describe your expected information and outreach effort, including communication materials that will be developed and how they will be used to market the program. Provide a description of other communication channels that will be used to educate and enroll Medicare beneficiaries (e.g., the Internet).

- Describe your efforts to accommodate beneficiaries with disabilities and non-English speaking beneficiaries.

- Discuss your communication plan concerning the availability of pharmacy services or discounts on over-the-counter drugs, if any, that will be offered for no additional fee.

- Describe how you will monitor and track written inquiries for information and outreach materials. Include the average response time to send out materials.

3.5.10 Privacy/HIPAA Transactions

Qualifications:

- Applicant is a covered entity and complies with the regulations issued pursuant to the Health Insurance Portability and Accountability Act (HIPAA) at 45 CFR parts 160 and 164, subparts A and E [the Privacy Rule] as it applies to health plans. (NOTE: In applying the definition of "marketing" under the Privacy Rule, Applicant's information and outreach efforts under the drug card program that are directly related to covered drugs and non-prescription drugs for which the Applicant will offer a discount, including information on drug interactions, are permitted uses of protected health information as health care operations.)

- Applicant complies with the Privacy Rule as it applies to business associates of CMS for the purposes of operating the transitional assistance portion of the drug card program.

- Applicant notifies each beneficiary, prior to enrollment or at the time of enrollment, of expected uses and disclosures of the beneficiary's protected health information, as well as the beneficiary's rights and Applicant's duties with respect to such information. Such notice is provided in plain language containing sufficient detail to advise the beneficiary of the uses and disclosures permitted or required under applicable law.

- Applicant obtains written authorization for all uses and disclosures of protected health information not otherwise permitted under the Privacy Rule. Beneficiaries may authorize disclosure of their protected health information to a third party, such as their employer. Such authorization may NOT be requested for marketing products or services outside the drug card program's approval.

- Applicant ensures that its agents and subcontractors comply with all the requirements of 45 CFR Parts 162 and 164 when performing functions on the Applicant's behalf.

- Applicant complies with the requirements applicable to covered entities to the provisions of 45 CFR Part 160 relating to use of national identifiers. Applicant complies with any applicable standards, implementation specifications, and requirements in the Standards for Electronic Transactions under 45 CFR Parts 160 and 162 subparts I *et seq.*

Application Requirements:

- Indicate your understanding of and agreement to protect protected health information in accordance with the privacy provisions, (stated in Section 3.5.10 of this document) of the drug card program.

- Pursuant to the privacy provisions under this initiative:

    - Describe how your organization will routinely use beneficiary data.

    - Describe how your organization will obtain beneficiary written authorization for the uses and disclosures of beneficiary data, and to permit an enrollee to revoke that authorization. NOTE: Such authorization may not be requested for marketing for services considered outside the scope of approval (that is, (a) not directly related to a covered discount card drug or (b) not involving discounts on non-prescription drugs).

3.5.11 Security

Qualification:

- Applicant has, as of the initial enrollment date, appropriate administrative, technical, and physical safeguards in place to protect the privacy of protected health information in accordance with 45 CFR §164.530(c), and meets the standards, requirements, and implementation specifications as set forth in 45 CFR part 164, subpart C, the HIPAA Security Rule, prior to beginning enrollment of beneficiaries. If the Applicant will not fully meet this requirement, the Applicant must describe the Applicant's plan for coming into compliance with the specifications as set forth in the Security Rule. Applicants are encouraged , but not required, to use Information Security Program references as provided by the National Institute for Standards and Technology (NIST) in describing their efforts to implement reasonable security measures.

Application Requirements:

- Provide your attestation that, as of the initial enrollment date, appropriate administrative, technical, and physical safeguards will be in place to protect the privacy of protected health information in accordance with 45 CFR §164.530(c), and that you will meet the standards, requirements, and implementation specifications as set forth in 45 CFR part 164, subpart C, the HIPAA Security Rule, prior to beginning enrollment of beneficiaries. If you are unable to provide this later attestation, provide your plan for coming into compliance with the specifications as set forth in the Security Rule as of the compliance date of the Security Rule. You are encouraged, but not required, to use the Information Security Program references as

provided by the National Institute of Standards and Technology (NIST) in describing your efforts to implement reasonable security measures.

3.6 Card Sponsor Reporting to CMS

Qualification:

Request for Waiver: Applicants who did not request any waivers requested by responding "yes" to any item on the chart in Section 2.10 must provide a response to Section 3.6 of the General Solicitation. Applicants who did request a waiver must meet the meet the qualifications as described below

Application Requirements:

- Describe how your organization will adhere to the reporting requirements and schedule outlined in Attachment 4 with the following exceptions:
    - If you requested a waiver of duplicative reporting requirements under Item 3 of the waiver chart, you need not address Items 1,3, and 10 of Attachment 4.
    - If you requested a waiver of Item 2 of the waiver chart, you need not address the manufacturer price concessions in Item 4 of Attachment 4.

- Describe the procedures your organization has adopted to ensure that you will keep CMS informed of any material modifications to your program.

3.7 Record Retention

Qualifications:

- Applicant complies with the record retention standard requiring that the approved sponsor retain records that it creates, collects, or maintains as part of its operations while participating in the program as part of its operation of an approved program for at least 6 years following the termination of the program, or in the event that the contract with CMS is terminated, at least 6 years following such termination.

- Applicant must continue to apply the security and privacy protections described in Sections 3.5.10 and 3.5.11 to the maintained records.

Application Requirements:

- Describe your record retention policies and practices, and indicate your intention to retain records related to your operation of your approved card program for 6 years following the termination of the program or your contract with CMS.

- Indicate your intention to apply the security and privacy protections required of card sponsors to the records related to the operation of your drug card program you will maintain.

3.8 Requests for Waiver or Modification of Requirements

Qualification:

- Applicant may request additional waivers from or modifications of requirements applicable to other drug card sponsors. Applicant must demonstrate that the requirements at issue are duplicative of, or conflict with, requirements applicable to Medicare managed care organizations, or that they interfere with the coordination of benefits offered under their drug card with benefits provided under the Medicare managed care program.

Application Requirement:

- Indicate whether your organization wishes to request any additional waivers from or modifications of requirements applicable to drug card sponsors under this program. Demonstrate that the requirements at issue are duplicative of or conflict with requirements applicable to Medicare managed care organizations, or that they interfere with the coordination of benefits offered under their drug card with benefits provided under the Medicare managed care program.

4.0 CERTIFICATION

I, the undersigned, certify to the following:

1) I have read the contents of the completed application and the information contained herein is true, correct, and complete. If I become aware that any information in this application is not true, correct, or complete, I agree to notify the Centers for Medicare & Medicaid Services (CMS) immediately and in writing.

2) I authorize CMS to verify the information contained herein. I agree to notify CMS in writing of any changes that may jeopardize my ability to meet the qualifications stated in this application prior to such change or within 30 days of the effective date of such change. I understand that such a change may result in termination of the Medicare approval contract.

3) I agree that if my program meets the minimum qualifications and is Medicare-approved, I will abide by the requirements contained in Section 3.0 of this Application and provide the services outlined in my application.

4) Neither I, nor any owner, director, officer, or employee of the [Applicant] or other organization on whose behalf I am signing this certification statement, or any contractor retained by the company or any of the aforementioned persons, currently is subject to sanction under the Medicare or Medicaid program, or debarred, suspended or excluded under any other Federal agency or program, or otherwise prohibited from providing services to CMS or other Federal Agency.

5) I understand that in accordance with 18 U.S.C. § 1001, any omission, misrepresentation or falsification of any information contained in this application or contained in any communication supplying information to CMS to complete or clarify this application may be punishable by criminal, civil, or other administrative actions including revocation of approval, fines, and/or imprisonment under Federal law.

6) I further certify that I am an authorized representative, officer, chief executive officer, or general partner of the business organization that is applying for the approval of the a prescription drug discount card program.

_____	_____
Authorized Representative Name (printed)	Title
_____	_____
Authorized Representative Signature	Date (MM/DD/YY)

ATTACHMENT 1 – DRUGS COMMONLY USED BY MEDICARE BENEFICIARIES

DRUGS COMMONLY USED BY MEDICARE BENEFICIARIES

Place a check mark next to the drugs listed below which will be included for a discount at your pharmacy network under your proposed program. This list represents top drugs commonly used by Medicare beneficiaries, according to results from the 2000 Medicare Current Beneficiary Survey.

NOTE: In some cases, both the brand name and its generic equivalent are listed separately.

- ☐ ACCUPRIL
- ☐ ACTOS
- ☐ ADALAT
- ☐ ALBUTEROL
- ☐ ALLEGRA
- ☐ ALLOPURINOL
- ☐ ALPHAGAN

- ☐ AMARYL
- ☐ AMBIEN
- ☐ AMIODARONE HCL
- ☐ AMITRIPTYLINE HCL

- ☐ ARICEPT
- ☐ ATENOLOL
- ☐ ATROVENT
- ☐ AVANDIA

- ☐ AXID

- ☐ BETAPACE
- ☐ BUSPAR
- ☐ CAPTOPRIL
- ☐ CARBIDOPA/LEVO
- ☐ CARDIZEM
- ☐ CARDIZEM CD

- ☐ CARDURA
- ☐ CASODEX
- ☐ CELEBREX
- ☐ CELLCEPT
- ☐ CIMETIDINE
- ☐ CIPRO

- ☐ CLOZARIL
- ☐ COMBIVENT INHALER
- ☐ COMBIVIR
- ☐ COREG
- ☐ COUMADIN
- ☐ COZAAR
- ☐ DEPAKOTE
- ☐ DETROL
- ☐ DIFLUCAN
- ☐ DIGOXIN
- ☐ DILANTIN
- ☐ DILTIAZEM
- ☐ DIOVAN
- ☐ EFFEXOR
- ☐ EPIVIR
- ☐ EVISTA
- ☐ FLOMAX
- ☐ FLOVENT
- ☐ FOLICACID
- ☐ FOSAMAX
- ☐ FUROSEMIDE
- ☐ GEMFIBROZIL
- ☐ GLIPIZIDE
- ☐ GLUCOPHAGE
- ☐ GLUCOTROL
- ☐ GLYBURIDE

- ☐ HYDROCHLOROTHIAZIDE
- ☐ HYDROCODONE/APAP
- ☐ HYTRIN
- ☐ HYZAAR
- ☐ IBUPROFEN
- ☐ IMDUR
- ☐ IPRATROPIUMBROMIDE
- ☐ ISOSORBIDEDN
- ☐ ISOSORBIDEMN
- ☐ K-DUR

- ☐ KLOR-CON
- ☐ LANOXIN
- ☐ LASIX
- ☐ LESCOL
- ☐ LEVAQUIN
- ☐ LEVOTHROID
- ☐ LEVOTHYROXINE
- ☐ LIPITOR
- ☐ LOPRESSOR

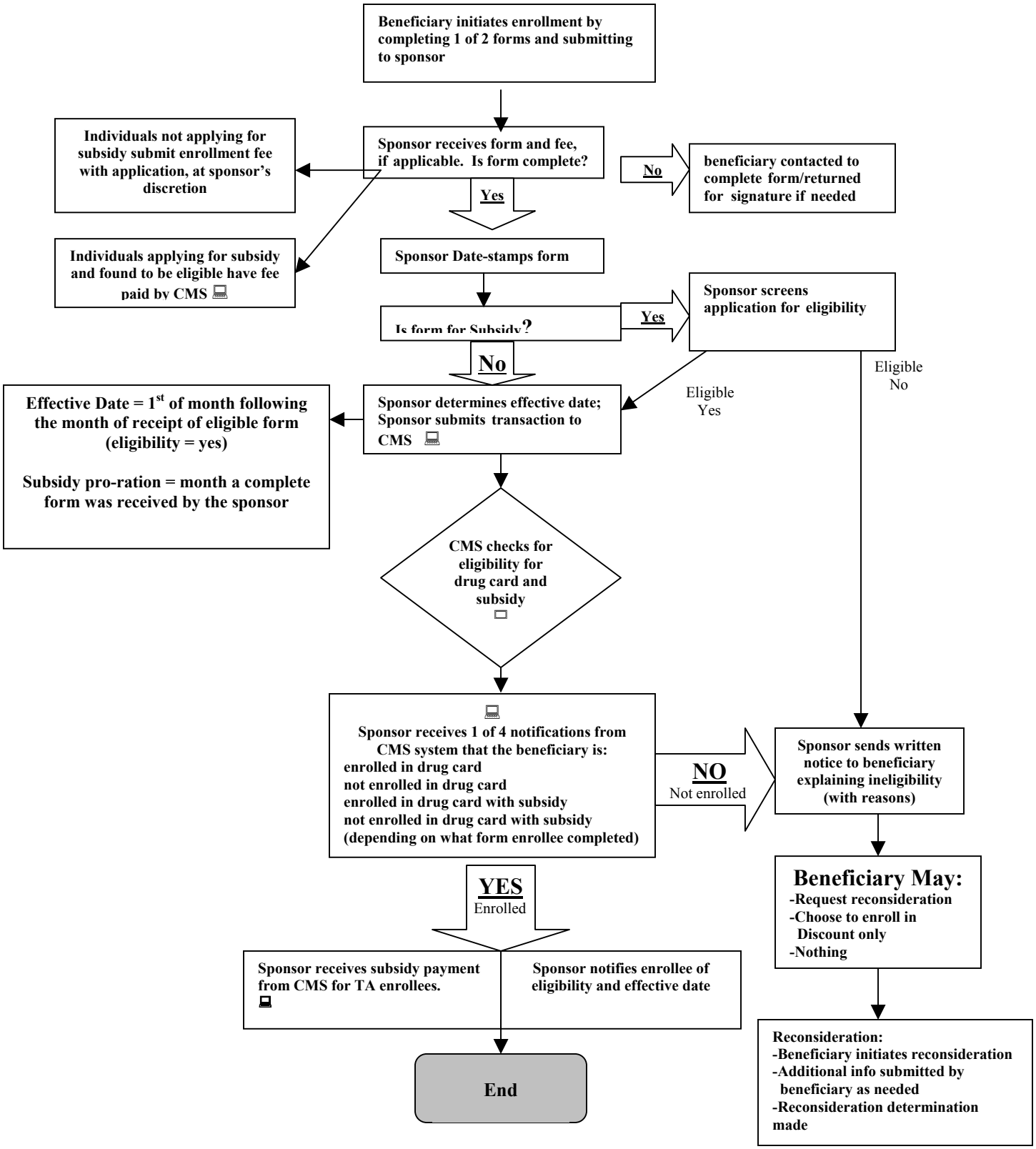
- ☐ LOTENSIN
- ☐ LOTREL
- ☐ MECLIZINE
- ☐ METOPROLOL
- ☐ MEVACOR
- ☐ MIACALCIN
- ☐ MINITRAN
- ☐ MONOPRIL
- ☐ MSCONTIN
- ☐ NAPROXEN
- ☐ NEORAL
- ☐ NEURONTIN
- ☐ NITROGLYCERIN

- ☐ NORVASC
- ☐ OXYCONTIN
- ☐ PAXIL
- ☐ PEPCID
- ☐ PLAVIX
- ☐ PLENDIL
- ☐ POTASSIUM
- ☐ POTASSIUM CHLORIDE
- ☐ PRAVACHOL
- ☐ PREDNISONE
- ☐ PREMARIN
- ☐ PREMPRO
- ☐ PREVACID
- ☐ PRILOSEC
- ☐ PRINIVIL
- ☐ PROCARDIAXL
- ☐ PROGRAF
- ☐ PROPOXY-N/APAP
- ☐ PROPRANOLOL
- ☐ PROSCAR
- ☐ PROZAC
- ☐ RANITIDINE
- ☐ RELAFEN
- ☐ RIBAVIRIN
- ☐ RISPERDAL
- ☐ SEREVENT
- ☐ SINGULAIR
- ☐ SYNTHROID
- ☐ TAMOXIFEN
- ☐ TEGRETOL
- ☐ TERAZOSIN
- ☐ TIAZAC
- ☐ TOPAMAX

- ☐ TOPROL XL
- ☐ TRAZODONE
- ☐ TRENTAL
- ☐ TRIAMTERENE/HCTZ
- ☐ ULTRAM
- ☐ VASOTEC
- ☐ VERAPAMIL
- ☐ VIOXX
- ☐ VIRACEPT
- ☐ WARFARIN SODIUM
- ☐ WELLBUTRIN
- ☐ XALATAN
- ☐ ZANTAC
- ☐ ZERIT
- ☐ ZESTRIL
- ☐ ZIAC
- ☐ ZOCOR
- ☐ ZOLOFT
- ☐ ZYPREXA
- ☐ ZYRTEC

ATTACHMENT 2

Drug Card Enrollment Process Flowchart



ATTACHMENT 3 – PAYMENT INFORMATION FORM

As Government vendors, organizations with Medicare contracts are paid by the Department of Treasury through an Electronic Funds Transfer (EFT) program. Government vendor payments are directly deposited into corporate accounts at financial institutions on the expected payment date. Additionally, CMS must have the EIN/TIN and associated name as registered with the IRS.

ORGANIZATION INFORMATION

NAME OF ORGANIZATION: _____
DBA, if any: _____

ADDRESS: _____
CITY: _____ STATE: _____ ZIP CODE:_____

CONTACT PERSON NAME: _____
TELEPHONE NUMBER: _____

CONTRACT NO's.: H _____; H _____; H _____; H _____
(If known)

TIN/EIN NAME of business for tax purposes (as registered with the IRS: a W-9 may be required)
_____

EMPLOYER/TAX IDENTIFICATION NUMBER (EIN or TIN): _____

Mailing address for 1099 tax form:
STR1: _____
STR2: _____
CITY: _____
STATE: ____ ZIP: _____ - _____

FINANCIAL INSTITUTION

NAME OF BANK: _____
ADDRESS: _____
CITY: _____ STATE: ____ ZIP CODE: _____ - _____

ACH/EFT COORDINATOR NAME: _____
TELEPHONE NUMBER: _____

NINE DIGIT ROUTING TRANSIT (ABA) NUMBER: _____

DEPOSITOR ACCOUNT TITLE: _____

DEPOSITOR ACCOUNT NUMBER: _____

CIRCLE ACCOUNT TYPE: CHECKING SAVINGS (Please attach a copy of a voided check)

SIGNATURE & TITLE OF ORGANIZATION'S AUTHORIZED REPRESENTATIVE:

_____DATE: _____
Signature Title

_____ _____
Print Name Phone Number

ATTACHMENT 4 - Reporting Requirements

Routine Reporting Requirements

All data in this section are due to CMS on the 10th business day of the month following the reporting period and the data are to reflect the activity for that reporting period only. For example, aggregated grievance data for the month of May 2004 are due to CMS by 5:00 pm ET on June14, 2004 and should reflect the grievance activity for May 2004; and, customer service data for the months of May, June, and July 2004 are due to CMS on August 13, 2004 by 5:00 pm ET and should reflect the customer service activity for May – July 2004. Exact due dates for all data will be posted on CMS' website at www.cms.hhs.gov.

All data submissions to CMS must include a certification by the Sponsor that based on best knowledge, information, and belief, the reported information is accurate, complete, truthful, and supportable.

Applicant must report aggregated grievance and prescription data on a monthly basis and customer service information and information on price concessions and pass-through to beneficiaries on a quarterly basis directly into CMS' Health Plan Management System (HPMS). Please refer to the instructions posted on CMS' website at www.cms.hhs.gov for information about accessing HPMS. Applicant must report data on transitional assistance reimbursement on a monthly basis directly into the Medicare Beneficiary Database (MBD).

Item 1 - Aggregated Grievance data, due monthly, include:

- Sponsor identification;
- Number of filed grievances, broken down by category of grievance (i.e., enrollment, disenrollment, marketing, benefits/access, pricing/co-insurance, customer service, confidentiality, pharmacies, other);
- Number of resolved grievances; and
- Number of resolved grievances that favor beneficiaries.

Item 2 - Prescription data, due monthly, include:

- Sponsor identification;
- Total number of prescriptions (aggregate and decile);
- Average number of prescriptions (aggregate and decile) per enrollee.

Item 3 - Customer service data, due quarterly, include:

- Sponsor identification;
- Percent customer service rep time manning phones and responding to enrollee inquiries;
- Total number of calls;
- Number and percent of calls answered within 30 second;
- Number and percent of beneficiary calls that are abandoned from automated queue;
- Call center business hours;

- Percent of business hours when call center was not available;
- Average days to process new members;
- Average days to provide new or replacement discount cards;
- Average days to respond to written correspondence;
- Average days to fulfill mail order request - no intervention required; and
- Average days to fulfill mail order request - intervention required.

Item 4 - Reporting requirements for price concessions and pass-throughs to beneficiaries, due quarterly, include:

- Sponsor identification.
- Percent of total amount of the price concessions negotiated in each manufacturer contract for the drug card program that is passed through to beneficiaries.
- Average dollar amount of manufacturer price concessions per drug card script by each manufacturer.
- Percent of total amount of the price concessions negotiated across all retail pharmacy contracts, and by mail order, that is passed through to beneficiaries.
- Average negotiated price per script across all drugs produced by each manufacturer.
- Average dollar amount of pharmacy price concessions per drug card script by all retail pharmacy, and by mail order.
- Average dollar amount of manufacturer price concessions per brand name drug card script.
- Average dollar amount of manufacturer price concessions per generic drug card script.
- Average dollar amount of pharmacy price concessions per brand name drug card script.
- Average dollar amount of pharmacy price concessions per generic drug card script.
- Range and average negotiated price by NDC code (including by manufacturer on generics) at a given point in time.
- Average and range of dispensing fees.

Item 5 - Reporting requirements for transitional assistance reimbursement, due monthly, include:

- Sponsor identification.
- Each transitional assistance enrollee's:
    - HIC Number
    - Name
    - Sex
    - Date of Birth
- Amount spent from each transitional assistance enrollee's subsidy balance for that month.

Item 6 - Applicant must report to CMS immediately any aberrancies or high utilization and spend patterns (identified by Zip Code) observed in claims data for particular drugs/controlled substances. If no patterns are detected during a month, Applicant

certifies to CMS, by the 10th business day of the next month, that it checked for such patterns.

Reporting/monitoring requirements for irregular utilization patterns for specific drugs, due monthly, include:

- Sponsor identification.
- Check for aberrant or high outlier utilization patterns for drugs with abuse/misuse potential and alert CMS as soon as irregular utilization patterns are uncovered.
    - Drugs with significant abuse/misuse potential as denoted by DEA Control Schedule II through Schedule V.
- If no unusual utilization patterns are uncovered for a month, certify to CMS that such utilization patterns were not uncovered in the analysis.

Item 7 - Reporting requirements concerning any material modifications to the Card Sponsor's drug card program (e.g., changes to formulary, pharmacy network, customer service practices), due as soon as they occur, include:

- Sponsor identification.
- A description of the change.
- How the change will impact the Sponsor's drug card program.

Item 8 - Reporting requirements for any increase in prices in a calendar year that are due to anything other than changes in average wholesale price (AWP), due with the submission of the price comparison files, include:

- Sponsor identification.
- Rationale for negotiated price increase.

Note to above requirement: Sponsors do not have to report any increases in negotiated prices that occur during the week of November 15, 2004.

Item 9 - Claims-Based Data Elements

Our oversight strategy anticipates that we would audit the following claims-based data elements in the event we conduct an audit. At that time we will specify the format in which the data shall be provided.

- Sponsor ID;
- Beneficiary Name;
- Beneficiary HIC#;
- Eleven Digit National Drug Code (with Dosage Information);
- Sponsor's Negotiated Price without the Dispensing Fee;
- Dispensing Fee;
- Beneficiary Co-Pay Amount;
- Sales Tax Amount;
- Generic Indicator;
- Usual & Customary Price without the Dispensing Fee;
- AWP;
- DEA Number of Prescribing Physician;

- Prescription Number;
- NABP Number of Pharmacy that Filled Prescription; and
- Date Prescription Filled.

Item 10 - Grievance-Based Data Elements

Our oversight strategy anticipates that we would audit grievance logs in the event we conduct an audit. At that time we will specify the format in which the data shall be provided.

Grievance logs must consist of the following data fields:

- Sponsor ID;
- Beneficiary Name;
- Beneficiary HIC#;
- Date Grievance Received;
- Date Grievance Decided;
- Disposition of Grievance; and
- Category of Grievance based on those below.

Grievance log categories are:

- **Enrollment**
  - Enrollment materials (card) not distributed in a timely manner.
  - Beneficiary charged too much for enrollment fees.
  - Enrollment fees per sponsor are not the same for all beneficiaries enrolled in each State and all beneficiaries are not allowed to enroll in each State

- **Disenrollment**
  - Sponsors inappropriately encourage beneficiaries to disenroll or disenroll beneficiaries for an invalid reason.
  - Not correctly processing requests for disenrollment timely

- **Marketing**
  - Sponsors are falsely advertising product or services that aren't covered by the discount card.
  - Sponsors are falsely advertising network.
  - Sponsors are not advertising accurate drug prices.
  - Sponsors are participating in illegal marketing practices such as door-to-door marketing of the drug card, or offering illegal inducements to enroll in the drug card.
  - Sponsors are using unapproved marketing materials.

- **Benefits/Access**
  - Sponsors do not have a mechanism that informs the beneficiary on amount of transitional assistance remains (electronically or by telephone) at the point-of-sale of covered discount card drugs.

- Sponsor inaccurately tracks a beneficiary's transitional assistance spending.
- Sponsors do not provide that each pharmacy that dispenses a covered discount card drug shall inform a TA individual enrolled under the program of the differential between the price of the drug and the price of the lowest priced, therapeutically bioequivalent generic drug covered by the discount card program at the time of purchase? (Note: long-term care and Indian health services may not be required to provide this service.)
- Sponsors and/or providers are discouraging use of the card for all or certain drugs covered by the card.
- The service area represented in the solicitation is not available to beneficiaries.
- The sponsor does not provide an adequate grievance process.

- **Pricing/Co-Pays**
  - Enrollees do not have access to negotiated prices.
  - Pharmacies (sponsors) are charging more than the lower of the price based on negotiated prices or the U&C price.
  - TA beneficiaries are not being charged the proper co-insurance based on beneficiary status (e.g., 100% of FPL or 135% of FPL).

- **Customer Service**
  - Sponsors do not have an accessible toll-free number for providing, upon request, specific information such as negotiated prices and amount of transitional assistance remaining available through the program.
  - Sponsors are not meeting their self-reported timeframes for customer service.
  - Sponsors do not provide the required level of service to non-English speakers and the hearing impaired.
  - Sponsors are not providing accurate and/or timely information about the card.

- **Confidentiality**
  - Sponsors are not meeting HIPAA requirements (after HIPAA provisions are implemented).
  - Sponsors are using enrollee information to market products outside of the drug card provisions (e.g., are sponsors selling member mailing lists).

- **Pharmacies**
  - Pharmacies cannot access sponsor information in a timely manner.
  - Pharmacies are not getting paid by the sponsor in a timely manner.

- **Other (if grievance does not fit into one of the above categories)**