Medicare-Approved Prescription Drug Discount Card and Transitional Assistance Program

Solicitation for Applications
(for non-Medicare Managed Care Contractors)
December 16, 2003

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1.0 INTRODUCTION

The Centers for Medicare and Medicaid Services is seeking applications from qualified entities offering a prescription drug discount 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. Applications are to be submitted according to a process described under "Applicant Instructions" in Section 2.0.

NOTE: Medicare+Choice (M+C) Organizations and Medicare cost plan contractors (hereafter referred to as "Medicare managed care contractors") seeking the Medicare approval for a drug card they will offer exclusively to their enrollees should not complete this application. There is a separate solicitation, tailored to the unique qualifications for Medicare managed care contractors wishing to offer an exclusive product, posted on the CMS web site on the same date as this solicitation. However, Medicare managed care contractors wishing to offer an approved drug discount card for which enrollment is not limited to their M+C plan or cost plan enrollees should respond to this solicitation.

1.1 Background

Statutory Authority

The Medicare-Approved Prescription Drug Discount Card and Transitional Assistance Program (hereafter referred to as the "Medicare-Approved 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.

September 2002 Program Superceded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September 4, 2002 (67 FR 56618) and the solicitation published in conjunction with that final rule has already been withdrawn. This solicitation is in no way connected to the September 4, 2002 final rule.

1.2 Objectives

The Medicare-Approved 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 subsidy (referred to as "transitional assistance") of up to $600.

- Provide access to the discounts and transitional assistance 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.

- Permit approved entities to market their programs as Medicare-approved.

- Promote beneficiary awareness of the Medicare Drug Discount Card Program through CMS' 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 drug manufacturer and pharmacy rebates, discounts, and other price concessions which can be used to reduce prescription drug prices for enrolled beneficiaries.

- Ensure eligible residents of long term care facilities have access to transitional assistance. Also, ensure that beneficiaries using pharmacies operated by the Indian Health Service, Indian Tribes and Tribal Organizations, and Urban Indian Organizations (I/T/Us) have access to transitional assistance.

1.3 PROGRAM OVERVIEW

1.3.1 Summary of Card Program Responsibilities

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

- Obtain and pass through manufacturer discounts, rebates, other price concessions on prescription drugs.

- Enroll all eligible Medicare beneficiaries who apply and reside within the approved drug discount card's service area. A sponsor must establish a service area that is at least as large as a single state. The service area may not include a portion of a State.

- Process beneficiaries' enrollment applications for the drug discount card and transitional assistance.

- Administer transitional assistance funds, including ensuring that such funds are applied only to covered discount card drugs, applying appropriate coinsurance levels, and making available an enrollee's transitional assistance balance at the point of sale.

- Provide access to negotiated prices on at least one prescription drug in each of the therapeutic drug classes, groups and sub-groups provided by CMS, representing prescription drugs commonly needed by Medicare beneficiaries, including a broad selection of generic drugs.

- Offer a contracted retail pharmacy network, providing convenient retail access.

- 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.

- 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(s) to eligible Medicare beneficiaries only.

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

1.3.2 Summary of CMS Activities

Approval Process

CMS has determined the qualifications entities must meet to receive the 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 management of transitional assistance. *(NOTE: CMS will monitor approved drug card sponsors to ensure that they maintain the confidentiality of enrollee information required for endorsement. In addition, approved 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, and our own systems. Such data will include pricing information, 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 C.F.R. §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 for each drug card 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 to promote informed consumer choice among approved discount card programs, 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). 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 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 negotiated prices across approved card programs. These prices and fees will reflect an estimate of the maximum price charged at the point of sale. This web site will also include information about generic substitutes. All of this comparative information will assist beneficiaries in deciding which Medicare discount card will offer them the greatest financial advantage.

Information and Outreach Guidelines and Review

CMS has developed information and outreach guidelines which are posted on the CMS web site 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. CMS has retained a contractor to provide technical assistance in the development of these guidelines and conduct the review of submitted materials.

Enrollment Processing/Transitional Assistance Eligibility

CMS has developed a system to review an individual's eligibility for the Medicare drug discount card program and transitional assistance. For individuals applying for the drug card, we will review 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 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 Social Security Administration, the Internal Revenue Service, and possibly other data sources that we may choose to include. With regard to income and benefits information, we will verify Social Security benefits, Railroad Retirement benefits, Veteran's benefits, Supplemental Security Income benefits, and Adjusted Gross Income as defined by the Internal Revenue Service.

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/Medicaid 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.

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' enrollment and eligibility 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.

Residents of Long Term Care Facilities, American Indians/Native Americans, and Residents of the U.S. Territories

We intend to select, through a competitive process, at least two sponsors for Special Approval to serve residents of long-term care (LTC) facilities and two sponsors for Special Approval to serve American Indians/Alaskan Natives (AI/ANs) who use Indian Health Service, Indian tribe and tribal organization, and urban Indian organization (I/T/U) pharmacies. The competitive processes for becoming Special Approved sponsors for these groups is described in sections 4.1 and 4.2 of this solicitation.

We will further employ a competitive process to select at least one Special Approved sponsor to provide access to negotiated prices through discount card programs in the U.S. territories, which include American Samoa, Commonwealth of Northern Mariana Islands, Guam, Puerto Rico, and the Virgin Islands. Transitional assistance in the territories is a separate program that will be administered by the U.S. territories and will not be a feature of the Medicare Drug Discount Card Program. The competitive process for becoming a Special Approved sponsor for residents of the territories is described in section 4.3 of this solicitation.

1.4 Period of Approval Agreement

CMS plans to approve all prescription drug discount 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 1, 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 the earlier of each enrollee's effective date of enrollment in a Part D drug plan or the last day of the initial 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.

1.5 Eligible Applicants and Number of Programs That May Be Submitted for Approval

The Applicant itself must be one non-governmental legal entity, since CMS' contract will be with only one legal entity. Although we will sign a contract with only one entity, 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 arrangements. There is no limit to the number of applications the legal entity seeking a contract with CMS may submit for consideration.

2.0 APPLICANT INSTRUCTIONS

2.1 Application, Intent to Respond, and Application Inquiries

The legal entity seeking an agreement with CMS to offer a Medicare-approved discount card program may submit an application for approval for one or more drug discount cards into which a Medicare beneficiary may exclusively enroll. We encourage Applicants to submit only one application describing all the discount cards they may offer. 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;
- Mailing address; and
- Completed CMS Connectivity Request (available on the CMS web site)

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.

Inquiries about the application, including questions for the pre-application conference and the intent to apply should be sent by e-mail to: DrugCard@cms.hhs.gov.

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 and (if applicable) 4.0, the applicant shall provide a description of the proposed program, demonstrating how it meets the qualifications described under the "Qualifications" headings in Sections 3.0 and (if applicable) 4.0, 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.

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 Sections 3.0 and (if applicable) 4.0 of the application will provide the information necessary for CMS to determine, on the basis of a pass/fail evaluation, whether the Applicant and its proposed discount card program(s) meet the qualifications outlined in the table below. Only those Applicants that meet all stated qualifications described in Sections 3.0 and (if applicable) 4.0 will be approved. In addition, Applicants must participate in telecommunications and 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. Only those approved sponsors that successfully complete end-to-end system testing with CMS or establish a CMS-approved method for transferring data will be approved to initiate their programs.

Incomplete applications will not be considered.

2.3 Application Format

In preparing your application in response to the prompts in Sections 3.0 and (if applicable) 4.0 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 it 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 5.0 of this solicitation and submit an original document signed by an individual with 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	Register for Pre-Application Conference. 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.

Early February – 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 approve Applicants on the basis of Applicants' representations of arrangements (e.g. contracts with pharmaceutical manufacturers, network pharmacy contracts) made to meet the qualifications. In those situations, approved sponsors will be required to submit all required documentation to CMS before sponsors will be permitted to begin marketing and enrollment activities under the discount card program.

2.7 Data Available from CMS

In order for Applicants to prepare their applications, CMS will provide the following information upon request:

- Aggregate data on counts of Medicare beneficiaries by zip code -

The "Annual Zip Code Enrollment File" is a public use file and contains aggregated aged and disabled enrollment data by age range, race, and gender within zip code. The file is usually produced in April and reflects enrollment as of July 1 of the previous year. This file has been edited to protect the privacy of beneficiaries. Applicants will also be required to complete a Data Use Agreement (DUA), which is appended as Attachment 1 to this Application. There is an expedited process in place to review and approve DUAs for enrollment data and information should be available within 1 week after request. The data will be provided on a cartridge. We will also include data from the U.S. Census Bureau on Zip Code-level population density.

- Drug utilization data from the 2000 Medicare Current Beneficiary Survey – The data will be on a CD in ASCII format. The file will include a random sample of unnamed, non-identifiable, non-institutionalized Medicare beneficiaries. For each unidentified individual, the file includes: prescription drug utilization information (e.g., drug name, dosage, number of prescriptions), date of birth, gender and prescription drug insurance coverage status (e.g., no drug coverage, or covered through a payer such as Medicaid, a Medicare+Choice organization, Medigap, or employer-sponsored retiree plan). The data is self-reported by beneficiaries. The attached DUA can also be used for this information.

To obtain the above information, please submit a signed and completed DUA 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 (Original document must be also be mailed to CMS.)

2.7.1 CMS Connectivity

Card sponsors must have CMS-approved secure telecommunications connectivity with CMS' systems. CMS uses AT&T as the vendor for our secure line. CMS will fund the installation of a T-1 line for each Applicant. CMS will also provide the Connect:Direct software necessary for use in transmitting enrollment/disenrollment transactions. In order to allow sufficient time for the connection to be installed and tested, Applicants should submit their request for connectivity along with their intention to apply. Card Sponsors operating more than one program will be provided with only one secure connection to CMS; only one request for connectivity should be submitted. Applicants should immediately notify CMS of any change in the information provided in their connectivity request. CMS will initiate the planning and implementation of the connection during the application review period.

2.7.2 CMS User I.D.'s

Card Sponsors must request a CMS User I.D. and access to designated CMS applications in order to submit price comparison information, transactions, and other routine reporting data as noted in Attachment 6. Applicants should complete and submit the CMS User Access form available on the CMS Drug Card web site at the time of application. Additional information regarding access to CMS systems for reporting will be available separately on the CMS web site.

2.8 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).

2.9 Certification Instructions

Pursuant to the Certification Statement in Section 5.0, 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

2.10 Pre-Application Conference

CMS will hold a pre-application conference on December 18-19, 2003 for all interested applicants. Applicants must pre-register for the conference 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 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 Medicare drug discount card programs that serve I/T/U pharmacies, LTC facilities, and the U.S. territories. Questions submitted to CMS through DrugCard@cms.hhs.gov 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 .

3.0 SUMMARY OF QUALIFICATIONS AND APPLICATION REQUIREMENTS

3.1 Card Sponsor Organization, Structure, and Experience

3.1.1 Type of Applicant

Qualifications:

- CMS has established two different categories of application requirements for a Medicare-approved discount card sponsor: 1) an approved discount card sponsor or, 2) a Medicare managed care contractor seeking to operate an exclusive approved card program. Applicants in category 2 should refer to the separate Medicare Managed Care Organization solicitation posted on the CMS web site shortly after this solicitation is published.

- Additionally, sponsors may also enter a competitive process to become a Special Approved Card Sponsor. A Special Approved discount card sponsor for the territories offers negotiated prices in the territories. A Special Approved discount card sponsor for long-term care facilities or I/T/U pharmacies offers access to transitional assistance at long-term care pharmacies and/or I/T/U pharmacies. Those Applicants wishing to apply for Special Approval for one or more of these categories should follow the instructions in Sections 4.1, 4.2, or 4.3. Applicants that will not be applying for Special Approval may so indicate in the appropriate sections and otherwise leave those sections of their application blank.

Application Requirement:

- State which type of application requirements you are seeking to meet to qualify for approval and follow the relevant instructions for each category.

3.1.2 Years of Experience

Qualifications:

- Applicant is a non-governmental single legal entity doing business in the United States.

- The Applicant and/or its subcontractors or partners through legal arrangement must have 3 years of private sector experience in the following:
    - Adjudication and processing of pharmacy claims at the point of sale;
    - Negotiation with prescription drug manufacturers and others for rebates, discounts, or other price concessions on prescription drugs; and
    - Administration and tracking of individual enrollee health care subsidy or benefit in real time.

- Experience in these areas must have occurred in the United States.

- If the Applicant subcontracts to meet this requirement, each entity must have three years experience in its relevant activity. Thus, for example, an applicant could subcontract with three entities, the first with three years experience adjudicating and processing pharmacy claims at the point of sale, the second with three years experience negotiating with prescription drug manufacturers and others for rebates, discounts, or other price concessions on prescription drugs, and the third with three years experience administering and tracking of individual enrollee health care subsidy or benefit in real time. An Applicant could not, however, subcontract with one entity with two years experience in adjudicating and processing pharmacy claims and another entity with one year experience in such activity.

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. Provide copies of the contracts or other legal arrangements with these entities. This requirement applies to all entities with which the applicant is under contract or other legal arrangement and not just the entities that will meet the 3 years experience criterion.

- Describe the Applicant's and/or its subcontractors' experience, which must be at least for three years in each of the following, in:

    - Adjudication and processing of claims at the point of sale;
    - Negotiation with prescription drug manufacturers and others for rebates, discounts, or other price concessions on prescription drugs; and
    - Administration and tracking of individual enrollee health care subsidy or benefit in real time.

3.1.3 Covered Lives Currently

Qualifications:

- The applicant, or a single entity with which the applicant contracts or has some other legal arrangement, must, at the time of application for approval, operate a pharmacy benefit program, a drug discount card, a low-income drug assistance program, or similar program that serves at least 1 million covered lives.

NOTE: Covered lives are discrete individuals who have signed enrollment agreements or paid an enrollment fee or insurance premiums, or some other comparable and verifiable documentation. Covered lives are not demonstrated or accounted for by hits on a Web site or number of prescriptions filled or for which a discount was given. Nor are covered lives demonstrated by counting signed agreements and multiplying by an average family size (if a **family** enrollment fee was paid, the "family" is 2 people, unless the organization can document additional family members are included).

Application Requirements:

- For the single entity that meets the covered lives qualification, describe the type of program (e.g., pharmacy benefit, drug discount card) in which the covered lives are enrolled.

- For the entity that meets the covered lives qualification (i.e., serves at least 1 million covered lives), provide the information requested in the Years of Experience section, above, concerning experience in adjudication and processing of claims at the point of sale; negotiation with prescription drug manufacturers and others for rebates, discounts, or price concessions on prescription drug; and administration and tracking of individual enrollee health care subsidy or benefit in real time.

- For the entity that meets the covered lives qualification, complete the following table. If this entity underwent significant change in 2003, or it expects in 2004 to have substantially different business volumes, please comment and provide 2004 projected volumes (in addition to your business volumes for 2003).

2003 Business Volumes

(Pharmacy-Related Entities)

	Insured Pharmacy Benefits *(#1)*		**Prescription Drug Discount Card Programs**	
Metric	***Retail***	**Mail**	***Retail***	**Mail**
Covered lives (#2)				
Senior lives (if available)				
Claims processed or number of discounted prescriptions				
Drug spending managed			N/A	N/A

#1 Exclusive of any prescription drug discount card programs.

#2 a) Covered lives are discrete individuals for whom there is verifiable information / documentation that, on audit, would demonstrate their enrollment in the program through either hard copy signed

agreements, payment of fees, payment of insurance premiums, or some comparable verification. Covered lives are not demonstrated or accounted for by hits on a Web site or number of prescriptions filled or for which a discount was given. Nor are covered lives demonstrated by counting signed agreements and multiplying by an average family size (if a **family** enrollment fee was paid, the "family" is 2 people, unless the organization can document additional family members are included).

b) To calculate covered lives, use most recent data. Applicants should pick a point in time within the previous 12 months and provide the number of unique lives. Please specify month for point in time used.

3.1.4 Financial Stability and Business Integrity

Qualifications:

- Applicant is a non-governmental legal entity doing business in the United States which agrees to abide by the terms of a Medicare Drug Discount Card Approval contract with CMS.

- Applicant must provide evidence of and maintain contracts or other legal arrangements between or among the entities combined to meet the criteria concerning years of experience, covered lives, pharmacy access, discount and rebate negotiation, enrollment and transitional assistance eligibility, transitional assistance administration, grievance process, information and outreach materials, and the call center.

- Applicant must demonstrate a satisfactory record of business stability and integrity for itself and any of its subcontractors or other entity under legal arrangement that develops the card sponsor's pharmacy network, handles the negotiation of rebates, discounts, or other price concessions on behalf of the card sponsor, operates enrollment, handles eligibility for the discount drug card and/or transitional assistance, administers the transitional assistance funding, or provides the required 3 years operational and covered lives experience.

- Applicant and any subcontractor complies with Federal and State laws.

Application Requirements:

- Identify each of the entities with which you will subcontract to meet the qualifications of the drug discount card program.

- The Applicant must provide the following information for itself and for each subcontracting entity that develops or developed the pharmacy network, negotiates discounts/rebates/other price concessions, operates the Applicant's enrollment system, manages the Applicant's eligibility system for the discount drug card and/or transitional assistance, administers the Applicant's transitional assistance funding, operates the customer service call center, administers a grievance process, develops information and

outreach materials, has the three years experience, or the necessary covered lives to meet the qualifications in the Application:

- Provide a brief summary of the history, structure, and ownership. Include a chart showing the structure of ownership, subsidiaries, and business affiliations.

- Provide copies of executed contracts (or letters of agreement) with each subcontractor that:

  - Clearly identify the parties to the contract (or letter of agreement);
  - Describe the functions to be performed by the subcontractor;
  - Contain language clearly indicating that the subcontractor has agreed to participate in the Medicare drug discount card program (except for a network pharmacy if the existing contract would allow participation in this program);
  - Contain language describing the services to be performed in a manner that encompasses the services required to support the discount card program;
  - Describe the payment the subcontractor will receive for performance under the contract, if applicable;
  - Are for a term of at least the lifetime of the program;
  - Are signed by a representative of each party with legal authority to bind the entity; and
  - Contain language obligating the subcontractor to abide by State and Federal privacy and security requirements, including the privacy and security provisions stated in the regulations for this program at 42 CFR §403.812.

- For network pharmacy contracts, provide the unsigned terms and conditions for each type of contract and a listing of which pharmacies have signed which contract. Contracts should contain all of the required provisions described immediately above for contracts or letters of agreement with the Applicant's subcontractors. Contracts should also contain provisions requiring network pharmacies to comply with all applicable Federal and State laws (including anti-kickback statutes). No signature pages need be submitted.

- Provide the most recent audited financial statements (balance sheet, income statement, statement of cash flow), along with auditor's opinions and related footnotes. To receive the Medicare approval, Applicants and subcontracting entities, or entities under other legal arrangement, described above must demonstrate that total assets are greater than total unsubordinated liabilities and that sufficient cash flow exists to meet obligations as they come due.

- Report financial ratings, if any, for the past three years.

- List any past or pending, if known, investigations, legal actions, or matters subject to arbitration brought involving the Applicant, subcontractors, and any entities under legal arrangement (and the parent firm if applicable) by any financial institution, government agency (local, State, or Federal) or private organization over the past three years on matters relating to health care and prescription drug services and/or allegations of fraud, misconduct, or malfeasance. Provide a brief explanation of each action, including the following: 1) Circumstances; 2) Status (pending or closed); and 3) If closed, provide the details concerning resolution and any monetary damages. NOTE: CMS will conduct an independent investigation, including at least a review of Federal databases available to us for issues related to any of these entities.

- Include a list of names and proposed duties of key personnel that will be assigned to this program, including but not limited to, the account manager and customer service manager. Provide resumes for these individuals (excluding customer service manager) that include work history, education, and industry accomplishments.

- Provide contact information for 3 of your largest clients, including reference name, title, fax, company name and address, years as a client, and a brief description of the services you have provided.

3.2 Formulary and Discounts to Beneficiaries

3.2.1 Formulary

Qualifications:

- Beginning June 1, 2004, the program provides a negotiated price on at least one prescription drug in each of the therapeutic categories representing the prescription drugs most commonly needed by Medicare beneficiaries. (See Attachment 2**)** Although some drugs may be classified into more than one category, a drug may be listed in only one category to satisfy this requirement.

- Program sponsors must offer negotiated prices on generic drugs. Specifically, sponsors must offer a generic drug for a negotiated price in at least 55 percent of the categories in Attachment 2. Fifty-five percent of the entire category list represents about 95 percent of the categories in which a Class A generic drug exists.

- With the exception of specific arrangements made under Special Approvals for certain populations, the list of discounted drugs used to

meet the qualification must be offered through the card sponsor's contracted retail pharmacy network. Offering these drugs through mail order does not count toward meeting this qualification.

- Formularies may vary geographically and according to enrollee characteristics. For example, additional options may be available to enrollees based on certain characteristics (e.g., income), provided that for all Medicare beneficiaries enrolled in the program a discount is provided on at least one prescription drug in each category and discounts for generic drugs are provided for at least 55 percent of the categories.

Application Requirements:

- Following the instructions provided in Attachment 2, provide a listing of the drugs you intend to offer under the program and indicate the price as a percentage discount off of AWP, for each drug. To qualify for Approval, the card program must offer for a negotiated price at least one drug in each of the italicized categories in Attachment 2. A specific covered discount card drug may not be used to fill more than one category. With the possible exception of the U.S. territories as arranged by Special Approved sponsors for those regions as described in Section 4.3, offering these drugs through mail order only does not count toward meeting this qualification.

- Indicate in which categories a generic drug will be offered for a negotiated price. To qualify for approval, the card program must offer a negotiated price on at least one generic drug in at least 55 percent of the listed italicized categories.

- 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 3) your card will include.

- For the set of drugs to be offered described in the previous bullet, based on the Applicant's or its subcontractors' existing lines of business providing discounts on prescription drugs, report the maximum and minimum number of times in the past twelve months prices increased. Applicants shall report this information for classes of drugs. Describe the specific line(s) of business from which this information was derived.

- Describe whether and how the list of prescription drugs and/or negotiated prices reported in Attachment 2 will vary geographically or by type of enrollee. Discuss the rationale for such variations and how the drug card program will operationalize the different drug lists and negotiated prices for various regions and/or enrollees groups.

- 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).

- Describe the system your drug card will use to track the pricing of drugs available to your enrollees and to provide weekly updates of price changes and formulary listings to CMS. Specifically, Applicants must submit a disk with test data consistent with the instructions that will be posted on the CMS web site shortly after the release of this solicitation**.**

- 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 prices.

3.2.2 Pricing/Manufacturer Rebates, Discounts, and Other Price Concessions

Qualifications:

- 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 the pharmacy would charge a customer who does not have any form of prescription drug coverage).

- Applicant certifies that a contract exists with each manufacturer whose expected rebates/discounts/other price concessions are represented in the rebate/discount estimates provided and for the purpose of the discount card program described in the application under this solicitation.

- 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, it may increase the negotiated price for a covered drug in an amount proportionate to the change in the drug's average wholesale price (AWP), and/or in 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, discounts, and/or price concessions secured by contract with drug manufacturers or other sources. Indicate the amount of manufacturer rebate and/or discount to be passed through to beneficiaries directly at the point of sale. Your description must include the following information:

    - Estimate the aggregate level of manufacturer rebates/discounts/other price concessions to be secured from drug manufacturers 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 manufacturer rebates/discounts/other price concessions will be tracked to determine whether they reach the level of anticipated share.

    - Indicate that a contract exists with each manufacturer whose expected rebates, discounts, and/or price concessions are represented in the rebate/discount/other price concessions estimates reported for this program.

    - Indicate other sources of discounts (e.g., retail pharmacies), the aggregate level of these discounts to be secured, and the estimated share that will be passed through to card enrollees at the point of sale.

    - Explain how the process of passing through 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 you will not raise prices on covered drugs during a calendar year in an amount greater than the proportionate change in the drug's AWP, and/or an amount proportionate to the material change in your organization's cost structure, including material changes in any discounts, rebates, or other price concessions you receive from a pharmaceutical manufacturer or pharmacy.

3.3 Service Area and Access to Pharmacies

3.3.1 Service Area

Qualifications:

- A State is the smallest service area permitted under this program. A program's service area could also be regional, in which case it operates in more than one State or Washington, D.C. (contiguous or not). Further, we define "national" drug cards as operating in the 50 States and Washington, D.C., and a drug card could not be viewed or described as a "national" program if it did not operate in all of these areas.

- NOTE: Applicants are encouraged to provide a plan to offer negotiated prices in all of the U.S. Territories and transitional assistance access at pharmacies of the I/T/U and long-term care pharmacies. Special incentives and requirements for Applicants offering drug cards that have these features, as well as application instructions and program waivers, are discussed in Sections 4.1, 4.2, and 4.3.

Application Requirements:

- State whether you will be offering a state-level, regional, or national discount card program. Provide a list of the States (and the District of Columbia) that are included in the area served by your drug card. Confirm that your card program will be available to all eligible beneficiaries residing in each State included in your program's service area. If you want to obtain Special Approval for including U.S. Territories in your service area, please refer to Section 4.3 for additional instructions.

3.3.2 Retail Pharmacy Network

Qualifications:

- The Applicant must demonstrate that upon approval it will maintain a national or regional contracted retail pharmacy network in which 90% of Medicare beneficiaries live within 2 miles of a network pharmacy in urban areas, 90% of Medicare beneficiaries live within 5 miles of a network pharmacy in suburban areas, and 70% of Medicare beneficiaries live within 15 miles of a network pharmacy in rural areas. Urban areas are five-digit Zip Codes in which the population density is greater than 3,000 persons per square mile. Suburban areas are five-digit Zip Codes in which the population density is between 1,000 and 3,000 persons per square mile. Rural areas are five-digit Zip Codes in which the population density is less than 1,000 persons per square mile.

- NOTE: Applicants may offer a mail order option in addition to their contracted pharmacy network. (Mail order option only is precluded, except where noted under Special Approval for residents of the territories in Section 4.3.) 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:

- Our network pharmacy access standards must be met at the aggregate, not individual state, level. Using the Geographic Information Systems (GIS) software or similar methodology, demonstrate for the total area your drug card will serve that at least 90% of Medicare beneficiaries live within 2 miles of a network pharmacy in urban areas, 90% of Medicare beneficiaries live within 5 miles of a network pharmacy in suburban areas, and 70% of Medicare beneficiaries live within 15 miles of a network pharmacy in rural areas. Urban areas are five-digit Zip Codes in which the population density is greater than 3,000 persons per square mile. Suburban areas are five-digit Zip Codes in which the population density is between 1,000 and 3,000 persons per square mile. Rural areas are five-digit Zip Codes in which the population density is less than 1,000 persons per square mile.

  The demonstration of pharmacy access must be based on a computation using 100% of beneficiary counts by Zip Code (provided by CMS). Maps and tables must be generated with data for the pharmacy network under contract for the drug card. [CMS will provide Census Bureau population density figures by Zip Code so that sponsors can identify which Zip Codes are urban, which are suburban, and which are rural.] Maps and tables generated by the mapping software must include aggregate urban, suburban, and rural ratios for the entire service area under the discount card, as well as urban, suburban, and rural ratios for each state included under the program. Applicants must also provide an electronic list of all retail pharmacy outlets included in the analysis, including name of pharmacy, address (including Zip Code), contact person, and telephone number.

- 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 the pharmacy is licensed, how beneficiary education on generic substitutions is conducted, and the availability of a pharmacist to answer enrollee questions**.**

    - Of the drugs listed in Attachment 2, indicate which ones are included in the mail order program.

    - 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 (e.g., durable medical equipment related to a covered drug) or discounts on over-the-counter drugs for no extra charge to enrollees. These services would be in addition to the basic program requirements, such as 1) offering negotiated prices on covered discount card drugs, 2) ensuring convenient pharmacy access, 3) reducing the likelihood of medical errors and adverse drug interactions, 4) providing customer service and information and outreach materials, 5)

providing a grievance mechanism, and 6) administering transitional assistance.

- 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 additional fee (other than the enrollment fee) for any services offered by your approved card.

3.5 Card Program Administration and Customer Service

3.5.1 Beneficiary Eligibility/Enrollment/Enrollment Fee

NOTE: Applicants should refer to Attachment 4 for an illustration of the Drug Card Enrollment Process

Qualification:

- Applicant limits enrollment in its drug card to Medicare beneficiaries entitled to or enrolled in Part A and/or enrolled in Part B who do not receive any outpatient 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 beneficiaries who reside within the Applicant's service area and who are neither enrolled in another drug card nor members of a Medicare managed care plan offering an exclusive card program.

- Applicant charges each enrollee (or a State) an annual enrollment fee of no more than $30 for 2004 and 2005. Applicant may have different enrollment fee amounts for each State, but must charge a uniform enrollment fee within each state. The enrollment fee may not change during the year. The enrollment fee may not be pro-rated during the year. No enrollment fee may be charged in 2006.

- 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 for enrollment all eligible Medicare beneficiaries residing in the service area who apply and are not already enrolled in another

Medicare-approved drug card, or who are not members of an exclusive M+C or Medicare cost plan-sponsored card.

- Applicant accepts enrollment applications at any time from those eligible beneficiaries who are enrolling for the first time in an approved drug discount card.

- Applicant enrolls only those beneficiaries who are not already enrolled in another approved drug card, or who are not members of M+C or Medicare cost plans offering exclusive card programs. Applicant accepts enrollments from those already enrolled in another approved drug card only during the Annual Coordinated Election Period for Medicare Benefits, November 15 though December 31 in 2004, or during a Special Election Period.

- Applicant makes 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 and a determination that the beneficiary is eligible. Applicant makes enrollments received through the Annual Coordinated Election Period (November 15, 2004 through December 31, 2004) effective the following January 1, 2005.

- Applicant accepts enrollment applications from a beneficiary entitled to a Special Election Period when he or she 1) moves outside the drug card's service area, 2) changes his or her residence to or from a SNF and nursing facility, 3) enrolls in or disenrolls from a Part C (M+C coordinated care plans. Private fee-for-service plans, or medical savings accounts) or a Medicare cost plan; or 4) is enrolled in an approved program that terminates. CMS may define other exceptional circumstances that justify a Special Election Period. A beneficiary who becomes entitled to a Special Election Period during 2004 remains so entitled until the close of the Annual Coordinated Election Period between November 15 and December 31, 2004. A beneficiary who becomes entitled to a Special Election Period during 2005 remains so entitled until December 31, 2005.

- 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.

- Applicant may use model enrollment forms developed by CMS or may design its own forms, provided that such forms contain at least the same elements as in the CMS standard forms and are reviewed and approved by CMS prior to use. Applicants 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.

- 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 those beneficiaries who do not enroll in a new approved drug card during the Annual Coordinated Election Period and who do not otherwise disenroll. Such enrollees will automatically be charged any applicable annual enrollment fee for the second year of drug card enrollment.

- Applicants may require payment of the enrollment fee at the time they receive the enrollment form (or Internet or telephone request), except for transitional assistance 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., already enrolled in another approved drug card, reside outside service area).

- Applicant submits enrollment/eligibility transactions to CMS according to the instructions provided. CMS will provide responses to each submitted transaction.

- Applicant notifies beneficiary applicant of their confirmed eligibility for enrollment in the approved card program within five business days of receipt of the beneficiary's application.

- Applicant sends enrollment materials (including member handbook and identification card) to each new enrollee within 5 business days of receipt of reply from CMS for all accepted enrollment/eligibility transactions.

- 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 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.

- Enrollees may voluntarily disenroll at any time by notifying the Applicant. Applicant will submit these diesnrollments to CMS and make them effective on the last day of the month in which the request was received. Beneficiaries seeking a Special Election Period must request a disenrollment (except in the cases of beneficiaries disenrolling from or enrolling in an exclusive M+C-sponsored drug following their disenrollment from or enrollment in the corresponding M+C plan, disenrolling from an exclusive Medicare cost contractor-sponsored drug card following their disenrollment from the corresponding cost plan, or disenrolling from a terminating approved discount card program) from the drug card specifying the reason for disenrollment that qualifies them for a Special Election Period.

- Applicant determines whether Special Election Period applies and transmits the determination to CMS.

- Applicant may involuntarily disenroll a non-transitional assistance beneficiary who does not pay the 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. (If the disenrollment occurs in 2004, such notice shall include a statement that the beneficiary's next possible enrollment date in a card program will be the Annual Coordinated Election Period. If the disenrollment occurs in 2005, such notice shall include a statement that the beneficiary will not have another opportunity to enroll in an approved discount card.) If the enrollee fails to pay the delinquent amount within 10 days of this notice, the Applicant may disenroll the enrollee by submitting transaction to CMS and notifying the enrollee that his/her membership has ended. The effective date of disenrollment is the last day of the month in which the fee was due.

Application Requirements:

- Indicate your intention that all Medicare beneficiaries eligible for this program and residing in your service area will be permitted to enroll into your card program unless they are already enrolled in another drug card and do not disenroll from the other drug card during a Special Election Period or during the Annual Coordinated Election Period.

- Indicate your intention that you will limit enrollment in your drug card to those eligible Medicare beneficiaries who reside within your drug card's service area.

- Indicate your intention not to enroll any beneficiary who is already enrolled in another approved drug card or who is identified as a member of an exclusive M+C or Medicare cost plan-sponsored drug card.

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

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

- Indicate that you will refund enrollment fees paid by beneficiaries (or others on their behalf) applying for enrollment in your discount card who are determined ineligible for enrollment in your drug card program and by beneficiaries who are determined to be eligible for transitional assistance after they have been enrolled in your discount card.

- For the service area you intend to cover, indicate that your drug card can be ready to enroll beneficiaries and provide discounts and access to transitional assistance by as early as May 3, 2004.

- Describe your process for enrolling Medicare beneficiaries 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 and the systems used to verify program eligibility with CMS, how and when your will collect the enrollment fee (if any), communicating eligibility determinations back to the applying beneficiary within five days of receipt of the application, communicating with beneficiaries regarding incomplete applications, 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 CMS standard enrollment form shown in the model enrollment form posted on the CMS web site.

- 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 your organization's experience using Connect:Direct for on-line transactions, including volume of transactions transmitted and the time frame. Describe the processing environment that will be used to manage required transactions and data.

- Indicate that you will follow the telecommunications/system testing processes posted on the CMS web site.

- Describe your procedures for accepting and processing disenrollment requests from beneficiaries, including communicating such requests to CMS and making the disenrollments effective on the last day of the month in which the disenrollment is received. This description must include a discussion of your procedures for handling beneficiary requests for a Special Election Period and for verifying that the beneficiary is eligible for a Special Election Period.

- Describe your procedures for involuntarily disenrolling beneficiaries who fail to pay their annual enrollment fee, including how you will abide by the notice requirements.

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;
  - Group health plan or health insurance coverage that includes outpatient prescription drugs (such as an employer-sponsored or retiree group health plan or a privately purchased individual health insurance policy) other than coverage through a health care plan authorized under Part C, title 18 of the Social Security Act or a Medigap plan (even if an employer pays for the premium of the Part C plan or Medigap plan);
  - 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 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 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 their enrollment in the drug card program, regardless of any changes in beneficiaries' status. Applicant sends each eligible enrollee a confirmation of their enrollment, including the effective date. Certain individuals who are determined eligible will receive a notice that additional information should be sent to a third party contractor. Applicant must send enrollment materials (including a member handbook and ID card) and the appropriate enrollment confirmation letter to each accepted enrollee within 5 business days of receipt of CMS reply.

- For Medicare beneficiaries whom CMS initially 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 its drug discount card beneficiaries applying for transitional assistance until CMS determines that the beneficiaries are eligible for transitional assistance. If the beneficiary is determined ineligible for transitional assistance, they must have an opportunity to enroll in any discount card available in their service area.

- Applicants determine the appropriate coinsurance level 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 the your identification of ineligibility based on your review of data submitted on the enrollment form.

- 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 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. If an Applicant intends to offer more than one discount card program, it need only register once.

- Applicant submits EIN information (Attachment 5) 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 the 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 balance for that month. Such amount shall represent only claims which have been fully 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 the 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 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 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, 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 in cases where a beneficiary disenrolls outside the Annual Coordinated Election process and is not eligible for a Special Election Period, his or her transitional assistance balance will not be made available during the next calendar year.

- Applicant ensures that transitional assistance funds are applied only to covered discount card drugs. Applicant must apply such funds regardless of whether the particular drug being purchased is offered for a negotiated price by the sponsor (i.e., on the sponsor's formulary). 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 any drugs excluded from the definition of "covered discount card drug" as stated in 42 CFR § 403.802.

- 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 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 create 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 transitional assistance enrollees with incomes greater than 100 percent and not greater than 135 percent of the poverty line (or others on their behalf) are responsible for paying 10 percent of the charge for the covered discounts card drug, and transitional assistance enrollees whose income is not greater than 100 percent of the poverty line are responsible for paying 5 percent of the charge for the covered discount card drug.

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.

    - Describe how your organization will ensure that when transitional assistance funds are used, enrollees, receive the lower of the negotiated price (if any) or the usual and customary price.

    - Describe how your organization will ensure that transitional assistance is used only to purchase covered discount card drugs, not over the counter drugs.

    - 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 you would encounter the need for off-line claims adjudication (e.g., transactions involving pharmacies without real-time communication capabilities, institutional pharmacies). 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.

3.5.6 Call Center

Qualifications:

- 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. This means the applicant must comply with at least the following:
    - Call center operates Monday through Friday from 8:00 A.M. to 4:30 P.M. Eastern to Pacific Standard Times for those time zones in which the program operates.
    - Seventy percent of customer service representatives' time is spent manning telephones, responding to enrollee inquiries.
    - Eighty percent of all incoming customer calls are answered within 30 seconds.
    - Abandonment rate of all incoming customer calls does not exceed 5 percent.
    - Call center provides transitional assistance-eligible enrollees information on their remaining amount of their transitional assistance.
    - Call center features an explicit process for handling customer complaints.
    - Call center provides a convenient means for accommodating pharmacy inquiries regarding the card sponsor's program.
    - Call center can respond to Spanish and other non-English-speaking beneficiaries.
- 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:

- In the following areas, describe how the entity responsible for the call center function meets or exceeds the following qualifications:

    - Call center operates Monday through Friday from 8:00 A.M. to 4:30 P.M. Eastern to Pacific Standard Times for those time zones in which the program operates.

    - 70% of customer service representatives' time must be spent manning telephones, responding to enrollee inquiries.

    - 80% of all incoming customer calls must be answered within 30 seconds.

    - The abandonment rate of all incoming customer calls must not exceed 5%.

- 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, including changes in prices and formulary and varying prices based on geography and special health condition.

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

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

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

    - Questions concerning lost or stolen identification cards.

- Mail order pharmacy questions, issues, and concerns (if applicable).
- Questions concerning the use of the card with other drug programs or benefits.
- Questions concerning denial of use of the card by a network pharmacy.
- Questions from pharmacists concerning the Applicant's drug card program.

- Describe your call center staff's ability and experience in responding to Spanish and, as appropriate, other non-English-speaking beneficiaries.
- 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 achievements in reducing medication errors and adverse drug interactions and in improving medication use.

3.5.8 Grievance/Customer Complaints

Qualifications:

- Applicant establishes and maintains a grievance process designed 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;

    - 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.

- Applicant makes drug card enrollees aware of grievance process through information and outreach materials.

- Applicant accepts grievances from enrollees at least by telephone and in writing.

- Applicant is not required to accept grievances filed by enrollees more than 60 days after the event that precipitates the grievance.

- Applicant responds to all grievances within 30 days of the date the card sponsor receives the grievance.

- Applicant responds in writing to grievances submitted in writing and responds either in writing or orally to grievances filed by telephone, unless a written response is specifically requested by the enrollee.

- Applicant provides responses to the enrollee who filed the grievance as well as any other parties involved in the matter about which the grievance was filed, consistent with applicable State law.

- Applicant maintains a system to maintain records on all grievances received both orally and in writing, including a final disposition of the grievance in accordance with the specific grievance categories provided in Attachment 6.

- Applicant provides CMS with aggregate information on the number and disposition of grievances each month in accordance with the general grievance reporting requirements provided in Attachment 6.

Application Requirements:

- Provide a detailed description of your grievance (i.e., customer complaints) process for all aspects of your drug card's operations. Address specifically:

- Types of issues you consider grievances.
- Methods of informing enrollees about grievance process (e.g., information and outreach materials, inclusion in regular correspondence with enrollees, etc.)
- Method by which you receive (e.g., written, e-mail, telephone, etc.) and categorize complaints.
- Type of data you will collect when a complaint is received, and as grievance is processed.
- Type of follow-up actions for investigating and resolving grievances.
    - Communication protocols to provide feedback to the enrollee who submitted the grievance as well as any other parties involved in the matter about which the grievance was filed, consistent with applicable State law.
- Target and average response times for investigating grievances, and for resolving complaints.
- Skill level of employees that will be responsible for the grievance tracking system.
- Protocols and data used for grievance tracking to inform internal quality assurance, including corrective action procedures for problems identified in grievances.
- Types of issues that might warrant notification of CMS or State regulatory entities.
- Types of grievance reporting data that you will provide CMS.

3.5.9 Information and Outreach

Qualifications:

- Applicant provides information and conducts outreach to Medicare beneficiaries through the Internet and some other tangible medium (such as a mailing) 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, or discounts on over-the-counter drugs;

- 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.
- For information posted on the Applicant's web site, a statement regarding when the site was last updated and a disclaimer that the information on the web site may not be current;
- A privacy notice for protected health information consistent with the standards stated in the information and outreach guidelines; and
- A description (if applicable) of how information will be communicated for individuals in long-term care facilities and American Indians/Alaska Natives (AI/ANs) who use pharmacies operated by the Indian Health Services, Indian tribes and tribal organizations, and urban Indian organizations (I/T/Us)

- Applicant provides beneficiaries with information and outreach materials that comply with CMS information and outreach guidelines. Such guidelines are 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.

Application Requirements:

- Indicate your intention to follow the information and outreach guidelines, which are 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 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 discounts for non-prescription drugs, 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 for products or services outside the drug card program's approval.

- Applicant ensures that all 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 of beneficiary data.

    - Describe how your organization will obtain beneficiary written authorization for 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:

- Applicant certifies and complies with reporting routinely to CMS on major features of their program that correspond to the qualifications for approval.

- Applicant certifies that based on best knowledge, information, and belief the reported information is accurate, complete, truthful, and supportable.

- Applicant provides CMS with notice of, and the rationale for, negotiated price increases, except for increases during the week of November 15, 2004, due to reasons other than changes in average wholesale price (AWP).

- Applicant provides CMS with a plan to monitor any aberrancies or high utilization and spend patterns (identified by Zip Code) observed in claims data for drugs with significant abuse/misuse potential as denoted by DEA Control Schedule II through Schedule V.

Application Requirements:

- Describe how your organization will adhere to the reporting requirements and schedule outlined in Attachment 6.

- Describe the procedures your organization has adopted to ensure that you will keep CMS informed of any material modifications, such as network changes and covered drug price increases in an amount greater than AWP, 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 operations of an approved program for at least 6 years following the termination of the program, or in the event 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 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 six 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.

4.0 COMPETITION FOR SPECIAL APPROVALS

4.1 Competition for Special Approval to Serve Residents of Long Term Care Facilities

Overview

Pursuant to section 1860D-31(g)(5) of the Social Security Act and 42 CFR 403.816, CMS is required to make transitional assistance under the drug card program available to eligible individuals who reside in long-term care facilities. Long-term care pharmacies provide access to prescription drugs to residents of skilled nursing facilities and nursing facilities through medical benefits that are coordinated by the long term care facilities in cooperation with the long term care pharmacies. Also, the medications provided are often specifically packaged to provide quality control. These, and other circumstances, contribute to such pharmacies not being well integrated into the private networks maintained by the pharmacy benefit management industry.

To encourage card sponsors to include long term care pharmacies in their networks, we have developed a competitive application process through which we will award a special approval to at least two successful applicants in each State. Limiting the special approval to a select group of card sponsors will allow such sponsors to have a sufficient volume of new covered lives in order to cover the fixed costs associated with starting up the special provisions of contracts with long term care pharmacies.

Our selection of sponsors for Special approval will be based on the applicants' 1) understanding of the unique circumstances of long-term care pharmacy operations, in general, and how the Medicare drug discount card program may be integrated into long term care pharmacy practices; 2) accommodation of typical

operating practices of long term care pharmacies; 3) prior experience working with long term care pharmacies; 4) extensiveness of service area and long term care pharmacy network; 5) completeness and feasibility of the plan to operationalize the requirements of Special Approval to serve long term care facility residents; and 6) ability to implement the requirements of Special Approval to serve long term care facility residents in a timely fashion.

CMS will provide additional support to card sponsors receiving the special approval, including special recognition for these sponsors on the CMS web site that describes the sponsors' programs; a special break-out session at the pre-application conference, to the extent possible, a list of all pharmacies that support long-term care facilities; and expedited marketing review. Card sponsor contracts with long-term care facilities will be permitted to become effective on a separate timeline from the card sponsor's basic drug card to accommodate the added time that may be needed to negotiate contracts and make infrastructure changes to assure beneficiaries served by these pharmacies may use their transitional assistance to cover the costs of covered discount card drugs obtained from these pharmacies.

Qualifications

To compete for a special approval to provide access to transitional assistance for residents of long-term care facilities by including long term care pharmacies in its contracted network, Applicant must meet at the time of application or agree to meet the following:

- Applicant qualifies as a discount card sponsor in all respects as described in Section 3.0, except where otherwise noted below.

- Applicant agrees to contract with any willing long term care pharmacy in its service area, where such pharmacy is defined as any licensed pharmacy that contracts with at least one nursing facility or skilled nursing facility.

- Applicant agrees to process claims for transitional assistance for residents of long-term care facilities using long-term care pharmacies off-line, where necessary.

- Applicant agrees to process claims from any out-of-network long-term care pharmacies that supply covered drugs to long-term care facility residents enrolled in the drug card program when such beneficiaries have a transitional assistance balance remaining.

- Applicant agrees that closed-shop long term care pharmacies are permitted to provide covered discount card drugs only to enrollees of the special approved sponsor's approved program who reside in long term care facilities served by the pharmacy (i.e., these pharmacies are not required to serve other enrollees in the special approved sponsor's discount card, unless the pharmacy is also a retail pharmacy otherwise in the sponsor's network for such purpose).

- Applicant agrees to process special transaction type depending on whether the pharmacy is recognized under HIPAA as a retail pharmacy (that is, X12 versus NCPDP).

- Applicant agrees to process "late" claims from long-term care pharmacies without penalty as payer of last resort after other insurance has been processed first.

- For the purposes of administering the long term care portion of the drug card requirements, the Special Approved Sponsors will not be required to:

    - Meet the requirements of Section 3.2 (Formulary and Discounts); and
    - Have the long-term pharmacies make available at the point of sale the amount of transitional assistance remaining.

- Applicant may request waivers for other requirements in Section 3.0. Waivers or modifications may be granted if such waiver or modification is necessary to (A) ensure that you are able to initiate enrollment and operate your program within 6 months of enactment, or by June 8, 2004; (B) accommodate the unique needs of long-term care pharmacies; or (C) compliance would be impracticable or inefficient. NOTE: Applicants may not request a waiver or modification of requirements stated in 42 CFR §403.812 (governing HIPAA privacy, security, administrative data standards, and national identifiers) and §403.813 (governing marketing limitations and record retention requirements).

Application Requirements

- Indicate whether your organization is competing for Special Approval to serve residents of long term care facilities. Applicants not competing for this Special Approval may so indicate and leave section 4.1 of their application otherwise blank.

- Include a plan to provide access to transitional assistance for eligible enrollees who reside in long term care facilities. The plan should be organized as follows:

- Understanding, Background, and Experience

- Proposed approach, including recruiting long term care pharmacies for the network, special contracting provisions, administration of transitional assistance and whether negotiated prices will be offered, and plans to process off-line and out-of-network claims.

- Service area and pharmacy network, including a demonstration of the proportion of long term care pharmacies in the proposed service area that the applicant anticipates including in its long term care pharmacy network;

- Timeline for implementation

- Additionally, the plan should ensure that it addresses each of the explicit requirements set forth in the "Qualifications" section immediately above, except for the qualifications for which the plan is explicitly exempt, as stated above.

- Note any of the specific requirements in Section 3.0 that you wish to modify or waive. Include an explanation of why the waiver is necessary using the criteria described above in the Qualifications section. If you believe compliance with the requirement would delay enrollment or operation of your program, explain how such delay would occur, and the number of months of delay you would expect. If you believe the waiver is necessary to accommodate unique needs of long-term care pharmacies, please be explicit about what these needs are and how the waiver accomplishes the accommodation. If you believe compliance would be impracticable or inefficient, please provide a detailed explanation of why it would be impracticable or inefficient, as well as the costs and benefits of such waiver. Please provide an assessment of the impact you believe each waiver or modification would have on the long-term care population. If we determine that your application does not provide an adequate explanation for your requested waiver or modification, we may ask you to amend the application.

4.2 Competition for Special Approval to American Indians/Alaska Natives through Indian Health Service, Indian Tribe and Tribal Organization, and Urban Indian Organization Pharmacies

Overview

Pursuant to section 1860D-31(g)(5) of the Social Security Act and 42 CFR 403.816, CMS is required to ensure that, for purposes of providing transitional assistance, Indian Health Service, Indian Tribe and Tribal Organization, and Urban Indian Organization (I/T/U) pharmacies have the opportunity to participate in the pharmacy networks of at least two approved discount card programs in each of the 50 States and the District of Columbia where such a pharmacy operates. Generally speaking, I/T/U pharmacies provide access to prescription drugs off of the Federal Supply Schedule to American Indians/Alaska Natives (AI/ANs), and these pharmacies are not well integrated into the private networks maintained by the pharmacy benefit management industry. These provisions of section 1860D-31 of the Act provide an opportunity for I/T/U pharmacies to provide prescriptions to AI/ANs at the low Federal Supply Schedule rate, whereby coverage of the cost of such drugs would in part come from transitional assistance funds, and in part from Indian Health Service funds.

Identical to the process described above for Special Approval to serve residents of long term care facilities, to encourage card sponsors to include I/T/U pharmacies in their networks, we have developed a competitive application process through which we intend to award a special approval to at least two successful applicants. Limiting the special approval to a select group of card sponsors, will allow such sponsors to have a sufficient volume of new covered lives in order to cover the

fixed costs associated with starting up the special provisions of contracts with I/T/U pharmacies.

Our selection of Special Approved sponsors will be based on the applicants' 1) understanding of the unique circumstances of I/T/U pharmacy operations, in general, and how the Medicare drug discount card program may be integrated into I/T/U pharmacy practices; 2) accommodation of typical operating practices of I/T/U pharmacies; 3) prior experience working with I/T/U pharmacies; 4) extensiveness of service area and I/T/U pharmacy network; 5) completeness and feasibility of the plan to operationalize the requirements of Special Approval to provide transitional assistance to AI/ANs through I/T/U pharmacies; and 6) ability to implement the requirements of Special Approval to serve AI/ANs through I/T/U pharmacies in a timely fashion.

CMS will provide additional support to card sponsors receiving the special approval, including special recognition for these sponsors on the CMS web site that describes the sponsors' programs; a special break-out session at the pre-application conference, a list of all I/T/U pharmacies; and expedited marketing review. Card sponsor contracts with I/T/U pharmacies will be permitted to become effective on a separate timeline from the card sponsor's basic drug card to accommodate the added time that may be needed to negotiate contracts and make infrastructure changes to assure beneficiaries served by these pharmacies may use their transitional assistance to cover the costs of covered discount card drugs obtained from these pharmacies.

Qualifications

To compete for a special approval to provide access to transitional assistance through I/T/U pharmacies, Applicant must meet or agree to meet the following:

- Applicant qualifies as a discount drug card sponsor in all respects as described in Section 3.0, except where otherwise noted below.

- Applicant agrees to contract with any willing I/T/U pharmacy in its service area.

- Applicant agrees to process claims for transitional assistance from I/T/U pharmacies off-line, where necessary.

- Applicant agrees that I/T/U pharmacies may serve only AI/ANs (sponsor must structure network and educate so that non-AI/ANs understand these pharmacies generally are not available to them).

- Applicant agrees that AI/ANs will be given access to negotiated prices and transitional assistance for drugs purchased at any non-I/T/U pharmacies in the sponsor's network.

- Applicant agrees that I/T/U pharmacies are not required to stock a wide range of drugs.

- Applicant acknowledges that I/T/U pharmacies are required by law to waive copayments in all cases. (NOTE: The amount of a waived copayment may not be deducted from an enrollee's transitional assistance balance.)

- For the purposes of administering transitional assistance through I/T/U pharmacies, Special Approved Sponsors will not be required to:

    - Meet the requirements of Section 3.2 (Formulary and Discounts); and
    - Have I/T/U pharmacies make available at the point of sale the amount of transitional assistance remaining.

- Applicant may request waivers or modifications for other requirements in Section 3.0. Waivers or modifications may be granted if such waiver or modification is necessary to (A) ensure that you are able to initiate enrollment and operate your program within 6 months of enactment, or by June 8, 2004; or (B) compliance would be impracticable or inefficient. NOTE: Applicants may not request a waiver or modification of requirements stated in 42 CFR §403.812 (governing HIPAA privacy, security, administrative data standards, and national identifiers) and §403.813 (governing marketing limitations and record retention requirements).

- Application Requirements:

- Indicate whether your organization is competing for Special Approval to provide transitional assistance to AI/ANs through I/T/U pharmacies. Applicants not competing for this Special Approval may so indicate and leave section 4.2 of their application otherwise blank.

- Include a plan to provide access to transitional assistance for eligible AI/ANs who use I/T/U pharmacies. The plan should be organized as follows:

- Understanding, Background, and Experience

- Proposed approach, including recruiting I/T/U pharmacies for the network, special contracting provisions, administration of transitional assistance, and plans to process off-line claims, if necessary.

- Service area and pharmacy network, including a demonstration of the proportion of I/T/U pharmacies in the proposed service area that the applicant anticipates will accept contracts to be included in its I/T/U pharmacy network;

- Timeline for implementation.

- Additionally, the plan should ensure that it addresses each of the explicit requirements set forth in the "Qualifications" section immediately above, except for the qualifications from which the plan is explicitly exempt, as stated above.

- Identify any of the specific requirements in Section 3.0 that you wish to modify or waive. Include an explanation of why the waiver or modification is necessary using the criteria described above in the Qualifications section. If you believe compliance with the requirement would delay enrollment or operation of your program, explain how such delay would occur, and the number of months delay you would expect. If you believe compliance would be impracticable or inefficient, please provide a detailed explanation of why it would be impracticable or inefficient, as well as the costs and benefits of such a waiver. Please provide an assessment of the impact you believe each waiver or modification would have on the AI/AN population. If we determine that your application does not provide an adequate explanation for your requested waiver or modification, we may ask you to amend the application.

4.3 Competition for Special Approval to Serve Residents of the Territories

Overview

Medicare beneficiaries residing in the U.S. territories, which include American Samoa, Commonwealth of the Northern Mariana Islands, Guam, Puerto Rico, and Virgin Islands, are eligible to enroll in a Medicare-approved drug discount card program. Through a competitive process for Special Approval to serve residents of the territories, we intend to limit the number of approved programs operating in a territory to one or two programs for reasons similar to those justifying our policy of limiting to two the number of sponsors in a state that may include long term care and I/T/U pharmacies in their pharmacy networks. Specifically, we believe that promoting competition ensures that successful applicants are guaranteed volume of new covered lives and will thus encourage program sponsors to submit plans to provide services to these populations.

It is important for Applicants to note that transitional assistance in the territories is a separate program from the drug discount card program, with its own structure, process, and funding. Thus, drug discount cards in the territories will offer negotiated prices, but will not provide access to transitional assistance funds.

Our selection of Special Approved sponsors will be based on the applicants' 1) understanding of the unique circumstances of pharmacy operations in the territories; 2) prior experience working with pharmacies in the territories or providing pharmacy mail order access to residents in the territories; 3) inclusiveness of all five territories, extensiveness of network of retail pharmacies in the territories, and provisions for mail order access; 4) completeness and feasibility of the applicant's plan to operationalize the requirements of Special Approval to serve residents of the territories; and 5) ability to implement the requirements of Special Approval to serve residents of the territories in a timely fashion.

We will provide technical assistance and other benefits to Special Approved sponsors serving residents of the territories, including holding a special break-out session at the pre-application conference to discuss pharmacy issues in the

territories, providing expedited marketing review to the extent possible, and providing special recognition for these sponsors on the CMS web site describing sponsor programs. Also, since retail pharmacies in the territories may represent a new and untested set of business relationships for the sponsors, these contracts need not be in place in time for the start of the general program.

Qualifications

To compete for a special approval to provide access to drug discounts to resident of the U.S. territories, Applicant must meet or agree to the following:

- Applicant qualifies as a discount drug card sponsor in all respects as described in Section 3.0, except where otherwise noted below.
- Applicant agrees to make a good faith effort to contract with any willing retail pharmacy in each of the territories.
- In areas of the territories where the Applicant is unable to secure contracts with retail pharmacies, Applicant agrees to offer mail order access to all areas of the territories where it is practicable to do so.
- Applicant agrees to educate enrollees in the territories about any considerations they need to take into account to assure safe and timely access to their prescriptions by mail order (for example, order in advance of need).
- For the purposes of providing access to negotiated prices to residents of the territories, Special Approved Sponsors will not be required to:
- Inform at retail pharmacies in the territories discount card eligible individuals enrolled under the program of any differential between the price of the drug to the enrollee and the price of the lowest priced generic covered drug under the program that is therapeutically equivalent and bioequivalent.
- Meet the access standards described in Section 3.3.2. Specifically, so long as these Special Approved Sponsors make a good faith effort to contract with retail pharmacies in each of the territories and offer mail order access in areas where it is unable to secure retail pharmacy contracts, we will consider access requirements to be met in these regions. Mail order only will be acceptable if retail pharmacies do not accept offered contracts with the Special Approved Sponsor.
- For prescriptions sent via mail order, Applicant provides information on any differential between the price of the drug to the enrollee and the price of the lowest priced generic covered drug under the program that is therapeutically equivalent and bioequivalent in a manner consistent with the rules for providing this information by mail order to enrollees in the 50 States and the District of Columbia.
- Applicant may enroll Medicaid enrollees with coverage for outpatient prescription drugs.

- Applicant may request waivers or modifications for other requirements in Section 3.0. Waivers or modifications may be granted if such waiver or modification is necessary to (A) ensure that you are able to initiate enrollment and operate your program within 6 months of enactment; (B) accommodate the unique needs of pharmacies in the territories, or by June 8, 2004; or (C) compliance would be impracticable or inefficient. NOTE: Applicants may not request a waiver or modification of requirements stated in 42 CFR §403.812 (governing HIPAA privacy, security, administrative data standards, and national identifiers) and §403.813 (governing marketing limitations and record retention requirements).

Application Requirements:

- Indicate whether your organization is competing for Special Approval to serve residents of the territories. Applicants not competing for this Special Approval may so indicate and leave section 4.3 of their application otherwise blank.

- Include a plan to provide access to negotiated prices for enrollees who reside in the territories. The plan should be organized as follows:

- Understanding, Background, and Experience

- Proposed approach, including efforts to recruit retail pharmacies for the network and educational efforts regarding use of mail order;

- Pharmacy network and mail order, including a demonstration of the proportion of pharmacies in each of the territories that the applicant anticipates including in its territories pharmacy network, and plans for providing mail order access; and

- Timeline for implementation.

- Additionally, the plan should ensure that it addresses each of the explicit requirements set forth in the "Qualifications" section immediately above, except for the qualifications from which the plan is explicitly exempt, as stated above.

- Identify any of the specific requirements in Section 3.0 that you wish to modify or waive. Include an explanation of why the waiver or modification is necessary using the criteria described above in the Qualifications section. If you believe compliance with the requirement would delay enrollment or operation of your program, explain how such delay would occur, and the number of months delay you would expect. If you believe such a waiver or modification is necessary to accommodate the unique needs of pharmacies in the territories, describe those unique needs and how the waiver or modification addresses them. If you believe compliance would be impracticable or inefficient, please provide a detailed explanation of why it would be impracticable or inefficient, as well as the costs and benefits of such a waiver. Please provide an assessment of the impact you believe each waiver or modification would have on beneficiaries residing in the territories. If we

determine that your application does not provide an adequate explanation for your requested waiver or modification, we may ask you to amend the application.

5.0 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 approval.

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 a prescription drug discount card program.

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

ATTACHMENT 1 - Data Use Agreement
Applicants must complete the sections highlighted in the Directions below.

INSTRUCTIONS FOR COMPLETING THE DATA USE AGREEMENT (DUA)
(AGREEMENT FOR USE OF CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS) DATA CONTAINING INDIVIDUAL IDENTIFIERS)

This agreement must be executed prior to the release of data from CMS' Systems of Records to ensure that the disclosure will comply with the requirements of the Privacy Act, the Privacy Rule and CMS data release policies. It must be completed prior to the release of specified data files containing protected health information and individual identifiers.

Directions for the completion of the agreement follow:

DO NOT ALTER the language contained in this agreement.

- **First paragraph, enter the Requestor's Organization Name.**
- **Item #1, enter the Requestor's Organization Name.**
- **Item #4, enter the Custodian Name, Company/Organization, Address, Phone Number (including area code), and E-Mail Address (if applicable). The Custodian of files is defined as that person who will have actual possession of and responsibility for the data files. This section should be completed even if the Custodian and Requestor are the same.**
- **Item #5 will be completed by a CMS representative.**
- **Item #6 enter the Study and or Project Name and a brief description of the purpose for which the file(s) will be used.**
- **Item #7 should delineate the files and years the Requestor is requesting. Specific file names should be completed. If these are unknown, you may contact a CMS representative to obtain the correct names.**
- **Item #8, complete by entering the Study/Project's anticipated date of completion.**
- **Item #15 will be completed by CMS.**
- **Item #19 is to be completed by Requestor.**
- **Item #20 is to be completed by Custodian.**
- **Item #21 will be completed by a CMS representative.**
- **Item #22 should be completed if your study is funded by one or more other Federal Agencies. The Federal Agency name (other than CMS) should be entered in the blank. The Federal Project Officer should complete and sign the remaining portions of this section. If this does not apply, leave blank.**
- **Items #23a, b and c will be completed by a CMS representative.**

Once the DUA is received and reviewed for privacy and policy issues, a completed and signed copy will be sent to the Requestor for their files.

DUA # [ ]

DATA USE AGREEMENT

AGREEMENT FOR USE OF CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS) DATA CONTAINING INDIVIDUAL-SPECIFIC INFORMATION)

In order to secure data that reside in a CMS Privacy Act System of Records; in order to ensure the integrity, security, and confidentiality of information maintained by the CMS; and to permit appropriate disclosure and use of such data as permitted by law, CMS and _____ enter into this agreement to comply with the following specific paragraphs. (Requestor)

1. This Agreement is by and between the Centers for Medicare & Medicaid Services (CMS), a component of the U.S. Department of Health and Human Services (HHS), and _____, hereinafter termed "User." (Requestor)

2. This Agreement addresses the conditions under which CMS will disclose and the User will obtain, use, reuse and disclose the CMS data file(s) specified in item 7 and/or any derivative file(s) that contain direct individual identifiers or elements that can be used in concert with other information to identify individuals. This Agreement supersedes any and all agreements between the parties with respect to the use of data from the files specified in item 7 and preempts and overrides any instructions, directions, agreements, or other understanding in or pertaining to any grant award or other prior communication from the Department of Health and Human Services or any of its components with respect to the data specified herein. Further, the terms of this Agreement can be changed only by a written modification to this Agreement or by the parties adopting a new agreement. The parties agree further that instructions or interpretations issued to the User concerning this Agreement or the data specified herein, shall not be valid unless issued in writing by the CMS point-of-contact specified in section 5 or the CMS signatory to this Agreement shown in item 23.

3. The parties mutually agree that CMS retains all ownership rights to the data file(s) referred to in this Agreement, and that the User does not obtain any right, title, or interest in any of the data furnished by CMS.

4. The parties mutually agree that the following named individual is designated as Custodian of the file(s) on behalf of the User and will be the person responsible for the observance of all conditions of use and for establishment and maintenance of security arrangements as specified in this Agreement to prevent unauthorized use. The User agrees to notify CMS within fifteen (15) days of any change of custodianship. The parties mutually agree that CMS may disapprove the appointment of a custodian or may require the appointment of a new custodian at any time.

_____
(Name of Custodian)

_____
(Company/Organization)

_____
(Street Address)

_____
(City/State/ZIP Code)

_____
(Phone No. - Including Area Code

_____
(E-Mail Address, If Applicable)

5. The parties mutually agree that the following named individual will be designated as point-of-contact for the Agreement on behalf of CMS.

_____
(Name of Contact)

_____
(Title/Component)

_____
(Street Address)

_____
(Mail Stop)

_____
(City/State/ZIP Code)

_____
(Phone No. - Including Area Code

_____
(E-Mail Address, If Applicable)

6. The User represents, and in furnishing the data file(s) specified in item 7 CMS relies upon such representation, that such data file(s) will be used solely for the following purpose(s).

Data provided under this agreement will be used to support the Requestor's application to be an endorsed card sponsor under the Medicare Prescription Drug Discount Card and Transitional Assistance Program.

The User represents further that the facts and statements made in any study or research protocol or project plan submitted to CMS for each purpose are complete and accurate. Further, the User represents that said study protocol(s) or project plans, that have been approved by CMS or other appropriate entity as CMS may determine, represent the total use(s) to which the data file(s) specified in section 7 will be put.

The User agrees not to disclose, use ore reuse the data covered by this agreement except as specified in an Attachment to this Agreement or except as CMS shall authorize in writing or as otherwise required by law, sell, rent, lease, loan, or otherwise grant access to the data covered by this Agreement. The User affirms that the requested data is the minimum necessary to achieve the purposes stated in this section. The User agrees that, within the User organization and the organizations of its agents, access to the data covered by this Agreement shall be limited to the minimum amount of data and minimum number of individuals necessary to achieve the purpose stated in this section (i.e., individual's access to the data will be on a need-to-know basis).

7. The following CMS data file(s) is/are covered under this Agreement.

File	Year(s)
(1) Drug Utilization Data – Source: MCBS	2000
(2) Zip Code Level File with Enrollment by Medicare Status, Race, and Gender – Source: EDB	2002
(3) Zip Code Level File with population density – Source: Census	2000

8. The parties mutually agree that the aforesaid file(s) (and/or any derivative file(s) including those files that directly identify individuals and those that can be used in concert with other information to identify individuals may be retained by the User until December 31, 2004 , hereinafter known as the "Retention Date." The User agrees to notify CMS within 30 days of the completion of the purpose specified in item 6 if the purpose is completed before the aforementioned retention date. Upon such notice or retention date, whichever occurs sooner, CMS will notify the User either to return all data files to CMS at the User's expense or to destroy such data. If CMS elects to have the User destroy the data, the User agrees to destroy and send written certification of the destruction of the files to CMS within 30 days of receiving CMS's instruction. If CMS elects to have the data returned, the User agrees to return all files and any derivative files to CMS within 30 days of receiving notice to that effect. The User agrees not to retain CMS files or any parts thereof after the aforementioned file(s) are returned or destroyed unless the appropriate Systems Manager or the person designated in item number 23 of

this Agreement grants written authorization. The User acknowledges that the date is not contingent upon action by CMS, and the User agrees to assume the duty to ask CMS for instructions under this paragraph if instructions are not received within after 30 days of the retention date's passing.

The Agreement may be terminated by either party at any time for any reason upon 30 days written notice. Upon notice of termination by user, CMS will cease releasing data to the User under this Agreement and will notify the User to either return all previously released data files to CMS at the User's expense or destroy such data, using the same procedures stated in the preceding paragraph. Sections 3, 6, 8, 11, 12, 13, 14, 16, 17 and 18 shall survive termination of this Agreement.

9. The User attests to having in place appropriate administrative, technical, and physical safeguards to protect the privacy of protected health information in accordance with 45 CFR 164.530(c); and further attests its information and security measures will meet the standards, implementation specifications, and requirements of 45 CFR Part 164, subparts A and C as of the initial enrollment date, or provide a plan for coming into compliance with these requirements by the compliance date of the Security Rule set forth in 45 CFR Part 164, subpart C.

10. The User agrees to grant access to the data to the authorized representatives of CMS or DHHS Office of the Inspector General at the site indicated in item 4 for the purpose of inspecting to confirm compliance with the terms of this agreement.

11. The User agrees not to disclose direct findings, listings, or information derived from the file(s) specified in item 7, with or without direct identifiers, if such findings, listings, or information can, by themselves or in combination with other data, be used to deduce an individual's identity unless it obtains written authorization to do so from the appropriate System Manager or the person designated in item 23 of this Agreement. Examples of such data elements include, but are not limited to geographic location, age if > 89, sex, diagnosis and procedure, admission/discharge date(s), or date of death. The User agrees further that CMS shall be the sole judge as to whether any finding, listing, information, or any combination of data extracted or derived from CMS's files identifies or could, with reasonable effort, be used to identify an individual.

12. The User agrees that, absent express written authorization from the appropriate System Manager or the person designated in item 23 of this Agreement to do so, the User shall not attempt to link records included in the file(s) specified in item 7 to any other individually identifiable source of information. This includes attempts to link to the data to other CMS data file(s). A protocol that includes the linkage of specific files that has been approved in accordance with item 6 constitutes express authorization from CMS to link files as described in the protocol.

13. The User agrees to submit to CMS a copy of all findings within 30 days of making such findings. The parties mutually agree that the User has made findings with respect to the data covered by this Agreement when the User prepares any report other writing for submission to another party (including but not limited to any manuscript to be submitted for publication) concerning any purpose specified in item 6 (regardless of whether the report or other writing expressly refers to such purpose, to CMS, or to the files specified in item 7 or any data derived from such files). The User agrees not to submit such findings to any other party until CMS finds that the findings do not breach the confidentiality of CMS' data by allowing for the identification of the data's subject individuals. CMS agrees to make determination about approval and to notify the user within 4 to 6 weeks after receipt of findings. CMS may withhold approval for publication only if it determines that the format in which data are presented may result in identification of individual beneficiaries. The User agrees further to submit its findings to the National Technical Information Service (NTIS, 5285 Port Royal Road, Springfield, Virginia 22161) within 30 days of receiving notice from CMS to do so.

14. The User understands and agrees that they may not reuse original or derivative data file(s) without prior written approval from the appropriate System Manager or the person designated in item 22 of this Agreement.

15. The parties mutually agree that the following specified Attachments are part of this Agreement:

___N/A_____

_____

_____

16. The User agrees that in the event CMS determines or has a reasonable belief that the User has made or may have made a use, reuse or disclosure of the aforesaid file(s) that is not authorized by this Agreement or another written authorization from the appropriate System Manager or the person designated in item 23 of this Agreement, CMS, at its sole discretion, may require the User to: (a) promptly investigate and report to CMS the User's determinations regarding any alleged or actual unauthorized use, reuse or disclosure, (b) promptly resolve any problems identified by the investigation; (c) if requested by CMS, submit a formal response to an allegation of unauthorized use, reuse or disclosure; (d) if requested by CMS, submit a corrective action plan with steps designed to prevent any future unauthorized uses, reuses or disclosures; and (e) if requested by CMS, return data files to CMS or destroy the data files it received from CMS under this agreement. The User understands that as a result of CMS's determination or reasonable belief that unauthorized uses, reuses or disclosures have taken place, CMS may refuse to release further CMS data to the User for a period of time to be determined by CMS.

17. The User hereby acknowledges that criminal penalties under §1106(a) of the Social Security Act (42 U.S.C. § 1306(a)), including a fine not exceeding $10,000 or imprisonment not exceeding 5 years, or both, may apply to disclosures of information that are covered by § 1106 and that are not authorized by regulation or by Federal law. The User further acknowledges that criminal penalties under the Privacy Act (5 U.S.C. § 552a(i) (3)) may apply if it is determined that the Requestor or Custodian, or any individual employed or affiliated therewith, knowingly and willfully obtained the file(s) under false pretenses. Any person found to have violated sec. (i)(3) of the Privacy Act shall be guilty of a misdemeanor and fined not more than $5,000. Finally, the User acknowledges that criminal penalties may be imposed under 18 U.S.C. § 641 if it is determined that the User, or any individual employed or affiliated therewith, has taken or converted to his own use data file(s), or received the file(s) knowing that they were stolen or converted. Under such circumstances, they shall be fined under Title 18 or imprisoned not more than ten years, or both; but if the value of such property does not exceed the sum of $1,000, they shall be fined under Title 18 or imprisoned not more than one year, or both.

18. By signing this Agreement, the User agrees to abide by all provisions set out in this Agreement and acknowledges having received notice of potential criminal or administrative penalties for violation of the terms of the Agreement.

19. On behalf of the User the undersigned individual hereby attests that he or she is authorized to legally bind the User to the terms this Agreement and agrees to all the terms specified herein.

_____
(Name and Title of Individual - Typed or Printed)

_____
(Company/Organization)

_____
(Street Address)

_____
(City/State/ZIP Code)

_____
(Phone No. - Including Area Code)

_____
(E-Mail Address)

_____
(Signature)

20. The Custodian, as named in paragraph 4, hereby acknowledges his/her appointment as Custodian of the aforesaid file(s) on behalf of the User, and agrees to comply with all of the provisions of this Agreement on behalf of the User.

_____
(Typed or Printed Name and Title of Custodian of File(s)

_____
(Signature) (Date)

21. The disclosure provision(s) that allows the discretionary release of CMS data for the purpose(s) stated in paragraph 6 follow(s). (To be completed by CMS staff.) _____

22. On behalf of _____ the undersigned individual hereby acknowledges that the aforesaid Federal agency sponsors or otherwise supports the User's request for and use of CMS data, agrees to support CMS in ensuring that the User maintains and uses CMS's data in accordance with the terms of this Agreement, and agrees further to make no statement to the User concerning the interpretation of the terms of this Agreement and to refer all question of such interpretation or compliance with the terms of this Agreement to the CMS official named in item number 23 (or to his or her successor).

_____ _____
(Typed or Printed Name) (Title of Federal Representative)

_____
(Signature) (Date)

_____
(Phone No. - Including Area Code)

_____
(E-Mail Address, If Applicable)

23. On behalf of CMS the undersigned individual hereby attests that he or she is authorized to enter into this Agreement and agrees to all the terms specified herein.

a. _____
(Typed or Printed Name and Title of CMS Representative)

_____
(Signature) (Date)

b. Concur/Nonconcur _____ Date: _____
(Signature of CMS System Manager or Business Owner)

c. Concur/Nonconcur _____ Date: _____
(Signature of CMS Protocol or Project Review Representative)

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0734. The time required to complete this information collection is estimated to average 30 minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have any comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, N2-14-26, Baltimore, Maryland 21244-1850 and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, D.C. 20503.

ATTACHMENT 2

Therapeutic Classes and Subclasses/Groups for Medications Frequently Used by Medicare Beneficiaries

Instructions

The table below shows the drug therapeutic classes and groups (and in a few cases subgroups) that contain the drugs most commonly needed by Medicare beneficiaries.

Instructions for drug discount offering through pharmacy network:

1) For each category shown in italics, the Applicant must provide the name of one drug and a discount (expressed as AWP minus a percentage discount) to be offered under this program through the pharmacy network to meet the qualification of a discount on at least one drug in each therapeutic class, group, or subgroup.

NOTE: A drug can be used only once to satisfy the qualification of providing a discount through your pharmacy network on a drug in a therapeutic class, group, or subgroup. Card sponsors may include as many drugs as they choose beyond the minimum. Also, offering these drugs through mail order only does not count toward meeting this qualification, and such drugs should not be listed. Discounts listed should represent all types of discounts available at the point of sale, to the extent that these are known at the time of application, including manufacturer and pharmacy price concessions.

2) Card sponsors must offer a generic drug for a negotiated price in at least 55 percent of the therapeutic categories listed in this attachment. Indicate the categories for which your card program will offer a generic drug for a negotiated price by placing a pound sign (#) next to the category. List the name of the generic drug and the discount to be made available on it as AWP minus a percentage discount. Applicants may also choose to list an example of a brand name drug in these categories, as well, along with the discount to be made available on it.

EXTENDED THERAPEUTIC CLASS DESCRIPTION BY HIERARCHICAL LEVEL

Analgesic, Anti-inflammatory or Antipyretic
Analgesic, Anti-inflammatory or Antipyretic - Non-Narcotic
NSAID's
* *Cyclooxygenase Inhibitors Non-Selective and Combinations*
Cyclooxygenase-2 (COX-2) Selective Inhibitors and Combinations
* *Salicylates and Salicylate Combinations*
* *Analgesic or Antipyretic Non-Narcotic and Combinations*
* *Disease Modifying Anti-Rheumatoid Drugs (DMARD)*
Analgesics - Narcotic
Analgesic Narcotic Agonists and Combinations
* *Analgesic Narcotic Agonists*
* *Analgesic Narcotic Agonist Combinations*
* *Analgesic Narcotic Partial/Mixed Agonists and Combinations*

Anorectal Preparations
Anorectal - Glucocorticoids
Rectal/Lower Bowel- Glucocorticoids

Anti-Infective Agents
Antibacterial Agents
Aminoglycosides
* *Antibacterial Folate Antagonists*
Antibacterial Nitrofuran Derivatives and Combinations
Antimycobacterial Agents
Antitubercular Agents
Antileprotic Agents
BetaLactam Antibiotics
* *Penicillins*
* *Cephalosporins*
* *Glycopeptide Antibiotics (Vancomycin)*
* *Lincosamides*
* *Macrolides and Combinations*
Quinolones
Fluoroquinolones and Combinations
Tetracyclines and Combinations
* *Tetracyclines*
Antifungals
* *Antifungal - Amphoteric Polyene Macrolides*
* *Antifungal - Azole Agents*
* *Antifungal Other*
Antivirals
Antiretrovirals
CMV Agents
Hepatitis Agents
Hepatitis B Treatment Agents
Hepatitis C Treatment Agents
* *Herpes Agents*

Antiparasitics

* *Antiprotozoal*

Antiprotozoal/Antibacterial Agents

* *Antiprotozoal/Antibacterial - Nitroimidazole Derivatives*

Antineoplastics

Alkylating Agents

Antimetabolites

* *Antimetabolite - Folic Acid Analogs*

Antimetabolite - Purine Analogs

Antimetabolite - Pyrimidine Analogs

Antimetabolite - Urea Derivatives

Antineoplastic - Hormone/Hormone Antagonist Agents

* *Antineoplastic - Antiandrogens*

Antineoplastic - Aromatase Inhibitors

* *Antineoplastic - Selective Estrogen Receptor Modulators (SERMs)*

* *Antineoplastic - Progestins*

Chemotherapy Rescue/Antidote Agents

Cardiovascular Therapy Agents

Angina Therapy

* *Antianginal - Coronary Vasodilators (Nitrates) and Combinations*

Antiarrhythmics

Antiarrhythmic - Class I

* *Antiarrhythmic - Class I-A*

* *Antiarrhythmic - Class I-C*

* *Antiarrhythmic - Class II*

* *Antiarrhythmic - Class III*

* *Antiarrhythmic - Class IV*

Antihyperlipidemics

Antihyperlipidemic - Bile Acid Sequestrants

* *Antihyperlipidemic - Fibric Acid Derivatives*

* *Antihyperlipidemic - HMG CoA Reductase Inhibitors*

Antihyperlipidemic - Nicotinic Acid Derivatives

Antihyperlipidemic Agents Other (including ZETIA)

Beta Adrenergic Blockers

* *Beta Blockers Cardiac Selective, All*

* *Beta Blockers Non-Cardiac Selective, All*

* *Alpha-Beta Blockers*

Calcium Channel Blockers

* *Calcium Channel Blockers - Benzothiazepines*

* *Calcium Channel Blockers - Dihydropyridines*

* *Calcium Channel Blockers - Phenylakylamines*

* *Cardiac Inotropes*

Diuretics

* *Diuretic - Loop and Combinations*

Diuretic - Potassium Sparing Diuretics and Combinations

* *Diuretic - Potassium Sparing (Single Agent), All*

* *Diuretic - Potassium Sparing in Combination*

* *Diuretic - Thiazides and Related, and Combinations*

Antihypertensive Therapy Agents

*	*ACE Inhibitors*
	Angiotensin II Receptor Blockers (ARBs)
*	*Antihypertensive Therapy Combinations*
*	*Central Alpha-2 Receptor Agonists*
*	*Peripheral Alpha-1 Receptor Blockers*
	Pulmonary Antihypertensive Agents
	Vasodilators
*	*Direct Acting Vasodilators*
	Central Nervous System Agents
	Attention Deficit-Hyperact Disorder (ADHD) Therapy
*	*Attention Deficit-Hyperactivity (ADHD) Therapy, Stimulant-Type*
	Antianxiety Agents
*	*Antianxiety Agent - Antihistamine Type*
*	*Antianxiety Agent - Non-Benzodiazepine*
	Anticonvulsant
*	*Anticonvulsant - Carboxylic Acid Derivatives*
*	*Anticonvulsant - Hydantoins*
*	*Anticonvulsant - Iminostilbene Derivatives*
	Anticonvulsant Others
	Antidepressants
*	*Antidepressant - Alpha-2 Receptor Antagonists (NaSSA)*
	Antidepressant - Monamine Oxidase (MAO) Inhibitors
*	*Antidepressant - Norepinephrine & Dopamine Reuptake Inhibitors (NDRIs)*
*	*Antidepressant - Serotonin-2 Antagonist/Reuptake Inhibitors (SARIs)*
	Antidepressant - Selective Serotonin & Norepinephrine Reuptake Inhibitors (SSRIs & SNRIs)
*	*Antidepressant - Tricyclics & Related (Non-Select Reuptake Inhibitors)*
*	*Antidepressant Combinations*
*	*Antimanic Agents*
	Antiparkinson Therapy
*	*Antiparkinson Therapy - Anticholinergic Agents*
*	*Antiparkinson Therapy - Dopaminergic*
*	*Antiparkinson's Adjuvants*
*	*Antiparkinson Combination Agents*
	Antipsychotics
*	*Antipsychotic - Dopamine Antagonists*
*	*Antipsychotic - Dopamine/Serotonin Antagonists*
*	*Antipsychotic - Atypical Agents, General*
	Migraine Therapy
	Migraine Therapy - Serotonin Agonists
	Migraine Therapy - Carboxylic Acid Derivatives
	Sedative/Hypnotics
	Chemical Dependency, Agents to Treat
	Smoking Deterrents and Combinations
	Cognitive Disorder Therapy
	Cognitive Disorder Therapy - Antidementia
	Antidementia - Cholinomimetics (ACHE Inhibitors)
	Dermatological
	Acne Therapy
*	*Acne Therapy Topical*

Dermatological - Anti-infectives
Dermatological - Antibacterials
* *Dermatological - Antifungals*
* *Dermatological - Anti-infective Combinations*
Dermatological - Antineoplastic or Premalignant Lesions
Dermatological - Antipruritics
Dermatological - Antiseborrheic Products and Combinations
* *Dermatological - Burn Products*
* *Dermatological - Emollients and Combinations*
* *Dermatological - Glucocorticoids and Combinations*
* *Dermatological - Keratolytics/Antimitotics*
Dermatological - Protectants and Combinations
Dermatological - Rosacea Therapy, Topical

Electrolyte Balance/Nutritional Products

Prenatal Vitamins and Combinations

Endocrine

Corticosteroids
* *Glucocorticoids and Combinations*

Androgen-Anabolic
* *Anabolic Steroids*

Estrogens and Combinations
* *Estrogens*
Estrogen Combinations
* *Progestins*

Diabetic Therapy
Insulin
Insulin - Human and Combinations
Oral Antidiabetic Agents
Alpha-Glucosidase Inhibitors
* *Oral Antidiabetic - Biguanides*
* *Oral Antidiabetic - Insulin-Release Stimulant Type*
Insulin Response Enhancers
Oral Antidiabetic Combinations
Hyperglycemic Agents and Combinations

Thyroid Therapy
* *Thyroid Hormones and Combinations*

Anterior Pituitary Hormones and Hormone Antagonists
* *Calcium & Bone Metabolism Regulators*

Posterior Pituitary Hormones
* *Antidiuretic and Vasopressor Hormones*

Prolactin Inhibitors

Gastrointestinal Therapy Agents

Gastrointestinal Antispasmodics
* *GI Antispasmodic - Belladonna Alkaloids*
* *GI Antispasmodic - Quaternary Ammonium Compounds*
* *GI Antispasmodic - Synthetic Tertiary Amines*
GI Antispasmodic Combinations

Peptic Ulcer Therapy
Peptic Ulcer - Antisecretory Agents

* *Peptic Ulcer - H-2 Antagonists*
* *Peptic Ulcer - Proton Pump Inhibitors*
* *Peptic Ulcer - Cytoprotectives*
Peptic Ulcer - Prostaglandin Analogues
Peptic Ulcer Therapy Combinations
Antacids and Combinations
* *Antidiarrheals*
Laxatives
* *Laxative - Saline and Osmotic*
Laxative - Surfactant
Laxative Combinations
Antiemetics
* *Antiemetic - Antihistamines and Antihistamine Combinations*
* *Antiemetic - Phenothiazines*
Antiemetic - Selective Serotonin 5-HT3 Antagonists
* *Gastrointestinal Prokinetic Agents*
* *Gallstone Solubilizing Agents and Combinations*
* *Colonic Acidifier (Ammonia Inhibitor)*
* *Inflammatory Bowel Agents*
Phosphate Binders
Digestive Aids

Genitourinary Therapy

Urinary Anti-infectives
Urinary Antibacterials
* *Urinary Antibacterial - Quinolones*
* *Urinary Antibacterial - Nitrofuran Derivatives*
Urinary Antispasmodics
Urinary Antispasmodic - Anticholinergics
* *Urinary Antispasmodic - Smooth Muscle Relaxants*
Urinary Antispasmodic Combinations
Urinary Ph Modifiers
Urinary Ph Modifier - Alkalinizers
Urinary Analgesics
Prostatic Hypertrophy Agents
Prostatic Hypertrophy Agent - 5-Alpha Reductase Inhibitors

Gout and Hyperuricemia Therapy

Gout - Acute Therapy
* *Hyperuricemia Therapy*
Gout and Hyperuricemia Combination Drugs

Hematological Agents

* *Anticoagulants*
Hematopoietic Agents
Hematopoietic Agents - Hematopoietic Growth Factors
Erythropoietins
Granulocyte Colony-Stimulating Factor (G-CSF)
Granulocyte/Macrophage Colony-Stimulating Factor (GM-CSF)
* *Hematorheologic Agents*
* *Platelet Aggregation Inhibitors & Combinations*

* ***Immunosuppressive Agents***

	Impotence Agents
	Locomotor System
	Musculoskeletal Therapy Agents
	Skeletal Muscle Relaxants
*	*Skeletal Muscle Relaxant - Central Muscle Relaxants*
*	*Skeletal Muscle Relaxant Combinations*
	Neuromuscular Therapy Agents
*	*Neuromuscular Therapy Agents - ALS Agents*
	Mouth/Throat/Dental - Preparations
	Mouth and Throat - Anti-infectives
*	*Mouth and Throat - Antifungals*
*	*Mouth and Throat - Glucocorticoids*
	Multiple Sclerosis Agents
	Ophthalmic Agents
	Ophthalmic - Anti-infectives
	Ophthalmic Antibacterial
	Ophthalmic - Fluoroquinolones
*	*Ophthalmic - Macrolides*
	Ophthalmic - Steroidal Antibiotics
	Ophthalmic Anti-infective Combinations
	Ophthalmic - Anti-inflammatory
*	*Ophthalmic - Anti-Inflammatory, Glucocorticoids*
*	*Ophthalmic - Anti-Inflammatory, NSAIDs*
	Ophthalmic - Antiallergy
	Ophthalmic - Antihistamines
	Ophthalmic - Mast Cell Stabilizers
	Ophthalmic - Intraocular Pressure Reducing Agents
	Ophthalmic - Selective Alpha Adrenergic Agonists
*	*Ophthalmic - Beta-blockers*
	Ophthalmic - Prostaglandin Analogs
*	*Ophthalmic - Miotics*
	Ophthalmic - Carbonic Anhydrase Inhibitors
	Ophthalmic - Intraocular Pressure Reducing Combinations
	Ophthalmic - Mydriatics and Cycloplegics
*	*Ophthalmic - Anticholinergics*
	Ophthalmic Combinations
*	*Ophthalmic - Anti-infective/Anti-inflammatory Combinations*
	Otic
	Otic Combinations
*	*Otic - Anti-infective/Glucocorticoid Combinations*
	Respiratory Therapy Agents
	Antihistamines
*	*Antihistamines - 1st Generation*
*	*Antihistamines - 2nd Generation*
	Asthma Therapy Agents
*	*Asthma Therapy - Anticholinergics*
*	*Asthma Therapy - Beta Adrenergic Agents*
	Asthma Therapy - Glucocorticoids
	Asthma Therapy - Leukotriene Modulators

* *Asthma Therapy - Xanthines*
Asthma Therapy Combinations
Nasal Preparations
Nasal Anti-infectives
Nasal Antiallergy
* *Nasal Anticholinergics*
* *Nasal Corticosteroids*
Vaginal Products
Vaginal Anti-infectives
Vaginal Antifungals
Vaginal Estrogens

* Generic available according to the FDA Orange Book

ATTACHMENT 3 – 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

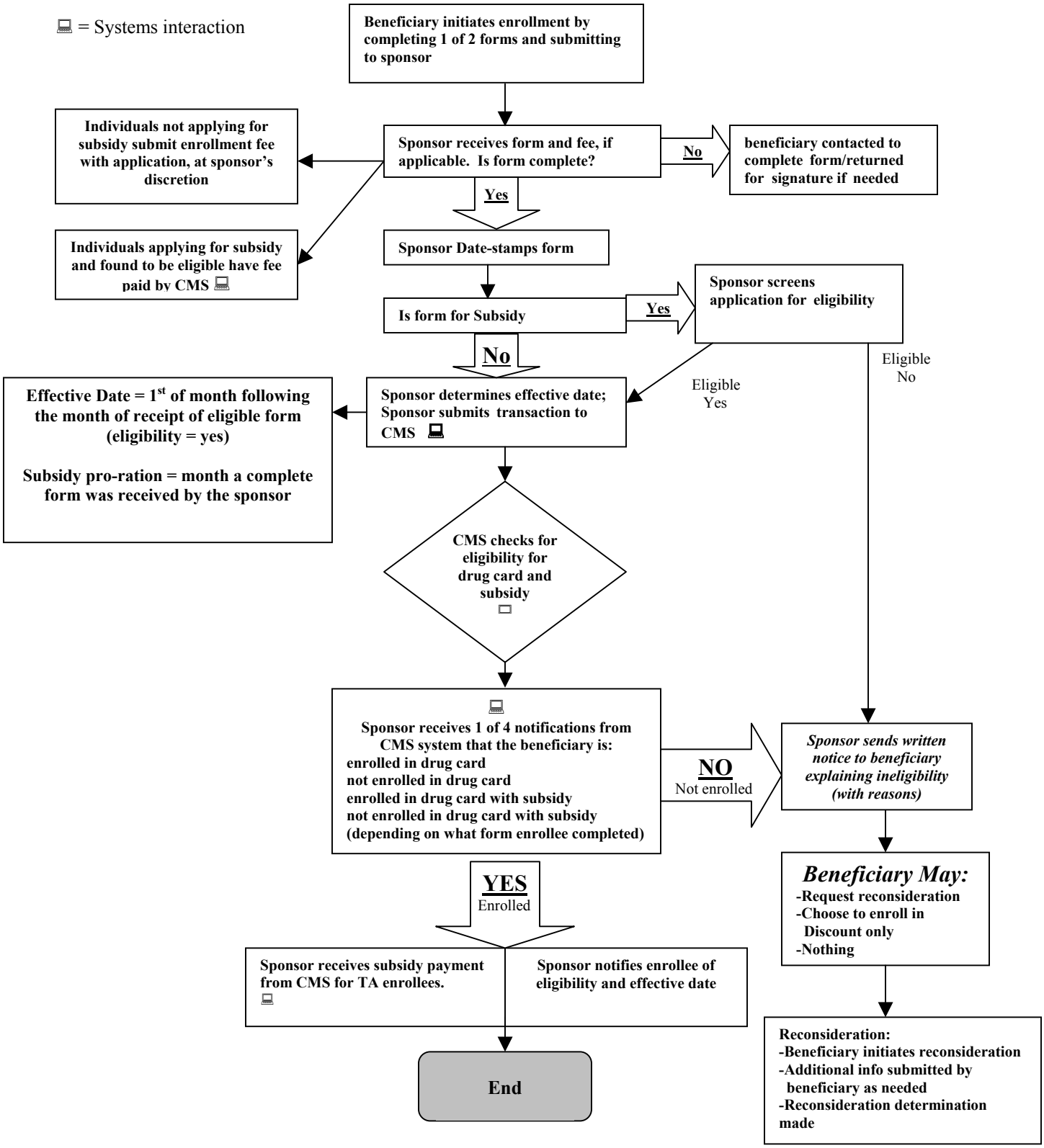
- ☐ ISOSORBIDEDN
- ☐ ISOSORBIDEMN
- ☐ K-DUR
- ☐ KLOR-CON
- ☐ LANOXIN
- ☐ LASIX
- ☐ LESCOL
- ☐ LEVAQUIN
- ☐ LEVOTHROID
- ☐ LEVOTHYROXINE
- ☐ LIPITOR
- ☐ LOPRESSOR
- ☐ LOTENSIN
- ☐ LOTREL
- ☐ MECLIZINE
- ☐ METOPROLOL
- ☐ MEVACOR
- ☐ MIACALCIN
- ☐ MINITRAN
- ☐ MONOPRIL
- ☐ MSCONTIN
- ☐ NAPROXEN
- ☐ NEORAL
- ☐ 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 4

Drug Card Enrollment Process – Flowchart



ATTACHMENT 5 – PAYMENT INFORMATION FORM

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 6 - 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).

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.

Prescription data, due monthly, include:

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

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.

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.

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.

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.

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.

Routine Reporting Requirements for Price Comparison Data

CMS will post data requirements for price comparison on www.cms.hhs.gov soon after the posting of this solicitation. Prospective Sponsors will need to submit an electronic test data file to CMS with their application. Sponsors who receive Medicare approval will need to submit their initial dataset containing real data in an electronic format with their signed contract. Sponsors will be able to submit updated data files for price comparison on a weekly basis. CMS will provide guidelines for submission of the weekly updates at a later time. Please refer to www.cms.hhs.gov for further information about pricing data due to CMS.

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.

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.

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)**