MEDICARE PRESCRIPTION DRUG BENEFIT

Solicitation for Applications for New Prescription Drug Plans (PDP) Sponsors

November 13, 2006

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1. GENERAL INFORMATION

1.1 Purpose of Solicitation

The Centers for Medicare & Medicaid Services is seeking applications from qualified entities to enter into contracts to offer Medicare Prescription Drug Plans (PDPs) as described in the Medicare Prescription Drug Benefit Final Rule published in the Federal Register on January 28, 2005 (70 Fed. Reg. 4194). Please submit your applications according to the process described in Section 2.0.
If your organization, or your parent or affiliated organization is already under a PDP contract with CMS to offer the Part D benefit, and you are expanding your service area offered under the existing contract please refer to the www.cms.hhs.gov/ website for the Part D Service Area Expansion application for instructions to complete an application for a Service Area Expansion (SAE). If your organization, or your parent or affiliated organization already has a MA-PD or Cost Plan contract with CMS to offer the Part D benefit, and you are seeking a PDP contract, you are required to complete this PDP application package.

1.2 Background

The Medicare Prescription Drug Benefit program was established by section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) and is codified in sections 1860D-1 through 1860 D-42 of the Social Security Act (the Act). Section 101 of the MMA amended Title XVIII of the Social Security Act by redesignating Part D as Part E and inserting a new Part D, which establishes the Voluntary Prescription Drug Benefit Program (hereinafter referred to as "Part D").

1.3 Objectives and Structure

The Part D benefit constitutes perhaps the most significant change to the Medicare program since its inception in 1965. The addition of outpatient drugs to the Medicare program reflects Congress' recognition of the fundamental change in recent years in how medical care is delivered in the U.S. It recognizes the vital role of prescription drugs in our health care delivery system, and the need to modernize Medicare to assure their availability to Medicare beneficiaries. Effective January 1, 2006, MMA established an optional prescription drug benefit, known as the Part D program for individuals who are entitled to Medicare Part A and/or enrolled in Part B.

In general, coverage for the prescription drug benefit is provided predominately through prescription drug plans (PDPs) that offer drug-only coverage, or through Medicare Advantage (MA) plans that offer integrated prescription drug and health care coverage (MA-PD plans). PDPs must offer a basic drug benefit and may also offer an enhanced or

alternative basic drug benefit. MA-PD sponsors must offer either a basic benefit, or broader coverage for no additional cost. If the MA-PD sponsor meets the basic requirement, then it may also offer supplemental benefits through enhanced alternative coverage for an additional premium. Medicare Cost Plans may, at their election, offer a Part D drug plan as an optional supplemental benefit, subject to the same rules that apply to an MA-PD plan. PACE organizations may elect to offer a Part D plan in a similar manner as MA-PD local sponsors in order to account for the shift in payor source from the Medicaid capitation rate to a private Part D Sponsors.

Applicants who offer either a PDP or MA-PD plan may offer national plans (with coverage in every region) or regional plans. MA-PD plan applicants may also offer local plans. CMS has identified 26 MA Regions and 34 PDP Regions; in addition, each territory is its own PDP region. Additional information about the regions can be found on the www.cms.hhs.gov/ website.

This solicitation is only for entities seeking to operate a PDP. Separate Part D solicitations are also posted on the CMS website for entities offering MA Plans with a Part D Drug benefit at the local or regional levels and for entities offering Cost Plans with a Part D benefit, for entities offering Employer Group Plans with a Part D Benefit, and for entities offering PACE Plans with a Part D benefit. Reference throughout this solicitation will be made to Part D Sponsor which is meant to encompass stand-alone PDPs; MA Plans with a Part D benefit and Cost Plans with a Part D benefit.

Part D Sponsors will have flexibility in terms of benefit design. This flexibility includes, but is not limited to, authority to establish a formulary that designates specific drugs that will be available within each therapeutic class of drugs, and the ability to have a cost-sharing structure other than the statutorily defined structure (subject to certain actuarial tests). (Sponsors are required to follow our formulary guidance. See Section 2.8.1 of this application for information regarding the submission of formulary materials). The plans also may include supplemental benefits coverage such that the total value of the coverage exceeds the value of basic prescription drug coverage.

1.4 Schedule

APPLICATION REVIEW PROCESS	
Date	**Milestone**
December 1, 2006	1. Submit Notice of Intent to Apply Form to CMS 2. Request HPMS Access (Includes User ID and Password Request) 3. Request CMS Connectivity
January 14, 2007	Final Applications posted by CMS
March 12, 2007	Applications due
March 26, 2007	Release of Health Plan Management System (HPMS) formulary submissions module.
April , 2007	Plan Creation module, Plan Benefit Package (PBP), and Bid Pricing Tool (BPT) available on HPMS

April 16,, 2007	Formulary submission due to CMS
May 2007	CMS sends Part D contract eligibility determination to Applicants, based on review of application. Applicant's bids must still be negotiated (see below)
May 18, 2007	PBP/BPT Upload Module available on HPMS
June4, 2007	All bids due
Early August 2007	CMS publishes national average Part D premium
September 2007	CMS completes review and approval of bid data. CMS executes Part D contracts to those organizations who submit an acceptable bid
November 15, 2007	2008 Annual Coordinated Election Period begins

NOTE: This timeline does not represent an all-inclusive list of key dates related to the Medicare Prescription Drug Benefit program. CMS reserves the right to amend or cancel this solicitation at any time. CMS also reserves the right to revise the Medicare Prescription Drug Benefit program implementation schedule, including the solicitation and bidding process timelines.

1.5 Summary of Part D Sponsor Role and Responsibilities

Key aspects of each Part D Sponsor shall include the ability to:

- Submit a formulary each year for CMS approval.
- Submit a Part D Sponsor plan bid each year for CMS approval.
- Enroll all eligible Medicare beneficiaries who apply and reside within the Part D Sponsor's approved service area. A sponsor must serve at least one entire region.
- Administer a Part D benefit plan which includes providing coverage for drugs included in a CMS-approved formulary, administering appropriate deductibles and co-payments, managing the benefit using appropriate pharmacy benefit managerial tools, and operating effective oversight of that benefit.
- Provide access to negotiated prices on covered Part D drugs, with different strengths and doses available for those drugs, including a broad selection of generic drugs.
- Ensure that records are maintained in accordance with CMS rules and regulations and that both records and facilities are available for CMS inspection and audit.
- Disclose the information necessary for CMS to oversee the program and ensure appropriate payments.
- Offer a contracted retail pharmacy network, providing convenient access to retail pharmacies.
- Process claims at the point of sale.

- Operate quality assurance, drug utilization review, and medication therapy management programs.

- Administer coverage determinations, grievances, exceptions, and an appeals process consistent with CMS requirements.

- Provide customer service to beneficiaries, including enrollment assistance, toll-free telephone customer service help, and education about the Part D benefit.

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

- Develop marketing materials and conduct outreach activities consistent with CMS standards.

- Develop and/or maintain systems to support enrollment, provide claims-based data to CMS, accept CMS payment (including subsidies for low-income beneficiaries), track true out-of-pocket costs, coordinate benefits with secondary insurers (or primary insurers when Medicare is secondary) and support e-prescribing.

- Provide necessary data to CMS to support payment, oversight, and quality improvement activities and otherwise cooperate with CMS oversight responsibilities.

1.6 Summary of CMS Role and Responsibilities

Application Approval, Part D Bid Review, and Contracting Processes
There are three distinct phases to the overall review to determine whether CMS will enter into a contract with an Applicant. The first phase is the application review process. CMS will review all applications submitted on or by March 12, 2007 to determine whether the Applicant meets the qualifications we have established to enter into a Part D contract.

The second phase has two steps – the formulary upload which begins March 26, 2007 and the bid upload which begins May 18, 2007. The formulary review entails determining that the proposed formulary (if one is used) has at least two drugs in every therapeutic category and class (unless special circumstances exist that would allow only one drug); does not substantially discourage enrollment by certain types of Part D eligible individuals; includes adequate coverage of the types of drugs most commonly needed by Part D enrollees; and includes an appropriate transition policy. CMS will contact Applicants if any issues are identified during the review for discussion and resolution. The intent is to provide an opportunity for Applicants to make any necessary corrections prior to the Part D bid submission date which is on the first Monday in June each year. . The second step involves the bid review and negotiations with applicants to assure valuations of the proposed benefits are reasonable and actuarially equivalent.

The third phase involves contracting. Applicants judged qualified to enter into a Part D contract as a result of successfully completing phase one and two will be offered a Part D contract by CMS.

Part D Program Oversight

CMS has developed a Medicare Prescription Drug Benefit program monitoring system to ensure that the Part D sponsors deliver good value through defined benefits and are compliant with program requirements. We focus on several operational areas critical to the value of the benefit, including beneficiary access to and satisfaction with their Part D benefit and protection of the financial integrity of the program. Specific areas include pharmacy access, adequacy and value of the benefit, benefit management, enrollment and disenrollment, marketing, program safeguard activities, customer service, confidentiality and security of enrollee information, and effectiveness of tracking true out-of-pocket costs. The types of reporting that CMS requires of Part D sponsors is presented in the application. For additional information on reporting requirements, refer to the www.cms.hhs.gov/ website. (*NOTE: Part D sponsors, as covered entities under the Health Insurance Portability and Accountability Act of 1996, are subject to investigation and penalties for findings of HIPAA violations as determined by the Department of Health and Human Services Office for Civil Rights and the Department of Justice.)*

We monitor compliance, through the analysis of data we collect from Part D sponsors, CMS contractors, and our own systems. The types of data we collect from sponsors include: certain benefit data, prescription drug event (PDE) claims data, cost data, benefit management data, marketing review information, customer satisfaction and complaints data, and information used to determine low-income subsidy (LIS) match rates. To monitor plan performance we : 1) conduct beneficiary satisfaction surveys and operate a complaints tracking system to monitor and manage complaints brought to our attention that are not satisfactorily resolved through PDP sponsors' grievance processes; and 2) conduct periodic site visits to verify PDP sponsor compliance with Part D program requirements. We use information from all the specified sources to analyze the appropriateness and value of the benefit delivered, and to evaluate the opportunity for additional value and quality improvement.

If any trends we identify indicate contract violations, significant departures from the marketed Part D offering, or fraud or other violations of State or Federal laws, appropriate action is taken consistent with 42 CFR 423.509 and Part 423, Subpart O. We also make referrals if appropriate to the Services Office of the Inspector General, or to Federal and State authorities where violations of laws under the jurisdictions of these agencies are in question.

Education and Outreach

CMS is committed to educating Medicare beneficiaries about the Part D program. CMS plans to continue to educate beneficiary and consumer groups, health care providers,

States, and other interested groups about the Part D program. Among the topics discussed with these groups is the identification and reporting of possible fraud and/or abuse. CMS also engages in other activities that publicize or otherwise educate beneficiaries about the program. For example, the Medicare Prescription Drug Plan Finder assists beneficiaries in finding a plan to meet their specific needs; refer to the www.medicare.gov/MPDPF website.

Marketing Guidelines and Review

Marketing Guidelines are posted on the www.cms.hhs.gov/ website. Part D sponsors are required to adhere to these guidelines in developing their marketing materials and marketing strategy. Part D sponsors are required to submit materials to CMS based on the marketing guidelines.

Eligibility for the Low Income Subsidy Program

Low-income Medicare beneficiaries receive full or partial subsidies of premiums and reductions in cost sharing under the Part D benefit. Certain groups of Medicare beneficiaries are automatically eligible for the low-income subsidy program. These beneficiaries include Medicare beneficiaries who are full-benefit dual eligible individuals (eligible for full benefits under Medicaid), Medicare beneficiaries who are recipients of Supplemental Security Income benefits; and participants in Medicare Savings Programs as Qualified Medicare Beneficiaries (QMBs), Specific Low-Income Medicare Beneficiaries (SLMBs), and Qualifying Individuals (QIs). Beneficiaries who are low-income and who do not fall into one of the automatic subsidy eligibility groups apply for a low-income subsidy and have their eligibility determined by either the state in which they reside or the Social Security Administration (SSA). CMS has developed a database to track individuals who are automatically deemed subsidy-eligible or who are determined subsidy-eligible by states or SSA, and communicates the names and eligibility category of those individuals to Part D sponsors as part of the enrollment files from the enrollment processing system described below. For additional information regarding the low income subsidy program, refer to the www.cms.hhs.gov/ website.

General Enrollment Processing

CMS has developed a system to review an individual's eligibility for the Part D benefit. For individuals applying for enrollment in a Part D plan, CMS reviews an individual's status as a Medicare beneficiary. CMS tracks enrollments and ensures that the beneficiary does not enroll in more than one plan. Also, CMS tracks low-income subsidy status and auto-enrollments of full-benefit dual eligible individuals into Part D plans and facilitated enrollments for other low-income Medicare beneficiaries. Finally, CMS tracks dis-enrollments from Part D plans and will deny new enrollments during any given year unless the enrollment occurs during an allowable enrollment period. For additional information regarding enrollment processing, refer to the www.cms.hhs.gov/ website.

Payment to Part D Sponsors

CMS provides payment to Part D sponsors in the form of advance monthly payments (consisting of the Part D Sponsor plan's standardized bid, risk adjusted for health status, minus the beneficiary monthly premium), estimated reinsurance subsidies, and estimated low-income subsidies. After the end of the payment year, CMS reconciles the correct amounts of low-income subsidies and reinsurance amounts against the amount paid as a part of the prospective monthly payments. Risk sharing amounts (if applicable) are determined after all other reconciliations have been completed. For a more complete description refer to *Prescription Drug Event Data* that is posted on the www.cms.hhs.gov website.

2. INSTRUCTIONS

2.1 Overview

There are six types of entities with which CMS contracts to offer the Medicare prescription drug benefit: PDP sponsors, Medicare Advantage organizations that offer MA-PDs (including local HMO plans, local, PPOs, regional PPOs, and Private Fee-for-Service plans); organizations with Cost Plans under section 1876 of the Social Security Act, Employer Groups, and PACE organizations. This application is to be completed only by non-employer entities seeking to offer new PDPs during 2008.

2.2 Other Technical Support

CMS conducts technical support calls, also known as User Group calls, for Applicants and existing Part D sponsors. CMS operational experts (e.g., from areas such as enrollment, information systems, marketing, bidding, formulary design, and coordination of benefits) are available to discuss and answer questions regarding the agenda items for each meeting. Registration for the technical support calls and to join the list serve to get updates on CMS guidance can be found at www.aspenxnet.com/partd.

CMS also conducts special training sessions, including user groups call, for sponsors that are new to the Part D program.

2.3 Health Plan Management System (HPMS) Data Entry

Part D organizations that submit a Notice of Intent to Apply form are assigned a pending contract number (S number) to use throughout the application and subsequent operational processes. Once the contract number is assigned, Part D Applicants receive their CMS User ID(s) and password(s) for HPMS access and need to input contact and other related information into the HPMS (see section 3.1.6). Applicants are required to provide prompt entry and ongoing maintenance of data in HPMS. By keeping the information in HPMS current, the Applicant facilitates the tracking of their application throughout the review process and ensures that CMS has the most current information for application updates, guidance and other types of correspondence.

In the event that an Applicant is awarded a contract, this information will also be used for frequent communications during implementation. Therefore, it is important that this information be accurate at all times.

2.4 Instructions and Format of Qualifications

Applications may be submitted until March 12, 2007. Applicants must use the 2008 solicitation. CMS will not accept or review in anyway those submissions using the prior versions of the solicitation (e.g. 2007 and earlier).

Instructions

Applicants will complete most of this solicitation via HPMS. Throughout the solicitation reference is made to submitting further documentation to CMS. In such instances, Applicants must include the contract ID number in the heading on each page of any attachments to be submitted to CMS.

In preparing your application in response to the prompts in Section 3.0 of this solicitation, please mark "Yes" or "No" or "Not Applicable" in sections organized with that format within HPMS.

In many instances Applicants are directed to affirm within HPMS that they will meet particular requirements by indicating "Yes" next to a statement of a particular Part D program requirement. By providing such attestation, an Applicant is committing its organization to complying with the relevant requirements as of the date your contract is signed, unless an alternative date is noted in Section 3.0.

Information that is required to be entered into HPMS will not be accepted in hard copy. If HPMS entry is required and an Applicant submits the information via hard copy, the application will be considered incomplete.

Additional supporting documentation is notated in the following manner throughout the application and is to be submitted as follows:

1. Appendices: documents supplied by CMS that are contained at the end of this application. They are to be completed by the Applicant and returned to CMS as indicated.

2. Attachments: documents that are to be created and/or supplied by the Applicant and sent to CMS with the application. Attachments are to be used only when the application does not indicate to respond directly within HPMS. (i.e., Subcontracts, Letters of Agreement, etc.)

Legal documents such as subcontracts should be provided in hard copy as an attachment to the application. In addition, all subcontracts and other legal documents should be provided on the CD copies of the application. The CD identification should include the appendix number.

CMS will check the application for completeness shortly after its receipt. A complete application consists of properly completing the appropriate sections within HPMS and CMS receipt of all appropriate attachments. We will notify Applicants of any deficiencies and afford them the opportunity to amend their applications.

CMS has established that all aspects of the program that the Applicant attests to must be ready for operation by the contract signature date. As with all aspects of a Part D sponsor's operations under its contract with CMS, we may verify a sponsor's compliance with qualifications it attests it will meet, through on-site visits at the Part D sponsor's

facilities as well as through other program monitoring techniques. Failure to meet the requirements attested to in this solicitation and failure to operate its Part D plan(s) consistent with the requirements of the applicable statutes, regulations, call letter, and the Part D contract may delay a Part D sponsor's marketing and enrollment activities or, if corrections cannot be made in a timely manner, the Part D sponsor will be disqualified from participation in the Part D program.

An individual with legal authority to bind the Applicant shall sign and submit the certification found in Section 4.0. CMS reserves the right to request clarifications or corrections to a submitted application. Failure to provide requested clarifications within a 2-day period could result in the applicant receiving a notice of intent to deny the application, in which case, the Applicant will then have 10 days to seek to remedy its application.

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

Format

- To assure that each CMS review panelist receives the application in the manner intended by the applicant, Applicants should deliver a total of two (2) hard copies of the supporting documentation (i.e. attachments and appendices).

- Applicant must include a cover letter with the supporting documentation that includes the following elements:

    - Organization Name
    - Parent organization if any
    - Organization Address
    - Organization Phone Number
    - Contract ID Number (or #s if applicable)
    - Contact Person
    - Contact Person Phone Number
    - Contact Person Email Address

- All attachments (such as existing contracts) can be submitted in Microsoft Word (in a version that is compatible with Windows 2003) or as a PDF file.

- Both hard copies should be in separate 3-ring binders. Tab indexing should be used to identify all of the major sections of the application. Page size should be 8 ½ by 11 inches and the pages should be numbered. Font size should be 12 point.

- One set of supporting documentation should be clearly marked, "Original" and contain all original signed certifications requested in the application.

- Additionally, the Applicant must submit the cover letter, appendices, attachments and all supporting documentation electronically on 4 duplicate CDs. This will support the review of the application by different CMS components.

- Each CD must be clearly labeled with the information in the table below:

Applicant's Organization Name
CMS Identification Number (Contract ID #s)
CD Number (Copy 1, Copy 2, Copy 3, Copy 4) **Note: If multiple CDs are required to include appendices, attachments and other supporting documentation, label the CDs as follows:** **Copy 1 (1 of 2), Copy 1 (2 of 2); Copy 2 (1 of 2), Copy 2 (2 of 2), etc.**

Failure to submit application supporting documentation consistent with these instructions may delay its review by CMS and could result in the sponsor receiving a notice of intent to deny.

- Application Supporting Documentation must be sent to:

Centers for Medicare & Medicaid Services (CMS)
Mail Stop: C1-26-12
Attn: Part D Application Supporting Documentation
7500 Security Boulevard
Baltimore, Maryland 21244-1850

- **In order for CMS to receive your application supporting documentation in a timely manner, please note that Federal Express and the US Postal Service possess a CMS Security Clearance. Application supporting documentation mailed through carriers that do not have CMS Security Clearance could be delayed due to clearance processing.**

- CMS will not review application supporting documentation received after 5:00 P.M. EST on March 12, 2007. CMS will lock access to application fields within HPMS as of 5:00 P.M. EST on March 12, 2007. CMS will not review any submissions based on earlier versions of the solicitation. Applicants must complete the 2008 solicitation in order to be considered for Part D sponsorship.

Single Application Representing Multiple Part D Contract Types
Separate entries **MUST** be submitted through HPMS for each pending contract number/application. However, Part D plans of the same type, offered by the same legal entity, regardless of their service areas may be represented in a single submission of supporting attachments. The Applicant must complete the table in 3.1.1 indicating that

multiple contracts are represented in the application's supporting attachment documentation.

If a subsidiary, parent, or otherwise related organization is also applying to offer Part D benefits, these entities **MUST** submit separate applications. There are four types of Part D solicitations for which applications are due on March 12, 2007; they are PDP, MA-PD, Cost Plan solicitations, and the Service Area Expansion Application. Organizations that intend to offer a combination of these types of Part D contracts must submit a separate application for each type. (Employer and PACE sponsors will also have separate solicitations.) **For example, a MA-PD and PDP product may not be represented in the same application.** Entities intending to have both local MA-PD and Regional PPO contracts must submit separate MA-PD applications.

Applicant Entity Same as Contracting Entity
The legal entity that submits this application must be the same entity with which CMS enters into a Part D contract, or in the case of an MA-PD and Cost Plan sponsor, the same legal entity seeking an addendum to an MA or Cost Plan contract. An entity that qualifies for a Part D contract, or for an addendum to an MA or Cost Plan contract, may offer multiple contracts or plans of the same type (e.g. PDP, MA-PD, or Cost Plan) in the service area described in the application.

Joint Enterprise as Applicant and Contracting Entity
CMS will recognize as Applicants those joint enterprises formed by agreement among multiple state-licensed organizations (or organizations that have applied to CMS for a licensure waiver) for the purpose of administering a Medicare Prescription Drug Plan in at least one entire PDP region. Each member of the joint enterprise will be contractually liable to CMS for the administration of the Part D benefit in the State(s) in which it is licensed or for which it has received a CMS licensure waiver.

The joint enterprise need submit only one application on behalf of the enterprise's member organizations and such application shall represent a uniform benefit. However, the information requested in Section 3.1 of this solicitation must be provided for each member of the joint enterprise with separate accompanying Appendices as necessary. For example, each joint enterprise member must provide identifying information about its organization, copies of its executed contracts with entities performing critical tasks related to the delivery of the Part D benefit, and information related to its business integrity. The responses provided in the remainder of the application may be made once by the joint enterprise applicant and will be considered binding on each member of the joint enterprise. Also, a separate certification statement, shown in Section 4.0, must be provided for each joint enterprise member organization. Each certification statement must be signed by an individual specifically granted the authority to bind the member organization.

Joint enterprise applicants are required to submit to CMS for approval a copy of the executed agreement among the joint enterprise member organizations. Please see Section 3.1.2.I, for instructions concerning this requirement.

Upon CMS' determination that the members of the joint enterprise are qualified to enter into a Part D contract and approval of the bid(s) submitted by the joint enterprise, CMS will enter into a multiple-party contract signed by authorized representatives of CMS and each member of the joint enterprise.

Automatic Enrollment of Full-benefit Dual Eligible Individuals

As provided for in section 423.34(d) of the regulations, individuals who are dually eligible for Medicare and full Medicaid benefits, and who fail to enroll in a Part D plan, will be enrolled automatically in a plan with a beneficiary premium that does not exceed the low-income premium subsidy amount. If there is more than one PDP with a premium that meets this description, CMS will enroll the beneficiaries in those PDPs, on a random basis.

For this purpose, CMS will count the Applicant and its parent and affiliates as a single PDP, regardless of how many of those entities have bids that are at or below the low income subsidy threshold.

Applicants eligible to receive auto-enrolled and reassigned beneficiaries as a result of the price of their approved bid(s) may expect a readiness audit from CMS. These audits are conducted to verify that all systems and processes are in place to ensure the Applicant is prepared to receive enrollments. In those instances where an Applicant fails to pass the readiness audit, CMS will not allow auto-enrollments or reassignments to occur until such time as CMS is satisfied that all systems and processes are properly in place.

Technical Assistance
For technical assistance in the completion of this Application, contact:
Marla Rothouse by email at marla.rothouse@cms.hhs.gov or by phone at 410-786-8063 or Linda Gousis by email at linda.gousis@cms.hhs.gov or by phone at 410-786-8616.

2.5 Submission Software Training

Applicants use the CMS Health Plan Management System (HPMS) during the application, formulary, and bid processes. Applicants are required to enter contact and other information collected in HPMS in order to facilitate the application review process.

Applicants are required to upload their plan formularies to HPMS using a pre-defined file format and record layout. The formulary upload functionality will be available on March

26, 2007. The deadline for formulary submission to CMS is by close of business on April 16, 2007.

In order to prepare plan bids, Applicants will use HPMS to define their plan structures and associated plan service areas and then download the Plan Benefit Package (PBP) and Bid Pricing Tool (BPT) software. For each plan being offered, Applicants will use the PBP software to describe the detailed structure of their Part D benefit and the BPT software to define their bid pricing information. The formulary must accurately crosswalk to the PBP.

Once the PBP and BPT software has been completed for each plan being offered, Applicants will upload their bids to HPMS. Applicants will be able to submit bid uploads to HPMS on their PBP or BPT one or more times between May 18, 2007 and the CY 2008 bid deadline of June 4, 2007. CMS will use the last successful upload received for a plan as the official bid submission.

CMS will provide technical instructions and guidance upon release of the HPMS formulary and bid functionality as well as the PBP and BPT software. In addition, systems training will be available at the Bid Training in April 2007.

2.6 System and Data Testing with CMS

HPMS

Part D sponsor organizations will use HPMS to communicate with CMS in support of the application process, formulary submission process, bid submission process, ongoing operations of the Part D program, and reporting and oversight activities. Part D applicants are required to secure access to HPMS in order to carry out these functions.

Enrollment and Payment

All Part D sponsors must submit information about their membership to CMS electronically and have the capability to download files or receive electronic information directly. Prior to the approval of your contract, Part D sponsors must contact the MMA Helpdesk at 1-800-927-4736 for specific guidance on establishing connectivity and the electronic submission of files. The MMA Helpdesk is the primary contact for all issues related to the physical submission of transaction files to CMS. Part D sponsors that enter into a contract with CMS must also submit the *Banking Information Form* (Appendix I) so that payments can be transmitted to your account.

Each month, CMS provides reports to each Part D sponsor for each of their plans with member and plan-level information by CMS. Part D sponsors must compare the membership and payment information in those reports on a monthly basis with their records and report any discrepancies to the Division of Payment Operations within thirty days. An analyst or group of analysts in that office is responsible for your geographic area and help sponsors resolve enrollment and payment issues. The Division of Payment Operations also approves any retroactive actions that your plans may need to submit to

correct member records. Contact Angela Wright at (410) 786-1125 for the name of the analyst for your geographic area. Definitive information about the format and submission of files can also be found in the Plan Communications User's Guide produced by the Division of Payment Operations (available at www.cms.hhs.gov/MedicareMangCareSys/). The MMA Helpdesk also provides additional information at that site regarding frequent questions and answers from PDP sponsors.

Payment – Part D Sponsors
Payments will be wired to sponsor accounts on the first business day of each month (or the last business day of the prior month if the first day of the month is not a business day). The monthly payment includes premiums that SSA or other agencies are deducting from beneficiary Social Security payments or other payments as well as those premiums CMS is paying on behalf of low-income individuals. Estimated monthly reinsurance subsidies, and low-income subsidies are also included.

2.7 Summary Instruction and Format for Bids

Each Part D Applicant must submit to CMS a bid for each prescription drug plan it intends to offer. Applicants using this solicitation may apply to offer full or limited risk plans. CMS reviews bids for limited risk plans only in those regions where there are not at least two prescription drug plans, one of them being a PDP plan. Note, that only PDP sponsor Applicants and not MA organizations may submit a bid to be limited risk. Furthermore, in the event a PDP region does not have two prescription drug plans, CMS will approve at a maximum two partial risk plans. (Please note that Applicants that indicate in their applications that they intend to offer limited risk plans are not precluded from later submitting full risk bids, but a PDP sponsor Applicant that does submit a limited risk bid must apply the same limitation of risk to all PDPs offered by the sponsor in the PDP region). Where there are not at least two plans offering qualified prescription drug coverage, one of them being a PDP plan, CMS will contract with entities to offer fallback plans. Applicants must submit their formularies to HPMS on or before April 16, 2007 and the PBPs and BPTs on or before the bid submission date.

2.7.1 Format of Bids

Bid-Related Sections Due Prior to Bid Submission Date
To facilitate the timely review of all the bid submissions, CMS requires Applicants to submit the portion of their bid related to formulary and covered drugs from March 26-April 16, 2007 CMS reviews areas of each proposed drug plan formulary by tier and drug availability and evaluates each element against evidence-based standards such as widely accepted treatment guidelines. Elements include, but may not be limited to the list of drugs, the categories and classes, tier structures (not cost sharing), and utilization management tools such as quantity limits, step therapy, and prior authorization. CMS makes the review criteria available to Applicants well in advance of the date Applicants must submit this information to CMS. Outliers are selected for

further evaluation during the formulary review process prior to CMS approval of the bid. CMS makes reasonable efforts to inform Applicants of their outliers so that they may substantiate their offering. If such substantiation is not satisfactory to CMS, the Applicant is given the opportunity to modify the formulary. CMS intends to complete as much of this work as possible before the, PBP and BPT submissions so that any modification may be reflected in those documents.

Bid Submissions

The Applicant's bid represents the expected monthly cost to be incurred by the Applicant for qualified prescription drug coverage in the approved service area for a Part D-eligible beneficiary on a standardized basis. The costs represented in each bid should be those for which the Applicant would be responsible. These costs would not include payments made by the plan enrollee for deductible, coinsurance, co-payments, or payments for the difference between the plan's allowance and an out-of-network pharmacy's usual and customary charge. The bid requires the separate identification, calculation, and reporting of costs assumed to be reimbursed by CMS through reinsurance. CMS requires that the bid represent a uniform benefit package based upon a uniform level of premium and cost sharing among all beneficiaries enrolled in the plan. The benefit packages submitted must be cross walked appropriately from the formulary. Pursuant to 423.505(k)(4), the CEO, CFO, or a delegee with the authority to sign on behalf of one of these officers, and who reports directly to such officer, must certify (based on best knowledge, information and belief) that the information in the bid submission, and assumptions related to projected reinsurance and low-income cost sharing subsidies, is accurate, complete, and truthful, and fully conforms to the requirements in section 423.265 of the regulations. In addition, the pricing component of the bid must also be certified by a qualified actuary.

In order to encourage successful bid submissions, CMS limits multiple bids to ensure that each bid submitted represents a meaningful variation based on plan characteristics that will provide beneficiaries with substantially different options. In general, CMS expects that more than two bids from a sponsoring organization would not provide meaningful variation, unless one of the bids is an enhanced alternative plan that provides coverage in the coverage gap. CMS reviews multiple bids received from a Part D Applicant as a whole and applies a reasonableness test to determine examples of a strong likelihood of incompetence and/or 'gaming', including, but not limited to: a) multiple bid submissions that would fail a reasonableness test; b) multiple bid submissions based on different formulary drug lists; c) multiple bid submissions based on different levels of utilization management control; and d) multiple bid submissions that reflect a significant unexplained variation in costs between the plans, particularly between plans offered to the group versus the individual market.

2.7.2 CMS Review of Bids

CMS evaluates the bids based on four broad areas: 1) administrative costs, 2) aggregate costs, 3) benefit structure, and 4) plan management. CMS evaluates the administrative costs for reasonableness in comparison to other bidders. CMS also examines aggregate costs to determine whether the revenue requirements for qualified prescription drug coverage are reasonable and equitable. In addition, CMS reviews the steps the Part D sponsor is taking to control costs, such as through various programs that encourage use of generic drugs. Finally, CMS examines indicators concerning plan management, such as customer service.

CMS is also required to make certain that bids and plan designs meet statutory and regulatory requirements. We conduct actuarial analysis to determine whether the proposed benefit meets the standard of providing qualified prescription drug coverage. Also, CMS reviews the structure of the premiums, deductibles, co-payments, and coinsurance charged to beneficiaries and other features of the benefit plan design to ensure that it is not discriminatory (that is, that it does not substantially discourage enrollment by certain Part D eligible individuals).

2.7.3 Overview of Bid Negotiation

CMS evaluates the reasonableness of bids submitted by Part D sponsors by means of an actuarial valuation analysis. This requires evaluating assumptions regarding the expected distribution of costs, including average utilization and cost by drug coverage tier. CMS could test these assumptions for reasonableness through actuarial analysis and comparison to industry standards and other comparable bids. Bid negotiation could take the form of negotiating changes upward or downward in the utilization and cost per script assumptions underlying the bid's actuarial basis. We could exercise our authority to deny a bid if we do not believe that the bid and its underlying drug prices reflect market rates.

2.8 Pharmacy Access

An integral component of this Solicitation concerns the pharmacy access standards established under section 1860D-4(b)(1)(C) of the Social Security Act. The standards require in part that each Part D sponsor must secure the participation in their pharmacy networks of a sufficient number of pharmacies to dispense drugs directly to patients (other than by mail order) to ensure convenient access to covered Part D drugs by Part D plan enrollees. To implement this requirement, specific access rules consistent with the TRICARE standards were developed and are delineated in 42 CFR §423.120. Furthermore, 42 CFR §423.120 mandates that the Part D sponsors must provide adequate access to home infusion and convenient access to long-term care, and Indian Health Service, Indian Tribe and Tribal Organization, and Urban Indian Organization (I/T/U)

pharmacies in accordance with 42 CFR § 423.120 and related CMS instructions and guidance.

2.8.1 Retail Pharmacy Access

Applicants must ensure that their retail pharmacy network meets the criteria established under 42 CFR §423.120. Applicants must ensure the pharmacy network has a sufficient number of pharmacies that dispense drugs directly to patients (other than by mail order) to ensure convenient access to Part D drugs. CMS rules require Applicants establish retail pharmacy networks in which:

- In urban areas, at least 90 percent of Medicare beneficiaries in the Applicant's service area, on average, live within 2 miles of a retail pharmacy participating in the Applicant's network;
- In suburban areas, at least 90 percent of Medicare beneficiaries in the Applicant's service area, on average, live within 5 miles of a retail pharmacy participating in the Applicant's network; and
- In rural areas, at least 70 percent of Medicare beneficiaries in the Applicant's service area, on average, live within 15 miles of a retail pharmacy participating in the Applicant's network.
- Applicants may count I/T/U pharmacies and pharmacies operated by Federally Qualified Health Centers and Rural Health Centers towards the standards of convenient access to retail pharmacy networks.

Section 3.4 of this Solicitation includes a reference to Appendix XIII that provides Applicants with detailed instructions to complete the retail pharmacy network access portion of this submission. For purposes of meeting the 2008 Pharmacy Access requirements, Applicants may use their contracted PBM's existing 2007 Part D network to demonstrate compliance. If an Applicant is creating a new Part D network, the submission must be based on executed contracts for Year 2008. While Applicants are required to demonstrate that they meet the Part D pharmacy access requirements at the time this solicitation is submitted to CMS, CMS expects that pharmacy network contracting will be ongoing in order to maintain access to Part D drugs. See Appendix XIII for detailed instructions for the retail pharmacy network analysis.

2.8.2 Home Infusion Pharmacy Access

Applicants must demonstrate that their contracted pharmacy network provides adequate access to home infusion pharmacies. In order to demonstrate adequate access to home infusion pharmacies, Applicants must provide a list of all contracted home infusion pharmacies (see section 3.4.4). CMS uses this pharmacy listing to develop a ratio for the number of contracted home infusion pharmacies in each State/Territory in the proposed service area compared to the number of Medicare beneficiaries in each State/Territory in the proposed service area and identify outliers amongst all Applicants.

2.8.3 Long-Term Care Pharmacy Access

Applicants must demonstrate that their contracted pharmacy network provides convenient access to long-term care pharmacies. In order to demonstrate convenient access to long-term care pharmacies, Applicants must provide a list of all contracted long-term care pharmacies (see section 3.4.5). CMS uses this pharmacy listing to develop a ratio for the number of contracted long-term care pharmacies in each State/Territory in the proposed service area compared to the number of nursing home beds in each State/Territory in the proposed service area and identify outliers amongst all Applicants.

2.8.4 Waivers Related to Pharmacy Access

Waivers for Plans in the Territories. To ensure access to coverage in the territories, §1860D-42(a) of the MMA grants CMS the authority to waive the necessary requirements to secure access to qualified prescription drug coverage for Part D eligible individuals residing in the territories. The regulations for the MMA under §423.859(c) allow access to coverage in the territories to be waived or modified either through an Applicant's request or at CMS' own determination. Under that authority, CMS will consider waiving the convenient access requirements for a plan's Part D contracted retail pharmacy network, found in §423.120(a)(1) of the Part D Final Regulation for the territories, if an Applicant requests such a waiver, and demonstrates that it has made a good faith effort to meet the requirements described in Section 3.4.1F of this solicitation.

2.9 Standard Contract with PDP Sponsors

Successful Applicants will be deemed qualified to enter into a Part D contract with CMS to operate one or more Medicare prescription drug plans after CMS has reviewed the Applicant's entire submission. It is only after the qualified Applicant and CMS have reached agreement on the Applicant's bid submissions will the Applicant be asked to execute its Part D contract.

2.10 Protection of Confidential Information

Applicants may seek to protect their information from disclosure under the Freedom of Information Act (FOIA) by claiming that FOIA Exemption 4 applies. The Applicant is required to label the information in question "confidential" or "proprietary", and explain the applicability of the FOIA exemption it is claiming. When there is a request for information that is designated by the Applicant as confidential or that could reasonably be considered exempt under Exemption 4, CMS is required by its FOIA regulation at 45 CFR §5.65(d) and by Executive Order 12,600 to give the submitter notice before the information is disclosed. To decide whether the Applicant's information is protected by Exemption 4, CMS must determine whether the Applicant has shown that— (1) disclosure of the information is likely to impair the government's ability to obtain necessary information in the future; (2) disclosure of the information is likely to cause substantial harm to the competitive position of the submitter; or (3) the records are considered valuable commodities in the marketplace which, once released through the FOIA, would result in a substantial loss of their market value. Consistent with our

approach under the Medicare Advantage program, we would not release information under the Medicare Part D program that would be considered proprietary in nature.

3. APPLICATION

Note: Nothing in this application is intended to supersede the regulations at 42 CFR Part 423. Failure to reference a regulatory requirement in this application does not affect the applicability of such requirement, and PDP sponsors and/or Applicants are required to comply with all applicable requirements of the regulations in Part 423 of 42 CFR.

For most of the Part D program requirements described in this solicitation, CMS has issued operational policy guidance that provides more detailed instructions to Part D sponsors. Organizations submitting an application in response to this solicitation acknowledge that in making the attestations stated below, they are also representing to CMS that they have reviewed the associated guidance materials posted on the CMS web site and will comply with such guidance should they be approved for a Part D contract. Applicants must visit the CMS web site periodically to stay informed about new or revised guidance documents.

3.1 Applicant Experience, Contracts, Licensure and Financial Stability

SPECIAL INSTRUCTIONS FOR JOINT ENTERPRISE APPLICANTS: If an application is being submitted by a joint enterprise, as described above in Section 2.4, a separate set of responses to the requirements in Section 3.1 must be provided as part of this application by each member organization of the joint enterprise.

3.1.1 Contracts

In HPMS, complete the table below if application applies to multiple contracts.

PROVIDE THE: NEW Part D CONTRACT NUMBER THAT WILL BE USED TO IDENTIFY ALL NEW CONTRACT NUMBERS DURING APPLICATION PROCESS. (Do not include existing CMS contract numbers) : _____		
PROVIDE THE ADDITIONAL New PDP CONTRACT NUMBERS THAT ARE TO BE ASSOCIATED WITH THIS APPLICATION. (ADD ADDITIONAL ROWS AS NECESSARY)		

NOTE: Only MA-PD contract numbers may be associated with other MA-PD contract numbers. Only PDP contract numbers may be associated with other PDP contract numbers. Only Regional Preferred Provider Organization (RPPO) contract numbers may be associated with other RPPO contract numbers.

3.1.2 Management and Operations

A. In HPMS, complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PART D CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN IN HPMS:	YES	NO
1. Applicant is applying to operate as a Part D sponsor.		
2. Applicant is a non-governmental legal entity that agrees to abide by the terms of a Medicare Prescription Drug Plan contract with CMS.		
3. Applicant is not applying to operate as a Fallback entity nor are its subcontractors that play an integral part in the drug benefit management activities. (NOTE: CMS does not anticipate soliciting Fallback contractors for 2008.)		
4. Applicant has administrative and management arrangements that feature a policy-making body (e.g., board of directors) exercising oversight and control over the PDP sponsor's policies and personnel (e.g., human resources) to ensure that management actions are in the best interest of the organization and its enrollees.		
5. Applicant has administrative and management arrangements that feature personnel and systems sufficient for the Part D sponsor to organize, implement, control and evaluate financial and marketing activities, the furnishing of prescription drug services, the quality assurance, medication therapy management, and drug and drug utilization management programs, and the administrative aspects of the organization.		
6. Applicant has administrative and management arrangements that feature an executive manager whose appointment and removal are under the control of the policy-making body.		
7. Applicant has administrative and management arrangements that feature a fidelity bond or bonds, procured by the Applicant, in an amount fixed by its policymaking body, but not less than $100,000 per individual, covering each officer and employee entrusted with the handling of its funds.		
8. Applicant has administrative and management arrangements that feature insurance policies secured and maintained by the Applicant, and approved by CMS to insure the Applicant against losses arising from professional liability claims, fire, theft, fraud, embezzlement, and other casualty risks.		
9. Applicant maintains contracts or other legal arrangements between or among the entities combined to meet the functions identified in subsection 3.1.3A.		

B. In HPMS, complete the form below:

IDENTIFY YOUR ORGANIZATION BY PROVIDING THE FOLLOWING INFORMATION
Full Legal Organization's Name:
Full Address of Your Organization's Headquarters *(Street, City, State, Zip):*
Type of Ownership: ☐ Sole Proprietorship ☐ Partnership ☐ Publicly-Traded Corporation ☐ Privately- Held Corporation ☐ Other (list type)_____
Name of Your Organization's Parent Organization, if any:
State in Which your Organization is Incorporated or Otherwise Organized to do Business:
Federal Taxpayer Identification Number:

C. Provide as an attachment a brief summary of the history, structure and ownership of your organization. Include a chart showing the structure of ownership, subsidiaries, and business affiliations. The organizational chart should depict the placement of the Part D

operations within your organization as well as the reporting structure within your organization.

D. Subcontractor Function Chart

In HPMS, provide names of the sub-contractors you will use to carry out each of the functions listed in this chart: (Indicate "APPLICANT" where applicant will perform those functions)	**Function**	**Subcontractor(s)**
	A pharmacy benefit program that performs adjudication and processing of pharmacy claims at the point of sale.	
	A pharmacy benefit program that performs negotiation with prescription drug manufacturers and others for rebates, discounts, or other price concessions on prescription drugs	
	A pharmacy benefit program that performs administration and tracking of enrollees' drug benefits in real time.	
	A pharmacy benefit program that performs coordination with other drug benefit programs, including, for example, Medicaid, state pharmaceutical assistance programs, or other insurance.	
	Develops and maintains a pharmacy network.	
	A pharmacy benefit program that operates an enrollee grievance and appeals process	
	A pharmacy benefit program that performs customer service functionality, that includes serving seniors and persons with a disability.	
	A pharmacy benefit program that performs pharmacy technical assistance service functionality.	
	Maintains a pharmaceutical and therapeutic committee.	

E. Provide as attachments (as instructed in Section 2.4) copies of executed contracts and fully executed letters of agreement with each subcontractor identified in Sections 3.1.2D that:

1. Clearly identify the parties to the contract (or letter of agreement).

2. Describe the functions to be performed by the subcontractor, as well as any reporting requirements the subcontractor has to the Applicant.

3. Contain language clearly indicating that the subcontractor has agreed to participate in your Medicare Prescription Drug Benefit program (except for a network pharmacy if the existing

contract would allow participation in this program), and flow-down clauses requiring their activities be consistent and comply with the Applicant's contractual obligations as a Part D sponsor.

4. Contain language describing the services to be performed in a manner that encompasses the services required to support the Medicare Prescription Drug Benefit program.

5. Describe the payment the subcontractor will receive for performance under the contract, if applicable.

6. Are for a term of at least the one-year contract period (i.e., January 1 through December 31) for which this application is being submitted.

7. Are signed by a representative of each party with legal authority to bind the entity.

8. Contain language obligating the subcontractor to abide by all applicable Federal and State laws and regulations and CMS instructions.

9. Contain language obligating the subcontractor to abide by State and Federal privacy and security requirements, including the confidentiality and security provisions stated in the regulations for this program at 42 CFR §423.136.

10. Contain language ensuring that the subcontractor will make its books and other records available in accordance with 42 CFR 423.505(i)(2). Generally stated these regulations give HHS, the Comptroller General, or their designees the right to inspect, evaluate and audit books and other records and that these rights continue for a period of 10 years from the final date of the contract period or the date of audit completion, whichever is later.

11. Contain language that the subcontractor will ensure that beneficiaries are not held liable for fees that are the responsibility of the Part D sponsor.

12. Contain language that if the Applicant, upon becoming a Part D sponsor, delegates an activity or responsibility to the subcontractor, that such activity or responsibility may be revoked if CMS or the Part D sponsor determines the subcontractor has not performed satisfactorily. The subcontract may include remedies in lieu of revocation to address this requirement.

13. Contain language specifying that the Applicant, upon becoming a Part D sponsor, will monitor the performance of the subcontractor on an ongoing basis.

14. If the subcontractor will establish the pharmacy network or select pharmacies to be included in the network contain language that the Part D sponsor retains the right to approve, suspend, or terminate any arrangement with a pharmacy.

F. Provide as an attachment as instructed in Section 2.4, the signed certification in Appendix V. The certification allows the Applicant to verify that the subcontracts submitted under 3.1.2E meet all of the requirements identified in 3.1.2E.

G. Provide electronic lists of the subcontract citations demonstrating that the requirements of Section 3.1.E are included in the subcontracts. Submit these data by creating a spreadsheet in Microsoft Excel that mimics Appendix VI. Provide this attachment as instructed in Section 2.4.

H. In HPMS, complete the table below:

APPLICANT MUST ATTEST 'YES'OR 'NO'' TO THE FOLLOWING QUALIFICATION TO BE APPROVED FOR A PART D CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATION BY PLACING A CHECKMARK IN THE RELEVANT COLUMN IN HPMS:	YES	NO
1. Applicant is applying to operate as a Part D sponsor through a joint enterprise agreement.		

I. SPECIAL REQUIREMENT FOR JOINT ENTERPRISE APPLICANTS: If Applicant answered 3.1.2H1 (table above) as YES, then Joint Enterprise Applicants must provide as an attachment as instructed in Section 2.4 a copy of the agreement executed by the State-licensed entities describing their rights and responsibilities to each other and to CMS in the operation of a Medicare Part D benefit plan. Such an agreement must address at least the following issues:

- Termination of participation in the joint enterprise by one or more of the member organizations; and
- Allocation of CMS payments among the member organizations.

3.1.3 Experience and Capabilities

A. In HPMS, complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PART D CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN IN HPMS.	YES	NO
1. Applicant and/or one of its subcontractors currently operate a pharmacy benefit program that performs adjudication and processing of pharmacy claims at the point of sale.		
2. Applicant and/or one of its subcontractors currently operates a pharmacy benefit program that performs negotiation with prescription drug manufacturers and others for rebates, discounts, or other price concessions on prescription drugs.		
3. Applicant and/or one of its subcontractors currently operate a pharmacy benefit program that performs administration and tracking of enrollees' drug benefits in real time.		
4. Applicant and/or one of its subcontractors currently operates a pharmacy benefit program that performs coordination with other drug benefit programs, including, for example, Medicaid, state pharmaceutical assistance programs, or other insurance.		
5. Applicant and/or one of its subcontractors currently develop and maintain a pharmacy network.		
6. Applicant and/or one of its subcontractors currently operate a pharmacy benefit program that operates an enrollee grievance and appeals process.		
7. Applicant and/or one of its subcontractors currently operate a pharmacy benefit program that performs customer service functionality, which includes serving seniors and persons with a disability.		
8. Applicant and/or one of its subcontractors currently operate a pharmacy benefit program that performs pharmacy technical assistance service functionality.		
9. Applicant and/or one of its subcontractors currently operate a pharmacy benefit program that maintains a pharmaceutical and therapeutic committee.		

3.1.4 Licensure and Solvency

A. Provide in HPMS the National Association of Insurance Commissioners (NAIC) number if currently licensed. _____

B. In HPMS, complete the table below:

NOTE: APPLICANT CAN ONLY BE APPROVED FOR CONTRACT IF: ITEM #3 IS ANSWERED 'YES' OR ITEM #4 BELOW IS ANSWERED 'YES' AND CMS APPROVES THE REQUEST AND ITEM #5 IS ANSWERED 'YES' AND THE APPLICANT SATISFIES THE REQUIREMENT "C" BELOW, IF APPROPRIATE. ATTEST 'YES' OR 'NO' TO THE FOLLOWING STATE LICENSURE REQUIREMENTS.	**YES**	**NO**	**DOES NOT APPLY**
1. Applicant is licensed under State law as a risk-bearing entity eligible to offer health insurance or health benefits coverage in at least one State.			
2. Applicant is currently under some type of supervision, corrective action plan or special monitoring by the State licensing authority in any State.			
3. Applicant is licensed under State law as a risk-bearing entity eligible to offer health insurance or health benefits coverage in each State in which the Applicant proposes to offer Part D drug benefits.			
4. If the Applicant does not meet Requirement #3, then the Applicant has completed and provided to CMS as an attachment to this application the *Application to Request Federal Waiver of State Licensure Requirement for Prescription Drug Plan (PDP* (Appendix II) for each State in which it is not licensed but seeks to offer Part D drug benefits.			
5. If Applicant is seeking a waiver of the licensure requirement, the Applicant meets the CMS-published financial solvency and capital adequacy requirements.			

C. If the answer to item B1 above is "NO", the Applicant must submit the *Financial Solvency Documentation* (Appendix IV), as a separate attachment.

D. If the answer to item B2 is "YES", include a separate attachment explaining the specific actions taken by the State license regulator. In these cases, CMS reserves the right to require the Applicant to demonstrate that it meets the CMS-published financial solvency and capital adequacy requirements.

E. If the answer to item B1 is "YES," then please provide documentation (e.g, licensing certificate or letter) from each State licensing authority of your organization's status as an entity licensed to bear risk.

3.1.5 Business Integrity

A. In HPMS, complete the table below:

APPLICANT MUST ATTEST 'YES' OR 'NO' TO THE FOLLOWING QUALIFICATION TO BE APPROVED FOR A PART D CONTRACT. ATTEST 'YES' OR 'NO' TO THE FOLLOWING QUALIFICATION BY PLACING A CHECKMARK IN THE RELEVANT COLUMN IN HPMS:	**Yes**	**No**
1. Applicant, applicant staff, and its affiliated companies, subsidiaries or subcontractors, and subcontractor staff agree that they are bound by 45 CFR Part 76 and attest that they are not excluded by the Department of Health and Human Services Office of the Inspector General or by the General Services. Please note that this includes any member of its board of directors, and any key management or executive staff or any major stockholder.		
2. Applicant agrees it does not have any past or pending investigations, legal actions, administrative actions, or matters subject to arbitration brought involving the Applicant		

(and Applicant's parent firm if applicable) and its Pharmaceutical Benefit Manager (PBM) (and PBM's parent firm if applicable), including any key management or executive staff, by a government agency (state or federal including CMS) over the past three years on matters relating to payments from governmental entities, both federal and state, for healthcare and/or prescription drug services.		

B. If Applicant answered No to 3.1.5A2, provide as an attachment, all past or pending, if known, investigations, legal actions, or matters subject to arbitration brought by a government agency (state or federal including CMS) over the past three years relating to payments from government entities, for healthcare and/or prescription drug services involving the following:

1. **Applicant (and Applicant's parent firm if applicable).**
2. **PBM (and PBM's parent firm if applicable).**
3. **Key management or executive staff.**

Provide as part of the attachment a brief explanation of each action, including the following:

1) Legal names of the parties.
2) Circumstances.
3) Status (pending or closed).
4) If closed, provide the details concerning resolution and any monetary payments.
5) Settlement agreements or corporate integrity agreements.

3.1.6 HPMS Part D Contacts

A. In HPMS, complete the table below: provide the name/title; mailing address; phone number; fax number; and email address for the following Applicant contacts:

Contact	Name/Title	Mailing Address	Phone/Fax Numbers	Email Address
Corporate Mailing				
CEO – Sr. Official for Contracting				
Chief Financial Officer				
Medicare Compliance Officer				
Enrollment Contact				
Medicare Coordinator				
System Contact				
Customer Service Operations Contact				
General Contact				
User Access Contact				
Backup User Access Contact				

Marketing Contact				
Medical Director				
Bid Primary Contact				
Payment Contact				
Pharmacy Benefit Manager Contact				
Part D Claims Submission Contact				
Formulary Contact				
Pharmacy Network Management Contact				
Medication Therapy Management Contact				
Patient Safety Contact				
Part D Benefits Contact				
Part D Quality Assurance Contact				
Part D Application Contact				
Pharmacy Director				
HIPAA Security Officer				
HIPAA Privacy Officer				
Part D Price File Contact (Primary)				
Part D Price File Contact (Back-up)				
Part D Appeals				
Government Relations Contact				
Emergency Part D Contact				
Pharmacy Technical Help Desk Contact				

Processor Contact				
CMS Casework Communication Contact				
Part D Exceptions Contact				
EOB Transfer Contact				
Coordination of Benefits Contact				
CEO – CMS Administrator Contact				
Plan to Plan Reconciliation Contact				

B. In HPMS, complete the table below:

APPLICANT MUST ATTEST 'YES' TO THE FOLLOWING QUALIFICATION TO BE APPROVED FOR A PART D CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATION BY PLACING A CHECKMARK IN THE RELEVANT COLUMN IN HPMS.	YES	NO
1. Applicant agrees that CMS may release contact information to States, SPAPs, providers, Part D sponsors, and others who need the contact information for legitimate purposes.		

3.2 Benefit Design

3.2.1 Formulary/Pharmacy and Therapeutics (P&T) Committee

A. In HPMS, complete the table below:

APPLICANT MUST ATTEST 'YES' OR 'NO' TO THE FOLLOWING QUALIFICATION TO BE APPROVED FOR A PART D CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN IN HPMS.	YES	NO
1. Applicant will submit a formulary to CMS for the Part D benefit.		

B. In HPMS, complete the table below:

IF APPLICANT IS INTENDING FOR ITS PART D BENEFIT TO INCLUDE THE USE OF A FORMULARY, THEN APPLICANT MUST ALSO PROVIDE A P&T COMMITTEE MEMBER LIST EITHER DIRECTLY OR THROUGH ITS PHARMACY BENEFITS MANAGER (PBM). APPLICANT MUST ATTEST 'YES' OR 'NO' THAT IT IS USING ITS PBM'S P&T COMMITTEE, IN ORDER TO BE APPROVED FOR A PART D CONTRACT. ATTEST 'YES' OR 'NO' BY PLACING A CHECKMARK IN THE RELEVANT COLUMN IN HPMS.	YES	NO
1. Applicant is using the P&T Committee of its PBM for purposes of the Part D benefit.		

2. 2. If answered yes to B1, Applicant's PBM is operating under a confidentiality agreement for purposes of the P&T Committee. (If not applicable, check "NO.") Note: If answer is YES, then Applicant and PBM must complete Appendix XII.		
3. Applicant will develop and use a P&T committee to develop and review the formulary and to ensure that the formulary is appropriately revised to adapt to both the number and types of drugs on the market. *Note: While the P&T committee may be involved in providing recommendations regarding the placement of a particular Part D drug on a formulary cost-sharing tier, the ultimate decision maker on such formulary design issues is the Part D plan, and that decision weighs both clinical and non-clinical factors.*		
4. Applicant's P&T committee will first look at medications that are clinically effective. When two or more drugs have the same therapeutic advantages in terms of safety and efficacy, the committee may review economic factors that achieve appropriate, safe, and cost-effective drug therapy.		
5. Applicant will assure that the P&T committee uses appropriate scientific and economic considerations to consider utilization management activities that affect access to drugs, such as access to non-formulary drugs, prior authorization, step therapy, generic substitution, and therapeutic interchange protocols.		
6. Applicant will adhere to P&T guidelines that will, from time to time, be promulgated with regard to such subject areas as membership, conflict of interest, meeting schedule, meeting minutes, therapeutic classes, drug review and inclusion, formulary management, utilization management and review, formulary exceptions, and educational programs for providers.		
7. Applicant's P&T committee will make a reasonable effort to review within 90 days, and will make a decision on each new chemical entity, and new FDA clinical indicators, within 180 days of its release onto the market, or a clinical justification will be provided if this timeframe is not met.		
8. Applicant's P&T committee will approve inclusion or exclusion of the therapeutic classes in the formulary on an annual basis.		
9. The majority of the membership of the Applicant's P&T committee shall be practicing physicians and/or practicing pharmacists.		
10. The membership of the Applicant's P&T committee will include at least one practicing physician and at least one practicing pharmacist who are both free of conflict with respect to the Applicant organization and pharmaceutical manufacturers.		
11. The membership of the Applicant's P&T committee will include at least one practicing physician and at least one practicing pharmacist who are experts in the care of the elderly or disabled persons.		
12. Applicant's P&T committee will recommend protocols and procedures for the timely use of and access to both formulary and non-formulary drug products.		
13. Applicant will verify that their P&T Committee members (listed in 3.2.1 C) do not appear on the HHS Office of Inspector General's Exclusion List. This list can be found at http://exclusions.oig.hhs.gov/search.html		

C. If Applicant is intending for its Part D benefit to include use of a formulary, then the members of the P&T committee must be provided either directly by the Applicant or by the Applicant's PBM. The membership of the P&T committee must be comprised as described in items B, 10, 11 and 13 above. If Applicant is providing names of P&T committee directly, then complete the form below. If PBM is providing the P&T committee, refer to Appendix XIIII for additional instructions:

PROVIDE THE NAMES OF THE MEMBERS OF YOUR ORGANIZATION'S P&T COMMITTEE. INDICATE WHICH MEMBERS ARE PRACTICING PHYSICIANS OR PRACTICING PHARMACISTS. FURTHER, INDICATE WHICH MEMBERS ARE EXPERTS IN THE

CARE OF THE ELDERLY OR DISABLED, AND FREE OF ANY CONFLICT OF INTEREST WITH YOUR ORGANIZATION AND PHARMACEUTICAL MANUFACTURERS. (APPLICANTS SHOULD MARK THE INFORMATION AS PROPRIETARY). SUBMITTHIS DATA BY CREATING A SPREADSHEET IN MICROSOFT EXCEL THAT MIMICS THE TABLE BELOW. PROVIDE THIS ATTACHMENT ON A CD AS INSTRUCTED IN SECTION 24					
	Practice/Expertise *Mark an 'X' in Appropriate Column*			**Free of Any Conflict of Interest** *Type Yes or No* *Type Yes if the member has no conflict of interest and No if there is a conflict of interest.* *Please complete for each member of the P&T Committee.*	
Full Name of Member Start Date and End Date	Practicing Physician	Practicing Pharmacist	Elderly/Disabled Expert	With Your Organization?	With Pharmaceutical Manufacturers?

3.2.2 Utilization Management Standards

A. In HPMS, complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PART D CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN IN HPMS.	**YES**	**NO**
1. Applicant maintains policies and procedures to prevent over-utilization and under-utilization of prescribed medications, including but not limited to the following elements: • Compliance programs designed to improve adherence/persistency with appropriate medication regimens • Monitoring procedures to discourage over-utilization through multiple prescribers or multiple pharmacies • Quantity versus time edits • Early refill edits		
2. Applicant maintains methods to ensure cost-effective drug utilization management. Examples of these tools include, but are not limited to: • Step therapy • Prior authorization • Tiered cost-sharing		
3. Applicant makes enrollees aware of utilization management (UM) program requirements through information and outreach materials.		
4. Applicant develops incentives to reduce costs when medically appropriate such as, but not limited to encouragement of generic utilization.		
5. Applicant will report to CMS data for UM standards in the manner prescribed by CMS. (See Section 3.16 Reporting Requirements)		

3.2.3 Quality Assurance and Patient Safety

A. In HPMS, complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE		

APPROVED FOR A PART D CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN IN HPMS	YES	NO
1. Applicant agrees to comply with formulary guidance that is posted on the www.cms.hhs.gov/ website.		
2. Applicant establishes a quality assurance (QA) program that includes measures and reporting systems such as, but not limited to: • Reducing medication errors • Reducing adverse drug interactions		
3. Applicant performs drug utilization review at a minimum of what is specified in the regulation 42CFR 423.153 (c) (2) and (3).		
4. Applicant develops and implements internal medication error identification and reduction systems.		
5. Applicant will report to CMS data for QA standards in the manner prescribed by CMS. (See Section 3.16 Reporting Requirements)		
6. Applicant will establish appropriate transition policies and procedures for beneficiaries on drug regimens that are not on the plan's Part D formulary. These policies and procedures must address all the elements specified in current formulary transition guidance and the description is not due in March.		
7. Applicant agrees, where appropriate, to extend transition periods beyond 30 days for enrollees using non-formulary drugs that have not been transitioned to a formulary drug or gone through the plan exception process within 30 days.		
8. The Applicant agrees to submit to CMS a description of the organization's approach to transitioning beneficiaries on drug regimens that are not on the plan's Part D formulary by close of business on April 16, 2007 to PartDformularies@cms.hhs.gov		
9. Applicant agrees to ensure that staffs are trained on and information systems are in place to accommodate administration of the transition policy. This includes adoption of necessary information system overrides.		
10. Applicant will establish policies and procedures for P & T committee involvement in reviewing non-formulary drug requests to ensure Utilization Management tools are appropriate in situations in which a new enrollee is already stabilized on a drug and the description is not due in March.		
11. Applicant will establish an emergency supply of non-formulary Part D drugs for long term care residents to allow the plan and/or the enrollee time for the completion of an exception request to maintain coverage of an existing drug based on reasons of medical necessity.		
12. Applicant will establish appropriate timeframes and "first fill" procedures to non-formulary Part D medications in long term care and retail settings.		

3.2.4 Medication Therapy Management

A. In HPMS, complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PART D CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN IN HPMS.	YES	NO
1. Applicant will develop and implement a Medication Therapy Management (MTM) Program designed to : • Ensure optimum therapeutic outcomes for targeted beneficiaries through improved medication use • For targeted beneficiaries, reduce the risk of adverse events, including adverse drug interactions		
2. Applicant will develop the MTM program in cooperation with licensed and practicing pharmacists and physicians.		

3. Applicant will target beneficiaries for enrollment in the MTM program based on all three of the following criteria: Beneficiary must have multiple chronic diseases (list to be determined by plan); Beneficiary must be taking multiple covered Part D medications (specifics to be determined by plan); and Beneficiary must be identified as likely to incur annual costs for covered Part D drugs that exceed $4,000.00		
4. Applicant will not establish discriminatory exclusion criteria. If an enrollee meets all three of the required criteria (as determined by your plan), the enrollee should be eligible for MTM intervention.		
5. Applicant will establish appropriate policies and procedures for their MTM program, including, but not limited to, services, payments and criteria used for identifying beneficiaries eligible for the MTM program.		
6. The Applicant agrees to submit a description of its MTM program including, but not limited to, policies, procedures, services, payments and criteria provided in item #3 above used for identifying beneficiaries eligible for the MTM program. Note: Instructions to submit a description of your MTM program will be forthcoming in future guidance from CMS and is not due in March.		
7. Applicant will coordinate the MTM program with the Medicare chronic care improvement program (CCIP) under section 1807 of the Social Security Act.		
8. Applicant will provide drug claims data to Chronic Care Improvement Programs (CCIP) for those beneficiaries that are enrolled in CCIPs in a manner specified by CMS.		
9. Applicant will report to CMS specified data on MTM programs in the manner prescribed by CMS. (See Section 3.16 Reporting Requirements)		
10. Applicant will establish an appropriate policy on how they will set MTM fees to pharmacists or others providing MTM services for covered Part D drugs. The policy will explain how the Applicant's fee or payment structure takes into account the resources used and the time required for those providing MTM services.		
11. The Applicant agrees to submit a description of how they will set MTM fees to pharmacists or others providing MTM services for covered Part D drugs. The policy will explain how the Applicant's fee or payment structure takes into account the resources used and the time required for those providing MTM services. Note: Instructions to submit a description of MTM fees with a description of your MTM program will be forthcoming in future guidance from CMS and is not due in March.		
12. Applicant will establish an appropriate MTM enrollment policy in which once enrolled, beneficiaries will not be disenrolled from the MTMP program if they no longer meet one or more of the MTMP eligibility criteria (as determined by the plan) and will remain in the MTMP program for the remainder of the calendar year.		
13. Applicant will establish and maintain appropriate interventions for its MTM program for all enrollees who meet all three of the required criteria (as determined by the plan) regardless of setting (i.e. ambulatory, long term care, etc.).		
14. Applicant will establish and maintain safeguards against discrimination based on the nature of their MTM interventions (i.e. TTY if phone based, Braille if mail based, etc.).		

3.2.5 Electronic Prescription Program

A. In HPMS, complete the table below:

APPLICANT MUST ATTEST 'YES' TO THE FOLLOWING QUALIFICATION TO BE APPROVED FOR A PART D CONTRACT. ATTEST 'YES' OR 'NO' TO THE FOLLOWING QUALIFICATION BY PLACING A CHECKMARK IN THE RELEVANT COLUMN IN HPMS.	YES	NO
Applicant agrees to follow the electronic prescribing rules. Available on line at: http://a257.g.akamaitech.net/7/257/2422/01jan20051800/edocket.access.gpo.gov/2005/pdf/05-22026.pdf		

3.2.6 Bids

A. In HPMS, complete the table below:

APPLICANT MUST ATTEST 'YES' TO THE FOLLOWING QUALIFICATION TO BE APPROVED FOR A PART D CONTRACT. ATTEST 'YES' OR 'NO' TO THE FOLLOWING QUALIFICATION BY PLACING A CHECKMARK IN THE RELEVANT COLUMN IN HPMS.	YES	NO
1. Applicant agrees to limit the number of submitted bids in a service area to those that would demonstrate meaningful differences to a beneficiary.		
2. Applicant has reviewed Section 2.4 of this application and understands that for the purpose of assigning autoenrollments, all bids that are below the low income subsidy threshold for all PDP contracts offered by the applicant's parent organization, its affiliates and itself will be counted as one.		
3. Applicant agrees to reflect 100% direct and indirect remuneration in their CY 2008 bids, including any price concessions for PBM services based on their best expectation for 2008 contracts.		

3.3 Service Area/Regions

A. In HPMS, complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PART D CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN IN HPMS.	YES	NO
1. Applicant will offer a prescription drug plan in at least one Part D region (e.g. PDP region, MA-PD region).		
2. For all regions in which the applicant offers a prescription drug plan, the Applicant will provide coverage in the entire region.		

B. Complete in HPMS, the service area information indicating the regions (including territories) you plan to serve. PDP and MA-PD region and Territory information may be found on the www.cms.hhs.gov/ website. Be sure to list both the region/territory name and associated number.

Region	Region Number
Territory	

3.4 Pharmacy Access

A. In HPMS, complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PART D CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING	YES	NO

QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN IN HPMS:		
1. Applicant agrees to permit in its plan networks any pharmacy that is willing to accept and meets the plans' standard terms and conditions. However, terms and conditions may vary, particularly with respect to payment terms to accommodate geographical areas (e.g. rural pharmacies) or different types of pharmacies (e.g. mail order and retail), provided that all similarly-situated pharmacies are offered the same standard terms and conditions.		
2. Applicant agrees not to require a pharmacy to accept insurance risk as a condition of participation in the Part D sponsor's network		
3. Where applicable, Applicant's network pharmacy contracts contain provisions governing the submission of claims to a real-time adjudication system, except in the limited case of pharmacies for which only batch processing is feasible (e.g. some I/T/U pharmacies and certain pharmacies that are allowed to submit claims in the X12 format)		
4. Applicant's network pharmacy contracts contain provisions governing providing Part D enrollees access to negotiated prices as defined in 42 CFR 423.100		
5. Applicant's network pharmacy contracts contain provisions regarding charging/applying the correct cost-sharing amount, including that which applies to individuals qualifying for the low-income subsidy.		
6. Where applicable, Applicant's network pharmacy contracts contain provisions governing informing the Part D enrollee at the point of sale (or at the point of delivery for mail order drugs) of the lowest-priced, generically equivalent drug, if one exists for the beneficiary's prescription, as well as any associated differential in price. (Note: 42 CFR 423.132(d) modifies the timing requirement for LTC pharmacies)		
7. Applicant agrees to maintain a contract log as specified in forthcoming CMS guidance.		
8. Applicant agrees that each of the contract provisions referenced in Appendices VIII-XII will be included in the respective downstream pharmacy network contracts.		
9. Applicant agrees to notify CMS when the Applicant changes its pharmaceutical benefit management subcontractor.		
10. Applicant agrees to notify CMS about any substantive change in your organization's pharmacy network that may impact your organization's ability to maintain a Part D pharmacy network that meets CMS' requirements.		

B. Provide as an attachment a contract template for each for the following types of pharmacies: Retail, Mail Order, Home Infusion, Long-Term Care and I/T/U. The mail order contract template is only necessary if the plan is offering mail order. The ITU template is only necessary if the plan's projected service area includes I/T/U pharmacies. If Applicant has contracted with a Pharmacy Benefit Management entity to provide a pharmacy network, those downstream contract templates must also be submitted. If there are several different types of standard terms and conditions for the same type of pharmacy, please provide a contract template for all versions and label according to type of pharmacy. For example, if different terms for retail pharmacies apply depending upon geographic location, a separate template representing each variation must be provided. Each contract template type must contain the unsigned standard terms and conditions, including the provisions listed in Appendix VII-XI.

C. Provide as attachments crosswalks of the Pharmacy Access Contract Citations [for Retail, Mail Order (if offered), Home Infusion, Long-Term Care and I/T/U Pharmacy networks] demonstrating that all applicable requirements in Appendix VII-XI are included in such contracts. Submit this data by creating separate spreadsheets in Microsoft Excel that mimic Appendix VII-XI. Provide these attachments on each of the 4 CDs as instructed in Section 2.4. If the applicant is a joint enterprise, this information must be clearly labeled to which party of the joint enterprise the information pertains.

3.4.1 Retail Pharmacy

A. In HPMS, complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PART D CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN IN HPMS:	YES	NO
1. Applicant agrees to meet the CMS Standards for Convenient Access [§423.120 (a) (1) and (2) no later than March of the current year (See Appendix XIII)		
2. Applicant agrees that when Applicant is offering extended supplies via mail order, it also has to contract with a sufficient number of network retail pharmacies so as to ensure that enrollees have reasonable access to the same extended day supply benefits at retail that are available at mail-order.		
3. Applicant agrees to use the CMS beneficiary counts in the data file "Medicare Beneficiaries by State, Region, Zip 09302006" to prepare the retail network analyses.		

B. Provide as attachments the Geo-Access Reports as described in Appendix XIII.

C. Provide as attachments, the Retail Pharmacy List:

To submit retail pharmacy listings to CMS, Applicants must complete, at a minimum, two worksheets within the Excel file labeled and "Retail Pharmacy List" (see reference document entitled "Retail Pharmacy List").

1. Assuming that Applicant has only one unique retail pharmacy network, they must complete the following:

   - Complete the worksheet labeled "Retail List – A".
   - Complete all columns with the information indicated in each column heading.
   - Complete all appropriate cells (columns) for every record (row) for which you are listing a pharmacy.

2. We recognize that in some instances, networks may exceed a single worksheet and ask that you label each worksheet properly. For instance, label multiple sheets for a single pharmacy list as "Retail List - A", "Retail List - A2", "Retail List - A3", etc. Only designate a worksheet as "Retail List – B" if you are referencing an alternate or separate retail pharmacy listing. In the event Applicant is representing more than one unique retail pharmacy network, create as many worksheets as may be necessary to provide your complete network. Label additional worksheets as "Retail List – B", "Retail List – C", etc.

The "Contract ID List" worksheet should list all of the contract numbers and the legal entity name(s) (as it appears in HPMS), that are represented by the retail list provided in the worksheet labeled "Retail List - A". For many, if not all, contract numbers, the retail pharmacy list may be the same. For those contract numbers associated with "Retail List – A", you will complete the "Contract ID List" worksheet by populating the "List Identifier", column C, with an "A". If there are any circumstances, where there are contract numbers that have an alternate retail pharmacy listing, you will populate the "List Identifier" column with the appropriate letter identifier (i.e., B, C, etc.).

D. Submission of Supporting Discussion in Areas Failing to Meet Access Standards

CMS will consider supporting discussion provided by an Applicant in evaluating the applicant's application to determine if Applicant is qualified to be a Part D Sponsor. While you have the opportunity to provide this discussion, CMS' expectation is that your organization will meet the required access standards in all cases. Providing the discussion below does not mean CMS will allow you to fail the access standards, but in extreme or unusual circumstances, we may consider this information.

Provide as an attachment the following information to demonstrate that meeting the access standard within the service area is not practical or impossible.

1. Indicate the geographic areas in which the applicant cannot demonstrate that it meets the retail pharmacy convenient access standards as defined in Appendix XIII;

2. Explain why these standards cannot be met. Include in the discussion relevant information such as geographic barriers, pharmacy infrastructure barriers, and/or market barriers;

3. Describe how the pharmacies in the Applicant's retail contracted network will provide access to all eligible Part D individuals enrolled in the Applicant's plan(s) in each of the geographic areas defined in item 1 above.

E. In HPMS, complete the table below if your pending service area includes any of the U.S. Territories:

Request for a Waiver of Convenient Access Standards for the Territories	YES	NO	N/A
Region 35 – American Samoa			
Region 36 – Guam			
Region 37 – Northern Mariana Islands			
Region 38 – Puerto Rico			
Region 39 – US Virgin Islands			

F. Complete the following if you marked YES to requesting a waiver of convenient access standards for any of the territories in 3.4.1E. In HPMS, provide the following information:

1. Explain why these standards cannot be met.
2. Describe the Applicant's efforts to identify and contract with all of the retail pharmacies in each of the applicable territories.
3. Describe how the pharmacies in the Applicant's contracted network demonstrate convenient access to all eligible Part D individuals enrolled in the Applicant's plan(s) in each of the territories listed above as not meeting the standards in §423.120(a)(1).

3.4.2 Out of Network Pharmacy

A. In HPMS, complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PART D CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN IN HPMS:	**YES**	**NO**
1. Applicant agrees to ensure that enrollees have adequate access to covered Part D drugs dispensed at out-of-network pharmacies when an enrollee cannot reasonably		

	be expected to obtain such drugs at a network pharmacy and provided such enrollees do not access Part D drugs at an out-of-network pharmacy (or a physician's office) on a routine basis. The coverage rules applicable to covered Part D drugs dispensed at out-of-network pharmacies may generally mirror those applicable to covered Part D drugs dispensed at network pharmacies (to the extent that the out-of-network pharmacy has the ability to effectuate those coverage rules). However, Applicant agrees to develop policies and procedures governing reasonable rules for appropriately limiting out-of-network access (for example, quantity limits, purchase of maintenance medications via mail-order for extended out-of-area travel, or plan notification or authorization processes).		
2.	Applicant agrees to ensure that enrollees have adequate access to covered Part D drugs dispensed at physician offices for covered Part D drugs that are appropriately dispensed and administered in physician offices (e.g. Part D-covered vaccines).		
3.	Applicant agrees to abide by Section 423.124(b) relating to the financial responsibility for out-of-network access to covered Part D drugs and may require its Part D enrollees accessing covered Part D drugs to assume financial responsibility for any differential between the out-of-network pharmacy's usual and customary price and the PDP sponsor plan allowance, consistent with the requirements of 42 CFR §§ 423.104(d)(2)(i)(B) and § 423.104(e).		

3.4.3 Mail Order Pharmacy

A. In HPMS, complete the table below:

APPLICANTS MAY OFFER A MAIL ORDER OPTION IN ADDITION TO THEIR CONTRACTED PART D PHARMACY NETWORK BUT MAIL ORDER PHARMACIES DO NOT COUNT IN MEETING NETWORK ADEQUACY STANDARDS. INDICATE IN HPMS 'YES' OR 'NO' WHETHER SUCH MAIL ORDER PHARMACY IS OFFERED.	**YES**	**NO**
1. Applicant will offer mail order pharmacy as part of its Part D plans		
2. If Applicant attests 'Yes' to 3.4.3A1, will mail order include an extended (e.g., 90) day supply, attest 'Yes"		
3. If Applicant attests 'YES' to 3.4.3A2 , then Applicant will include in its contracts with at least some retail pharmacies a provision that will allow a retail pharmacy to offer an extended supply of drugs to any Plan beneficiary at the same price, reimbursement rate and cost sharing as the Plan's mail order pharmacy or pharmacies—the network mail order pharmacy rate; or an Applicant may use an alternative retail/mail order pharmacy rate with a higher contracted reimbursement rate provided that any differential in charge between the Network Mail Order Pharmacy rate and the higher contract reimbursement rate would be reflected in higher cost sharing paid by the beneficiary.		

B. Provide as an attachment the Mail Order Pharmacy List

To submit mail order pharmacy listings to CMS, Applicants must complete, at a minimum, two worksheets within the Excel file labeled and "Mail Order Pharmacy List" (see reference document entitled "Mail Order Pharmacy List").

1. 1. Assuming that Applicant has only one unique mail order pharmacy network, they must complete the following:

2. Complete the worksheet labeled "Mail List – A".

    - Complete all columns with the information indicated in each column heading.

- Complete all appropriate cells (columns) for every record (row) for which you are listing a pharmacy.

3. We recognize that in some instances, networks may exceed a single worksheet and ask that you label each worksheet properly. For instance, label multiple sheets for a single pharmacy list as "Mail List - A", "Mail List - A2", "Mail List - A3", etc. Only designate a worksheet as "Mail List – B" if you are referencing an alternate or separate mail order pharmacy listing. In the event Applicant is representing more than one unique mail order pharmacy network, create as many worksheets as may be necessary to provide your complete network. Label additional worksheets as "Mail List – B", "Mail List – C", etc.

4. The "Contract ID List" worksheet should list all of the contract numbers and the legal entity name(s) (as it appears in HPMS), that are represented by the mail order list provided in the worksheet labeled "Mail List - A". For many, if not all, contract numbers, the mail order pharmacy list may be the same. For those contract numbers associated with "Mail List – A", you will complete the "Contract ID List" worksheet by populating the "List Identifier", column C, with an "A". If there are any circumstances, where there are contract numbers that have an alternate mail order pharmacy listing, you will populate the "List Identifier" column with the appropriate letter identifier (i.e., B, C, etc.).

3.4.4 Home Infusion Pharmacy

A. In HPMS, complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PART D CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN IN HPMS:	YES	NO
1. Applicant agrees to provide adequate access to home infusion pharmacies.		
2. Applicant agrees that its network contracts will address Part D drugs delivered in the home setting.		
3. Applicant agrees that its contracted home infusion pharmacies will deliver home infused drugs in a form that can be administered in a clinically appropriate fashion in the beneficiary' place of residence.		
4. Applicant agrees that its home infusion pharmacy network in the aggregate has a sufficient number of contracted pharmacies capable of providing infusible Part D drugs for both short term acute care (e.g. IV antibiotics) and long term chronic care (e.g. alpha protease inhibitor) therapies.		
5. Applicant agrees that its contracted network pharmacies that deliver home infusion drugs ensure that the professional services and ancillary supplies necessary for home infusion are in place before dispensing home infusion drugs to the beneficiary in his/her place of residence.		

B. Home Infusion Pharmacy List

Within HPMS Applicants will need to complete at a minimum, two worksheets within an Excel file labeled "Home Infusion Pharmacy List". (see reference document entitled "Home Infusion Pharmacy List").

1. Assuming that Applicant has only one unique home infusion pharmacy network, do the following:

Complete the worksheet labeled "H_I List – A". All columns should be completed with the information indicated in each column heading. Please be sure to complete all appropriate cells (columns) for every record (row) for which Applicant is listing a pharmacy. CMS recognizes that in some instances, networks may exceed a single worksheet and ask that Applicant label each worksheet properly. For instance, label multiple sheets for a single pharmacy list as "H_I List - A", "H_I List - A2", "H_I List - A3", etc. Only designate a worksheet as "H_I List – B" if Applicant is referencing an alternate or separate home infusion pharmacy listing.

2. In the event Applicant is representing more than one unique home infusion pharmacy network, create as many worksheets as may be necessary to provide all the unique networks. Label additional worksheets as "H_I List – B", "H_I List – C", etc.

3. The "Contract ID List" worksheet should list all of the contract numbers and the legal entity name(s) (as it appears in HPMS), that are represented by the home infusion list provided in the worksheet labeled "H_I List - A". For many, if not all, contract numbers, the home infusion pharmacy list may be the same. For those contract numbers associated with "H_I List – A", Applicant will complete the "Contract ID List" worksheet by populating the "List Identifier", column C, with an "A". If there are any circumstances, where there are contract numbers that have an alternate home infusion pharmacy listing, Applicant will populate the "List Identifier" column with the appropriate letter identifier (i.e., B, C, etc.).

C. Home Infusion Discussion
Provide as an attachment a discussion about how your organization's contracted home infusion network assures adequate access to Medicare beneficiaries.

3.4.5 Long -Term Care (LTC) Pharmacy

A. In HPMS, complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PART D CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN IN HPMS:	YES	NO
1. Applicant agrees to comply with the long-term care guidelines that are posted on the www.cms.hhs.gov/ website.		
2. Applicant agrees to offer standard contracting terms and conditions to all long-term care pharmacies in its service area. These terms and conditions must include all the performance and service criteria for long-term care pharmacies that are cited in the Long Term Care Guidance.		
3. Applicant agrees that all of the Part D contracted pharmacies in Applicant's LTC network have signed directly or through a power of attorney a contract that meets the LTC performance and service criteria established by CMS.		
4. Applicant agrees to recognize the CMS special election period (SEP) or open enrollment period for institutionalized individuals for Part D drug plan enrollment and disenrollment for beneficiaries entering, living in, or leaving a long-term care facility.		
5. Applicant agrees that it will ensure convenient access to network LTC pharmacies for all of their enrollees residing in an IMD or ICF-MR designated by the State as an institution and in which any institutionalized individuals reside.		
6. Applicant agrees that it will contract with a sufficient number of LTC pharmacies to provide the entire plan's institutionalized enrollees' convenient access to their Part D benefit.		
7. Applicant will ensure that, in contracting with LTC pharmacies, it does not agree to particular contracting terms and conditions containing provisions that have the net		

result of creating a non-uniform benefit for plan enrollees residing in LTC facilities serviced by network LTC pharmacies whose contracts with the Applicant may not include the same provisions.		

B. LTC Pharmacy List
Within HPMS, Applicants will need to complete, at a minimum, two worksheets within an Excel file labeled "Long Term Care Pharmacy List" (see reference document entitled "Long Term Care Pharmacy List").

1. Assuming that Applicant has only one unique long term care pharmacy network, do the following:

   Complete the worksheet labeled "LTC List – A". All columns should be completed with the information indicated in each column heading. Please be sure to complete all appropriate cells (columns) for every record (row) for which you are listing a pharmacy. CMS recognizes that in some instances, networks may exceed a single worksheet and ask that Applicant label each worksheet properly. For instance, label multiple sheets for a single pharmacy list as "LTC List - A", "LTC List - A2", "LTC List - A3", etc. Only designate a worksheet as "LTC List – B" if you are referencing an alternate or separate long-term care pharmacy listing.

2. In the event Applicant is representing more than one unique long term care pharmacy network, create as many worksheets as may be necessary to provide all the unique networks. Label additional worksheets as "LTC List – B", "LTC List – C", etc.

3. The "Contract ID List" worksheet should list all of the contract numbers and the legal entity name(s) (as it appears in HPMS), that are represented by the long-term care list provided in the worksheet labeled "LTC List - A". For many, if not all, contract numbers, the long-term care pharmacy list may be the same. For those contract numbers associated with "LTC List – A", Applicant will complete the "Contract ID List" worksheet by populating the "List Identifier", column C, with an "A". If there are any circumstances, where there are contract numbers that have an alternate long term care pharmacy listing, Applicant will populate the "List Identifier" column with the appropriate letter identifier (i.e., B, C, etc.).

C**. LTC Discussion**
Provide as an attachment a discussion about how your organization's contracted long-term care network assures convenient access to Medicare beneficiaries.

3.4.6 Indian Health Service, Indian Tribe and Tribal Organization, and Urban Indian Organization (I/T/U) Pharmacy

A. In HPMS, complete the table below:

APPLICANT MUST ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUAIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN IN HPMS TO BE APPROVED FOR A PART D CONTRACT.:	YES	NO	N/A
1. Using the list of I/T/U pharmacies provided at the www.cms.hhs.gov/PrescriptionDrugCovContra/indicate whether your service area includes at least one I/T/U pharmacy.			
NOT ALL PART D REGIONS HAVE I/T/U PHARMACIES. IF THE APPLICANT'S SERVICE AREA COVERS ANY REGION THAT INCLUDES I/T/U PHARMACIES, THEN THE APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PART D CONTRACT. IF ALL OF THE APPLICANT'S SERVICE AREA DOES NOT INCLUDE I/T/U PHARMACIES, THEN THE APPLICANT MAY ANSWER 'NO' or N/A AND STILL BE APPROVED FOR A PART D CONTRACT SINCE THESE			

REQUIREMENTS DO NOT APPLY. ATTEST 'YES,' 'NO' OR N/A TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN IN HPMS:			
2. Applicant agrees to offer standard terms and conditions that conform to the model contract addendum provided by CMS to all I/T/U pharmacies in its service area by sending a conforming contract offer to all such pharmacies. The model contract addendum is posted on the www.cms.hhs.gov/PrescriptionDrugCovContra/ website. The model contract addendum account for differences in the operations of I/T/U pharmacies and retail pharmacies.			
3. Applicant agrees to submit documentation upon CMS' request to demonstrate offering all I/T/U pharmacies in its service area a conforming contract. Such documentation may be proof of fax or U.S. postage mail receipt of delivery.			

B. Provide as an attachment the ITU Pharmacy List.
In order to demonstrate that a Part D Applicant meets these requirements Applicants must submit, as an attachment, a list of ALL I/T/U pharmacies (using the list of I/T/U pharmacies provided by CMS) that reside in their service area. This information must be submitted at the county-level and CMS designated contract level and include contracting status with each of the I/T/U pharmacies in the Applicant's service area.

To submit I/T/U pharmacy listings to CMS, Applicants will need to complete at a minimum, two worksheets within an Excel file labeled "ITU Pharmacy List" (see reference document entitled "ITU Pharmacy List").

1. Assuming that Applicant has only one unique I/T/U pharmacy network, do the following:

   Complete the worksheet labeled "ITU List - A". All columns should be completed with the information indicated in each column heading. Please be sure to complete all appropriate cells (columns) for every record (row) for which Applicant is listing a pharmacy. Only designate a worksheet as "ITU List – B" if Applicant is referencing an alternate or separate I/T/U pharmacy listing.

2. In the event Applicant is representing more than one unique I/T/U pharmacy network, create as many worksheets as may be necessary to provide all the unique networks. Label additional worksheets as "ITU List – B", "ITU List – C", etc.

3. The "Contract ID List" worksheet should list all of the contract numbers and the legal entity name(s) (as it appears in HPMS), that are represented by the I/T/U list provided in the worksheet labeled "ITU List - A". For many, if not all, contract numbers, the I/T/U pharmacy list may be the same. For those contract numbers associated with "ITU List – A", Applicant will complete the "Contract ID List" worksheet by populating the "List Identifier", column C, with an "A". If there are any circumstances, where there are contract numbers that have an alternate I/T/U pharmacy listing, Applicant will populate the "List Identifier" column with the appropriate letter identifier (i.e., B, C, etc.).

3.4.7 Specialty Pharmacy

A. In HPMS, complete the table below.

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PART D CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN IN HPMS:	YES	NO
1. Applicant agrees not to restrict access to Part D drugs by limiting distribution through a subset of network pharmacies, except when necessary to meet FDA limited distribution requirements or to ensure the appropriate dispensing of Part D drugs that require extraordinary special handling, provider		

	coordination, or patient education when such extraordinary requirements cannot be met by a network pharmacy.		
2.	Applicant agrees not to restrict access solely on the placement of a Part D drug in a "specialty/high cost" tier because this tier placement alone is not indicative of any special requirements associated with such drug. Applicant further agrees that requiring different reimbursement rates for certain "specialty" drugs is inconsistent with standard industry practice and that a Part D sponsor's use of such different reimbursement rates may demonstrate a violation of the convenient access standards by the Part D sponsor.		
3.	Applicant agrees not to require a pharmacy to be a "Specialty" pharmacy in order to dispense any drug that requires special attention if the network pharmacy is capable of appropriately dispensing the particular Part D drug or drugs in question.		

3.5 Enrollment and Eligibility

A. In HPMS, complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PART D CONTRACT. ATTEST 'YES' OR 'NO' TO E ACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN IN HPMS:	YES	NO
1. Applicant agrees to comply with the Enrollment and Eligibility guidelines that are posted on the www.cms.hhs.gov/ website.		
2. Applicant agrees to comply with forthcoming operational guidance on Creditable Coverage and the Late Enrollment Penalty.		
3. Applicant will permit the enrollment of all Medicare beneficiaries who are eligible for Part D and reside in the PDP service area during allowable enrollment periods according to CMS requirements.		
4. Applicant agrees to limit PDP enrollment to eligible Medicare beneficiaries who reside in the plan service area according to CMS requirements.		
5. Applicant will accept auto-enrollments and facilitated enrollments in accordance with procedures adopted by CMS for certain low-income beneficiaries who have failed to enroll in a Part D plan offering qualified prescription drug coverage		
6. Applicant agrees not to enroll beneficiaries except during allowable enrollment periods, including: the Annual Coordinated Enrollment Period, the Initial Enrollment Period, and any Special Enrollment Periods an individual might be eligible for.		
7. Applicant will collect and transmit data elements specified by CMS for the purposes of enrolling and disenrolling beneficiaries in accordance with the CMS Eligibility Enrollment and Disenrollment Guidance.		
8. Applicant agrees to transmit enrollment and disenrollment transactions within the timeframes provided in CMS Enrollment and Disenrollment Guidance.		
9. Applicant agrees that for enrollments, it will send individuals all required enrollment material and notices within the timeframes provided in the CMS Enrollment and Disenrollment Guidance.		
10. Applicant will develop and operate a process for enrolling Medicare beneficiaries in the PDP that includes: communicating with beneficiaries who are applying for enrollment in the PDP within timeframes specified by CMS in requirements initiating appropriate follow up with beneficiaries who have incomplete enrollment applications; and making enrollments effective according to the effective date policy associated with the enrollment period in which the enrollment is received.		
11. Applicant will permit voluntary disenrollments only during allowable periods as specified in CMS requirements.		
12. Applicant will accept and process disenrollment requests from beneficiaries, communicate these requests to CMS, and make the disenrollment effective according to the effective date policy associated with the enrollment period in which the disenrollment request is received.		
13. Applicant agrees that for disenrollments, it will send individuals an acknowledgement notice		

within 7 calendar days if it receives the disenrollment request directly from the individual; if the applicant only learns of disenrollment from CMS confirmation (e.g. as a result of enrollment in another plan), applicant must send notice confirming disenrollment within 7 calendar days.		
14. Applicant will notify enrolled beneficiaries in the event of a contract termination of the termination and alternatives for obtaining prescription drug coverage under Part D in accordance with Part 423 regulations.		
15. Applicant will develop and implement policies and procedures (including appropriate notice and due process requirements) for optional involuntary disenrollment as permitted by CMS.		
16. Applicant will ensure that information necessary to access the plan benefit, such as an ID card, is provided according to the timeframes described in section 30.4 of the PDP Enrollment and Disenrollment Guidance.		
17. Applicant will collect, review and transmit creditable coverage information in accordance with CMS guidance and policies		
18. Applicants that qualify to receive auto-enrollment and facilitated enrollment agree to process these enrollment in accordance with the guidance provided by CMS.		
19. Applicant agrees to establish business processes for quickly resolving urgent issues affecting beneficiaries, such as late changes in enrollment or copay status, in collaboration with CMS caseworkers.		
20. Applicant will query the Batch Eligibility Query (BEQ) or the Medicare Beneficiary Database User Interface (MBDUI) to receive: (a) Verification of Medicare Eligibility, (b) The end date of the beneficiary's Part D IEP, (c) Periods of enrollment in a Medicare plan that provides prescription drug coverage, and (d) Periods of enrollment in a retiree prescription drug plan whose sponsor receives a retiree drug subsidy from Medicare		
21. Applicant agrees to use the Low-Income Subsidy/Part D Premium Report Data File to determine match rates of their information to that of CMS within 72 hours of receipt. Applicant further agrees that their match rate should achieve 95 percent and that non-matches are resolved within 72 hours.		
22. Applicant agrees to provide CMS with the 4 Rx data for all their enrollees in a timely manner. The reports should verify that the Applicant's plan demonstrates the ability to have 4 Rx data in place for 95% of its prospective dual eligible enrollees by 3 days before the end of the month preceding the effective date of enrollment.		

3.6 Complaints Tracking

A. In HPMS, complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PART D CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN IN HPMS.	YES	NO
1. Applicant will resolve immediate needs complaints via the CMS Complaints Tracking Module within 2 business days.		
2. Applicant will continue to monitor and document complaint resolutions for complaints attributed to their contracts in the CMS' Complaint Tracking Module.		
3. Applicant will maintain Standard Operating Procedures that address how your organization will handle and quickly resolve immediate action cases, as well as, outline the steps your organization intends to take to have enrollees call your customer service directly for the prompt resolution of all inquiries.		

3.7 Medicare Prescription Drug Plan Finder

A. In HPMS, complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE		

APPROVED FOR A PART D CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN IN HPMS.	YES	NO
1. Applicant agrees to provide its CY 2008 drug pricing and pharmacy network data for publishing on the "Medicare Prescription Drug Plan Finder (MPDPF)" in the format and on a schedule required by CMS		
2. Applicant agrees to perform quality checks for data submitted to CMS for display on the MPDPF and agrees that failure to conduct quality checks may result in suppression of the Applicant's pricing data from the website.		
3. Applicant agrees that errors or omissions identified by CMS during analyses of the data will also result in the suppression of the Applicant's pricing data from the website.		

3.8 Grievances

A. In HPMS, complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PART D CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN IN HPMS.	YES	NO
1. Applicant will establish and maintain a process designed to track and address enrollees' grievances, and to assure that they will adopt appropriate timelines, policies and procedures and train the relevant staff and subcontractors on such policies and procedures in accordance with 42 CFR 423.564.		
2. Applicant agrees to abide by Chapter 18 of the Prescription Drug Benefit Manual and the Part D QIC Reconsideration Procedures Manual.		
3. Applicant will make enrollees aware of the grievance process through information and outreach materials.		
4. Applicant will accept grievances from enrollees at least by telephone and in writing (including facsimile)		
5. Applicant will maintain, and provides upon request by CMS access to records on all grievances received both orally and in writing, that includes, at a minimum: • Date of receipt of the grievance • Mode of receipt of grievance (i.e. fax, telephone, letter, etc.) • Person or entity that filed the grievance • Subject of the grievance • Final disposition of the grievance • Date the enrollee was notified of the disposition		

Note: A grievance is any complaint or dispute, other than one that involves a coverage determination, expressing dissatisfaction with any aspect of a PDP sponsor's operations, activities, or behavior, regardless of whether remedial action is requested. Examples of subjects of a grievance include, but are not limited to:

- Timeliness, appropriateness, access to, and/or setting of services provided by the PDP sponsor
- Concerns about waiting times, demeanor of pharmacy or customer service staff
- A dispute concerning the timeliness of filling a prescription or the accuracy of filling the prescription.

3.9 Exceptions and Appeals

A. In HPMS, complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PART D CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF	YES	NO

THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN IN HPMS.		
1. Applicant will adopt policies and procedures for beneficiary coverage determination, exceptions, and appeals consistent with 42 CFR §423 subpart M.		
2. Applicant will maintain an exceptions process that includes a written description of how your organization will provide for tiering exception requests, non-formulary requests, standard requests, and expedited requests, where applicable, and how your organization will comply with such description. Such policies and procedures will be made available to CMS on request.		
3. Applicant will assure that it will comply with 423.578(a) and 423.578 (b) which require a PDP sponsor to grant a tiering or off –formulary exception whenever it determines an exception is medically appropriate because the preferred drug (or on-formulary drug in the case of a formulary exception request): (a) would not be as effective for the enrollee as the requested drug; or (b) would have adverse effects for the enrollee, or (c) both. These requirements also apply to exceptions requests by Medicare eligible children for off-formulary Part D pediatric drugs and doses that are medically appropriate.		
4. Applicant will assure that the exceptions policy complies with the regulatory timelines for processing standard coverage determinations and exceptions requests: as expeditiously as the enrollee's health condition requires, but no later than 72 hours after the receipt of the request/supporting statement.		
5. Applicant will assure that the exceptions policy complies with the regulatory timelines for processing expedited coverage determinations and exceptions requests: as expeditiously as the enrollee's health condition requires, but no later than 24 hours after receipt of the request/supporting statement.		
6. Applicant will assure that the exceptions policy complies with the regulatory timelines for processing standard redeterminations: as expeditiously as the enrollee's health condition requires, but no later than 7 calendar days from receipt of the request.		
7. Applicant will assure that the exceptions policy complies with the regulatory timelines for processing expedited redeterminations: as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receipt of the request.		
8. Applicant will assure that the exceptions policy complies with the regulatory timelines for processing expedited coverage determinations and exceptions requests and redeterminations, including but not limited to forwarding the enrollee's request to IRE within 24 hours of the expiration of the appropriate adjudication timeframe if a decision could not be made.		
9. Applicant will make its enrollees aware of the coverage determination, exceptions, and appeals process through information provided in the Evidence of Coverage and outreach materials.		
10. Applicant will establish and maintain a process designed to track and address in a timely manner enrollees' exceptions requests, requests for coverage determination or, re-determination, requests for reconsideration by the Independent Review Entity (IRE), and requests for review by an Administrative Law Judge (ALJ) received both orally and in writing, that includes, at a minimum: • Date of receipt; • Date of any notification; • Disposition of request; and • Date of disposition		
11. Applicant will make available to CMS upon CMS request, exception and appeals records.		
12. Applicant agrees that the exceptions process will not be overly burdensome or onerous. For example, a Part D Sponsor may not require that ALL exception requests are accompanied with laboratory evidence.		
13. Applicant agrees that approved non-formulary drugs must be assigned to a		

	single existing tier. Applicant may not assign such drugs to a high-cost specialty tier if the level of cost-sharing in that tier exceeds 25%, or create a tier specifically designed for non-formulary exceptions.		
14.	Applicant may not restrict the number of exception requests submitted by an enrollee.		

3.10 Coordination of Benefits

A. In HPMS, complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PART D CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN IN HPMS:	YES	NO
1. Applicant agrees to comply with Coordination of Benefits guidance that is posted on the www.cms.hhs.gov/ website.		
2. Applicant develops and operates a system for collecting information from enrollees about enrollees' other health insurance, including whether such insurance covers outpatient prescription drugs.		
3. Applicant will permit SPAPs and other third party payers to coordinate benefits as required by the regulations in 42 CFR Part 423, Subpart J and CMS' most recent COB guidance. For example, an SPAP might pay the premium for supplemental benefits on behalf of a beneficiary, or pay a beneficiary's cost sharing.		
4. Applicant agrees to pay user fees as required under 423.6 and as may be required under 423.464 (c).		
5. Applicant agrees not to impose fees on SPAPs or other third-party insurers unrelated to the cost of coordination of benefits.		
6. Applicant will collect and update enrollee information concerning other health insurance as required in the current Coordination of Benefit Guidance.		
7. Applicant will coordinate payment of claims by enrollees' other health insurance, including SPAPs as required in the current Coordination of Benefit Guidance.		
8. Applicant agrees to send a COB survey within 30 days of the date the Applicant processes an enrollment transaction to beneficiaries who are not exempted in accordance with CMS guidance from this requirement (beneficiaries exempted would include, for example, autoenrollees and those who are passively enrolled in an MA-PD special needs plan).		
9. Applicant agrees to send a COB survey at least annually to all enrollees who are Medicare beneficiaries.		
10. Applicant agrees to send additional information captured on the COB survey about its enrollees' other sources of prescription drug coverage by sending electronic updates to the COB contractor.		
11. When a supplemental payer wishes to pay premiums on behalf of plan enrollees, Applicant will: • Accept premium payments made by these supplemental payers; • Suppress premium billing to the beneficiaries for whom it accepts premium payments from supplemental payers; • Advise enrollees not to use the SSA withhold when another payer is paying their premium (in whole or in part); and • Ensure that,the overall premium payment made by or on behalf of a beneficiary does not vary among plan enrollees.		
12. If Applicant agrees to enter into an agreement with SPAPs, accepting a risk-based, per capita amount to administer a wrap-around benefit on behalf of the beneficiary,		

the Applicant must follow the requirements set forth in the current COB guidance.		
13. When the Applicant's service area includes States that subsidize a portion of beneficiary cost-sharing through their SPAPs through a non-risk lump-sum contract with reconciliation, Applicant will: • Enter into an agreement to receive such subsidies; • Apply such subsidies to the first dollar of beneficiary cost sharing under the Applicant's Part D plan; and • Submit claims information to the State to support reconciliation.		
14. Applicant will provide clear and prominently displayed information identifying the SPAP as a co-sponsor of benefits when the Applicant participates in a risk- or non-risk lump sum per capita contract with an SPAP to provide wrap-around benefits to Part D enrollees.		

3.11 Tracking Out-of Pocket Costs (TrOOP)

A. In HPMS, complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PART D CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN IN HPMS:	YES	NO
1. Applicant will track each enrollee's true out of pocket (TrOOP) costs reflecting the amount the enrollee has spent out of pocket during a program year on covered Part D drugs.		
2. Applicant will accept data concerning third party payers in a format to be specified by CMS for use in the Applicant's TrOOP calculation.		
3. Applicant will process claims and track TrOOP in real time using the current HIPAA-approved NCPDP standard.		
4. Applicant will provide enrollees with a report on their TrOOP status at least monthly.		
5. Applicant will provide enrollees daily access to their current TrOOP status through the organization's toll-free customer service phone number.		
6. In the event of disenrollment, Applicant agrees to provide TrOOP status of the beneficiary as of the effective date of the disenrollment to the beneficiary and, as applicable, the new Part D Sponsor of record		
7. Applicant will retroactively adjust claims and recalculates TrOOP balances based on N1 transactions received from the TrOOP Facilitation Contractor that were created based on other than real-time TrOOP-eligible claims.		
8. Applicant will retroactively adjust claims and recalculate TrOOP balances based on receipts received from its Medicare enrollees that reflect amounts the enrollee paid on other than real-time TrOOP-eligible claims.		
9. Applicant agrees that when it receives an N1 transaction, but has no supplemental payer information on file to identify the payer, the Applicant contacts the beneficiary to identify the payer and sends the payer information to the COB Contractor via ECRS verification.		
10. Applicant agrees to retroactively adjust claims, recalculate TrOOP balances, and reimburse other payers (when applicable) whenever it receives information indicating that errors were made in the order of payment and there are multiple other payers on a beneficiary record.		
11. Applicant will count other payer paid amounts as satisfying the Part D deductible whether or not the entire amount counts toward TrOOP.		
12. Applicant will establish and identify in the Health Plan Management System (HPMS) a COB contact who can be contacted by CMS, the States and other payers to resolve		

COB issues.		
13. Applicant will establish an EOB Transfer contact who can be contacted by CMS, the States and other payers to resolve EOB transfer issues.		
14. Applicant agrees that when they receive notice that a beneficiary has disenrolled from the Applicant's Part D plan due to reenrollment in another Part D plan during the coverage year, the Applicant will send the beneficiary's TrOOP balance and gross covered drug spending amount to the other Part D Sponsor's EOB Transfer Contact, and update these amounts when applicable.		

- NOTE: For information regarding the TrOOP facilitator, Applicant may link to http://medifacd.ndchealth.com/home/medifacd_home.htm

3.12 Medicare Secondary Payer

A. In HPMS, complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PART D CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN IN HPMS:	YES	NO
1. Applicant is familiar with rules that determine when other payers are primary or secondary to Medicare as referenced in 42 CFR 423.462		
2. Applicant will adhere to MSP laws and any other Federal and State laws in establishing payers of last resort.		
3. Applicant will follow the Rules for Coordination of Benefits adopted in the most current National Association of Insurance Commissioner Coordination of Benefits Model Regulation.		
4. Applicant will process claims in real time to support the TrOOP facilitation process when it is a secondary payer in accordance with the application of MSP rules.		
5. Applicant will collect mistaken primary payment from insurers, group health plans, employer sponsors, enrollees and other entities.		
6. Applicant agrees that in situations involving workers' compensation claims, the Applicant makes an effort to determine which Part D drugs will be included as part of workers' compensation future medical payments (i.e., those services and items provided after the final settlement) and ensures that it does not make (or recovers) payment for such drugs.		

3.13 Marketing/Beneficiary Communications

A. In HPMS, complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PART D CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN IN HPMS.	YES	NO
1. Applicant will comply with marketing guidelines and approval procedures that are posted on the www.cms.hhs.gov/ website.		
2. Applicant will make available to beneficiaries only those marketing materials that comply with CMS' marketing guidelines.		
3. Annually and at the time of enrollment, the Applicant agrees to provide enrollees information about the following Part D features, as described in the marketing guidelines: • Enrollment Procedures • Beneficiary Procedural Rights • Potential for Contract Termination		

• Benefits • Types of Pharmacies in the Pharmacy Network • Out-of-network Pharmacy Access • Formulary • Premiums • Service Area		
4. Applicant agrees to provide general coverage information, as well as information concerning utilization, grievances, quality assurance, and sponsor financial information to any beneficiary upon request.		
5. Applicant will maintain a toll-free customer service call center that is open during usual business hours and provides customer telephone service in compliance with standard business practices. This means that the Applicant must comply with at least the following: • Call center operates during normal business hours, seven days a week from 8:00 AM to 8:00 PM for all time zones in which the Applicant offers a Part D plan. • A customer service representative will be available to answer beneficiary calls directly during the annual enrollment period and 60 days after the annual enrollment period. • After March 2nd, a customer service representative or an automated phone system may answer beneficiary calls on Saturdays, Sundays and holidays. • Eighty percent of all incoming customer calls are answered within 30 seconds. • The abandonment rate of all incoming customer calls does not exceed 5 percent. • Call center provides thorough information about the Part D benefit plan, including co-payments, deductibles, and network pharmacies. • Call center features an explicit process for handling customer complaints. • Call center shall provide service to non-English speaking and hearing impaired beneficiaries.		
6. Applicant will operate an Internet Web site that a) provides all the information described in Item #2 of this table, b) describes the Applicant's Part D current formularies, and c) provides 60-days' notice to potential and current plan enrollees of the removal or change in the tier placement of any drug on the plan's formulary		
7. Applicant will provide its plan enrollees, in a form understandable to enrollees and on at least a monthly basis for those months in which the enrollees use their Part D benefits, an explanation of benefits that states a) the item or service for which payment was made; b) notice of the enrollee's right to an itemized statement; c) a year-to-date statement of the total Part D benefits provided in relation to deductibles, coverage limits, and annual out-of-pocket thresholds; d) cumulative year-to-date total of incurred costs; and e) applicable formulary changes.		
8. Applicant agrees not to include co-branding names and/or logos of contracted providers or names and/or logos that are substantially similar to a provider's name and/or logo on member identification cards.		
9. Applicant agrees that the CY 2008 Annual Notice of Change (ANOC) / Summary of Benefits (SB) / Formulary must be received by members by October 31, 2007.		

3.14 Provider Communications

A. In HPMS, complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PART D CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN IN HPMS:	YES	NO
1. Applicant will operate toll-free call center to respond to inquiries from pharmacies and		

providers regarding the Applicant's Medicare prescription drug benefit. Inquiries will concern such operational areas as claims processing, benefit coverage, claims submission, and claims payment		
2. Applicant agrees that it will have a "one-stop" area on their website that provides needed information on the procedures, the forms and the contact information for their prior authorization and exceptions processes.		
3. Applicant will operate a toll-free call center to respond to physicians and other providers for information related to exceptions and prior authorizations as well as beneficiary appeals. The call center must operate during normal business hours and never less than 8:00 a.m. to 6:00 p.m., Monday through Friday according to the time zones for the regions in which they operate. Applicant may use voicemail provided the message: • Indicates that the mailbox is secure. • Lists the information that must be provided so the case can be worked (e.g., provider identification, beneficiary identification, exception (or appeal, if appeals call) being requested, whether an expedited exception (or appeal, if appeals call) is being requested). • For exceptions calls: articulates and follows a process for resolution within 24 hours of call for expedited coverage determination requests (including exceptions requests), 72 hours for standard coverage determinations. • For appeals calls: articulates and follows a process for resolution within 72 hours for expedited appeals, and 7 calendar days for standard appeals. • Provides and follows a process for immediate access in situations where an enrollee's life or health is in serious jeopardy.		

3.15 Compliance Plan

A. In HPMS, complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PART D CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN IN HPMS:	YES	NO
1. Applicant will implement a compliance plan in accordance with all Federal and State regulations and guidelines, including Chapter 9—Part D Program to Control Fraud, Waste and Abuse of the Prescription Drug Benefit Manual by time of CMS contract with the Part D Sponsor.		
2. Applicant will implement a compliance plan that consists of written policies, procedures, and standards of conduct articulating your organization's commitment to abide by all applicable Federal and State standards.		
3. Applicant will implement a compliance plan that designates an employee as the compliance officer and compliance committee accountable to senior management. (Note: This requirement cannot be delegated to a subcontractor.)		
4. Applicant will implement a compliance plan that includes effective training and education between the compliance officer, organization employees, contractors, agents, and directors.		
5. Applicant will implement a compliance plan that includes effective lines of communication between the compliance officer and organization employees, contractors, agents and directors and members of the compliance committee.		
6. Applicant will implement a compliance plan that includes disciplinary standards that are well-publicized.		
7. Applicant will implement a compliance plan that includes procedures for internal monitoring and auditing.		
8. Applicant will implement a compliance plan that includes procedures for ensuring		

prompt response to detected offenses and development of corrective action initiatives, relating to the Applicant's contract as a Part D sponsor.		
9. Applicant will implement a compliance plan that includes a comprehensive plan to detect, correct, and prevent fraud, waste and abuse.		

Note: Please be advised that the Part D Sponsor is ultimately responsible for the implementation and monitoring of the day-to-day operations of its Part D compliance program. Section 40.9 of Chapter 9 of the Prescription Drug Benefit Manual indicates that the compliance officer and compliance committee functions may not be delegated or subcontracted. A compliance plan adopted and operated by a Part D Sponsor's subcontractor is not sufficient to demonstrate that the Part D Sponsor meets the compliance program requirement.

B. Provide as an attachment a copy of your organization's Compliance Plan that you intend to use for this contract.

3.16 Reporting Requirements

A. In HPMS, complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PART D CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN IN HPMS:	YES	NO
REPORTING REQUIREMENTS GUIDANCE		
1. Applicant agrees to comply with the Reporting Requirements Guidance that is posted on the **www.cms.hhs.gov/** website.		
BUSINESS TRANSACTIONS AND FINANCIAL REQUIREMENTS		
2. Applicant will report, consistent with 42 CFR §423.514(b), information related to significant business transactions between the Part D plan sponsor and a party in interest within 120 days of the end of each fiscal year. This qualification includes combined financial statements, where required under 42 CFR §423.514(c).		
3. Applicant will notify CMS of any loans or other special financial arrangements made with contractors, subcontractors, and related entities as that term is defined in 42 CFR §423.501.		
4. Applicant will submit audited financial statements to CMS annually.		
CLAIMS DATA		
5. The Applicant or the Applicant's representative, such as a third party administrator (TPA), has data management processes and data systems capable of accomplishing collection of data in either an NCPDP or X12 format. Data to be collected will encompass quantity, type, and costs of pharmaceutical prescriptions filled for enrollees. The plan must link this information to Medicare beneficiary identification numbers (HIC#s).		
6. The Applicant or the Applicant's representative, such as a TPA, has data management processes and data systems capable of accomplishing submission of prescription drug claims information for Medicare enrollees for every Part D drug prescription in the format required by CMS, using batch submission processes. Data to be submitted will encompass quantity, type and costs of pharmaceutical prescriptions filled for enrollees. The plan must link this information to Medicare beneficiary identification numbers (HIC#s).		

7. The Applicant or the Applicant's representative, such as a TPA, has data management processes and data systems capable of accomplishing submission of data to CMS via the Medicare Data Communications Network (MDCN).		
8. The Applicant or the Applicant's representative, such as a TPA, has data management processes and data systems capable of accomplishing performance of data edit and quality control procedures to ensure accurate and complete prescription drug data.		
9. The Applicant or the Applicant's representative, such as a TPA, has data management processes and data systems capable of accomplishing correction of all data errors identified by CMS.		
10. The Applicant or the Applicant's representative, such as a TPA, has data management processes and data systems capable of accomplishing collection of data for dates of service within the coverage period with a 3-month closeout window for the submission of remaining unreported claims data.		
11. The Applicant or the Applicant's representative, such as a TPA, has data management processes and data systems capable of accomplishing provision of additional information for the purposes of reconciliation of risk factors, low income subsidy payments, reinsurance payments, and risk corridor as required by CMS.		
12. Applicant will send and receive claims data for third party payers from the CMS contractor that will serve as the clearinghouse for all Part D beneficiary outpatient drug claims.		
REBATE DATA		
13. The Applicant or the Applicant's representative has accounting systems capable of accomplishing the provision of documentation, as specified by CMS, to support the accuracy and completeness of rebate data. Documentation will be provided to CMS in response to an audit-based request.		
14. The Applicant will report rebate dollars on a quarterly basis at the manufacturer/brand name level (unique strength and package size not required) in the manner specified by CMS.		
15. The Applicant or the Applicant's representative has accounting systems capable of accomplishing the production of financial reports to support rebate accounting. The rebate accounting must allow for step-down cost reporting in which rebates received at the aggregate level may be apportioned down to the level of plan enrollees.		
16. Applicant agrees to report 100% of the remuneration it receives, including any process concessions for PBM services.		
17. Applicant will report Long-Term Care pharmacy rebate dollars on a quarterly basis at the manufacturer/brand name level (unique strength and package size not required) in a manner specified by CMS.		
OTHER DATA		
18. Applicant will report at a frequency determined by CMS specified data (pursuant to 42 CFR §423.514(a)) on a variety of measures to support payment, program integrity, program management, and quality improvement activities in a manner prescribed by CMS in the Part D Reporting Requirements.		
19. The Applicant will provide CMS with routine administrative reports (pursuant to 42 CFR 423.514 (a)) on a variety of measures that concern the Applicant's performance in the administration of the Part D benefit. Such reports shall be submitted according to instructions issued with timely notice by CMS.		
SUPPORTING WWW.MEDICARE.GOV		
20. The Applicant will submit pricing and pharmacy network information to be publicly reported on www.medicare.gov in order to provide Medicare beneficiaries with necessary information regarding prescription drug costs under the respective plans. Details regarding this data requirement will be posted on www.cms.hhs.gov by April 2007.		

CONFLICT OF INTEREST		
21. The Applicant will provide financial and organizational conflict of interest reports to CMS, pursuant to instructions to be issued by CMS.		

Note: Further detail on our approach to monitoring and oversight, including the updated reporting measures will be posted on the CMS website not later than May 2007.

3.17 Data Exchange Between Part D Sponsor and CMS

A. In HPMS, complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PART D CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN IN HPMS:	YES	NO
HPMS		
1. Applicant will use HPMS to communicate with CMS in support of the application process, formulary submission process, bid submission process, ongoing operations of the Part D program, and reporting and oversight activities. Part D sponsors are required to secure access to HPMS in order to carry out these functions.		
ENROLLMENT & PAYMENT		
2. Applicant will establish connectivity to CMS via the AT&T Medicare Data Communications Network (MDCN).		
3. Applicant will submit test enrollment and disenrollment transmissions.		
4. Applicant will obtain CMS User ID and Password.		
5. Applicant will submit enrollment, disenrollment and change transactions to communicate membership information to CMS each month.		
6. Applicant will reconcile Part D data to CMS enrollment/payment reports within 45 days of availability.		
7. Applicant will submit enrollment/payment attestation forms within 45 days of CMS report availability.		

3.18 Upgrades of Health Information Technology

A. In HPMS, complete the table below:

APPLICANT MUST ATTEST 'YES' TO THE FOLLOWING QUALIFICATION TO BE APPROVED FOR A PART D CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATION BY PLACING A CHECKMARK IN THE RELEVANT COLUMN IN HPMS:	YES	NO
1. As the Applicant implements, acquires, or upgrades health information technology systems, it shall utilize, where available and as applicable, health information technology systems and products that meet interoperability standards recognized by the Secretary of HHS. These interoperability standards will be further defined in guidance and may include interoperability specifications recommended by the Health Information Technology Standards Panel or specified in the Nationwide Health Information Network architecture standards, and interoperability standards		

recommended by the Certification Commission for Health Information Technology or other certifying bodies recognized by the Secretary.		

3.19 Health Insurance Portability and Accountability Act of 1996 (HIPAA)

A. In HPMS, complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PART D CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN IN HPMS:	YES	NO
1. Applicant will comply with all applicable standards, implementation specifications, and requirements in the Standards for Privacy of Individually Identifiable Health Information under 45 CFR Parts 160 and 164 subparts A and E.		
2. Applicant will comply with all applicable standards, implementation specifications, and requirements in the Security Standards under 45 CFR Parts 160, 162 and 164		
3. Applicant will comply with all applicable standards, implementation specifications, and requirements in the Standard Unique Health Identifier for Health Care Providers under 45 CFR Parts 160 and 162.		
4. Applicant will comply with all applicable standards, implementation specifications, and requirements in the Standards for Electronic Transactions under 45 CFR Parts 160 and 162.		
5. Applicant agrees to transmit payment and remittance advice consistent with the HIPAA-adopted ACS X12N 835, Version 4010/4010A1: Health Care Claim Payment and Remittance Advice Implementation Guide ("835").		
6. Applicant will report to CMS any unauthorized public disclosures of protected health information within 48 hours of the Applicant's detection of such disclosure.		
7. Applicant agrees that it, and its subcontractors, shall not perform any activities under its Part D sponsor contract at a location outside of the United States without the prior written approval of CMS. In making a decision to authorize the performance of work outside of the United States, CMS will consider the following factors, including but not limited to: • The Applicant's/subcontractor's compliance with, and the enforceability of, Part D program requirements concerning system security. • The Applicant's/subcontractor's compliance with and the enforceability of, Part D program requirements concerning information and data confidentiality and privacy. • The Applicant's/subcontractor's compliance with, and the enforceability of, other relevant Part D program requirements. • The Applicant's/subcontractor's compliance with, and the enforceability of, Part D corporate compliance plan requirements. • The Applicant's/subcontractor's compliance with, and enforceability of all laws and regulations applicable to work performed outside of the United States. • The performance the work outside of the United States is in the best interests of the United States.		
8. Applicant agrees, in accordance with forthcoming CMS guidance, it should contract with an unrelated organization qualified to review and certify that the Applicant has developed and implemented systems, policies, and procedures sufficient to protect individual beneficiary information from unauthorized		

disclosure. Applicant agrees it should obtain re-certification from a qualified reviewer once every two years.		

3.20 Prohibition on Use of SSN or Medicare ID number on Enrollee ID Cards

A. In HPMS, complete the table below:

APPLICANT MUST ATTEST 'YES' TO THE FOLLOWING QUALIFICATION TO BE APPROVED FOR A PART D CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATION BY PLACING A CHECKMARK IN THE RELEVANT COLUMN IN HPMS:	YES	NO
1. Applicant agrees not to use an enrollee's Social Security Number (SSN) or Medicare ID Number on the enrollee's identification card.		

3.21 Record Retention

A. In HPMS, complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PART D CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN IN HPMS:	YES	NO
1. The Applicant will maintain books, records, documents, and other evidence of accounting procedures and practices consistent with 42 CFR §423.505(d).		
2. Applicant agrees to have pharmacies, contracted for the Part D benefit, maintain prescription records in their original format for the greater of 3 years or the period required by State law and allow those records to be transferred to an electronic format that replicated the original prescription for the remaining 7 years of the 10 year record retention requirement.		
3. Applicant agrees to keep all other records—except prescription records—that must be retained for Medicare under Part C and Part D in the format(s) required by State law or at the Applicant's discretion.		

3.22 Claims Processing

A. In HPMS, complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PART D CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN IN HPMS:	YES	NO
1. Applicant develops and operates an on-line claims processing system that operates in real time to ensure accurate and timely payment of all claims submitted by network pharmacies on behalf of Part D plan enrollees. System operates according to the following standards: • 98% response within 4 seconds • 99% of all claims paid with no errors • 99% system availability *Note: In preparation for implementation CMS (except for scheduled down time and disasters) will conduct testing and otherwise monitor for the impact of TrOOP system interfaces with plan claims processing systems, and adjust these standards as appropriate if necessary.*		
2. Applicant develops and operates a paper claims processing system designed to pay		

claims submitted by non-network pharmacies on behalf of Part D plan enrollees. Applicant processes claims according to the following standards: • 100% of claims requiring no intervention handled within 15 calendar days • 100% of claims requiring intervention handled within 30 calendar days • 99% of all manually keyed claims paid with no errors		
3. Applicant will develop and have available for CMS inspection a complete description of your claims adjudication system including: • Hardware and software • Operating system • MediSpan or First Data Bank database, including number of iterations saved • Number of sites processing claims (including disaster recovery back-up system) • System volume in covered lives, including the number of transactions the system can support per day and per hour.		
4. Applicant will develop and have available to CMS upon request policies and procedures that include a complete description and flow chart detailing the claims adjudication process for each: • Contracted network pharmacies • Out-of-network pharmacies • Paper claims • Batch-processed claims • Manual claim entry (e.g. for processing direct member reimbursement)		
5. Applicant will develop and will make available to CMS upon request policies and procedures that include a complete description of claim detail management, including: • The length of time that detailed claim information is maintained online (not less than 12 months) • The data storage process after it is no longer online • The length of time that detailed claim information is stored when it is no longer online (not less than 10 years)		
6. Applicant will develop and have available to CMS upon request policies and procedures that include a complete description of the accessibility of this information for data capture purposes and flow chart of the claims data retrieval process for each: • Entire claims history file • Encounter data required by state mandates • Encounter data required by alternate funding sources • Out-of-pocket maximum/deductible files		
7. Applicant will develop and have available to CMS upon request policies and procedures that include a description of how overpayments and underpayments to pharmacies, as well as enrollees, are handled and recovery procedures		
8. Applicant will develop and have available to CMS upon request policies and procedures that include a complete description of procedures surrounding disputed claims, including: • The steps that a pharmacy and/or enrollee must follow to dispute a claim reimbursement • The average amount of time needed to resolve a claims dispute • Turnaround time standards for dispute resolution.		
9. Applicant will have a robust testing process that will identify and correct any plan configuration errors prior to implementation.		
10. Applicant will accept eligibility files and any prior claims data electronically in NCPDP format.		
11. Applicant can and will document the manner and extent to which it has tested benefit designs such as drug exclusions or quantity limitations and plan parameters such as co-payments or benefit maximums.		
12. Applicant agrees to implement within 90 days any new messaging approved by the NCPDP Workgroup to adjudicate a Part D claim and appropriately coordinate benefits in real time.		

Submit as an attachment, per the instructions in Section 2.4, the following certification:

4.0 CERTIFICATION

I, the undersigned, certify to the following:

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

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

3) I agree that if my organization meets the minimum qualifications and is Medicare-approved, and my organization enters into a Part D contract with CMS, I will abide by the requirements contained in Section 3.0 of this Application and provide the services outlined in my application.

4) I agree that CMS may inspect any and all information necessary including inspecting of the premises of the Applicant's organization or plan to ensure compliance with stated Federal requirements including specific provisions for which I have attested. I further agree to immediately notify CMS if despite these attestations I become aware of circumstances which preclude full compliance by January 1, 2008 with the requirement stated here in this application as well as in Part 423 of 42 CFR of the regulation.

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 qualification to enter into a Part D contract with CMS.

7) I acknowledge that I am aware that there is operational policy guidance, including the forthcoming 2008 Call Letter, relevant to this application that is posted on the CMS website and that it is continually updated. Organizations submitting an application in response to this solicitation acknowledge that they will comply with such guidance should they be approved for a Part D contract.

_____ _____
Authorized Representative Name (printed) Title

_____ _____

Authorized Representative Signature Date (MM/DD/YYYY)

5.0 APPENDICES

APPENDIX I

Banking Information Form

As Government vendors, organizations with Medicare contracts are paid by the Department of Treasury through an Electronic Funds Transfer (EFT) program using the Automated Clearing House Network (ACH). 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.

Please provide the following information to assist the Centers for Medicare and Medicaid Services in establishing payment arrangements for your organization. Mail the completed chart to the following address by March 12, 2007.

Centers for Medicaid & Medicare Services
Attention: Yvonne Rice
Mail Stop C1-05-17
7500 Security Blvd.
Baltimore, MD 21244

ORGANIZATION INFORMATION

Name of Organization:	DBA, if any:
Full Address of Organization *(Street, City, Zip):*	
Contact Person Name:	Telephone Number:
Contract Numbers, if known:	
Employer/Tax Identification Number (EIN/TIN):	
EIN/TIN Name (*Name of Business for tax purposes as registered with the IRS):* *A W-9 may be required*	
Full Address for 1099 Tax Form *(Street, City, Zip)*:	

FINANCIAL INSTITUTION

Name of Bank:	
Full Address of Bank *(Street, City, Zip):*	
ACH/EFT Coordinator Name:	Telephone Number:
Nine Digit Routing Transit (ABA Number):	
Depositor Account Title:	
Depositor Account Number:	
Check Account Type: *(Please Attach a Copy of A Voided Check)* ☐Checking ☐Savings	

SIGNATURE & TITLE OFAPPLICANT'S AUTHORIZED REPRESENTATIVE

Signature: _____

Date: _____

Title: _____

Print Name: _____

Phone Number: _____

APPENDIX II

Application to Request Federal Waiver of State Licensure Requirement for Prescription Drug Plan (PDP)

A. COMPLETE THE TABLE BELOW **Contract#** _____

IDENTIFY THE CORPORATION SEEKING WAIVER OF STATE LICENSURE REQUIREMENT FOR PDP PLAN	
Full Legal Corporate Name:	D.B.A:
Full Address of Corporation: *(Street, City, State, Zip – No Post Office Boxes):*	
Corporation Telephone Number:	Corporation Fax Number:
PROVIDE THE CORPORATION'S CONTACT INFORMATION FOR THE PERSON WHO WILL ACT AS THE MAIN CONTACT	
Name of Individual:	Title:
Address of Individual: *(Street, City, State, Zip – No Post Office Boxes):*	
Direct Telephone Number:	Fax Number:
Email Address:	

B. REQUEST
I, on behalf of the legal entity identified in Section A, above, hereby request that the Secretary of the Department of Health and Human Services, pursuant to the authority granted under Section 1855(a) (2) and Section 1860D-12(c) of the Social Security Act, grant a waiver of the requirement that our organization be licensed under (Name of State or for Regional Plan Waiver, States) _____ State laws as a risk-bearing entity eligible to sponsor prescription drug benefits coverage.

D. CERTIFICATION
The undersigned officer has read this completed request for federal waiver form and does hereby declare that the facts, representations, and statements made in this form together with any attached information are true and complete to the best of my knowledge, information, and belief. The information herein declared by me represents matters about which I am competent, qualified, and authorized to represent the corporation. If any events, including the passage of time, should occur that materially change any of the answers to this request for federal waiver, the corporation agrees to notify the Centers for Medicare & Medicaid services immediately.

Corporate Name: _____ Date: _____
By: _____
Print Name: _____
Title: _____
Witness/Attest: _____

E. SUBMTTING FORM
If submitting separately from Part D, send 3 copies of this waiver request form to the below address. Applicants must send no later than March 12, 2007.

Centers for Medicare & Medicaid Services (CMS)
Center for Beneficiary Choices
Attention: Part D Application
7500 Security Boulevard

Mail Stop C1-26-12
Baltimore, Maryland 21244-1850

F. INSTRUCTIONS FOR COMPLETING COVER SHEET OF LICENSURE WAIVER APPLICATION

Section A **Contract #**_____

- Enter the corporate name
- Enter the name under which your PDP will do business (D.B.A)
- Enter the street address, telephone number and facsimile number of the Corporation at its corporate headquarters
- Enter the name, title, telephone number, fax number, and email address of the main contact person

Section B

- Indicate the State for which you are requesting a waiver or the States for which you are requesting a Regional Plan Waiver.

Section C

- Have a duly appointed corporate officer sign and date this form in the presence of a witness

If you have any questions regarding this form please contact:
Joseph Millstone
410-786-2976

INSTRUCTIONS FOLLOW

(THIS SECTION FOR OFFICIAL USE ONLY)

Supporting Documentation for Request of Federal Waiver of State Licensure Requirement for Prescription Drug Plan (PDP) Sponsors
Complete Sections II and IV

I. BACKGROUND AND PURPOSE

This waiver request form is for use by Applicants who wish to enter into a contract with the Centers for Medicare and Medicaid Services (CMS) to become Prescription Drug Plan (PDP) sponsors and provide prescription drug plan benefits to eligible Medicare beneficiaries without a State risk-bearing entity license.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) generally requires Applicants who wish to become PDP sponsors to be licensed under State law as a risk-bearing entity eligible to offer health insurance or health benefits coverage in each State in which the Applicant wishes to offer a PDP. However, the MMA created several exceptions to this State licensure requirement.

In general, there are 2 types of waivers – both of which are more fully explained in Section II below. The waivers are: (1) Single State waivers. For these waivers, the Applicant should submit a separate waiver request for each State, and the waiver is effective only with respect to the single State. (2) Regional plan waivers. These waivers may be obtained if an Applicant is licensed in one State in a region and wishes to receive a waiver for all the other States in the region in which it is not licensed. In this case, the entity need only submit one waiver request – not one for each and every State in which it is not licensed.
Waiver requests should be submitted to CMS using the criteria described in the remainder of this paper.

Approval of a waiver request, in no way suggests that the Applicant is approved for a Medicare contract with CMS. In addition to approval of a waiver request, the Applicant will be required to submit a Medicare contract application that demonstrates that the Applicant can meet the Federal definition of a PDP sponsor and that the prescription drug plan being offered will meet all plan requirements for PDPs.

Applicants who receive a waiver from State licensure must also comply with CMS standards for financial solvency and capital adequacy if they wish to receive a PDP contract.

II. WAIVER ELIGIBILITY

The following constitute the waivers available to Applicants. These are the sole grounds for receiving waivers.

A. SINGLE STATE WAIVER

The Applicant is requesting a single state waiver for the following state: _____. Please indicate the grounds upon which you are requesting a waiver (check all applicable areas).

1. The State has failed to complete action on a licensing application within 90 days of the date of the State's receipt of a substantially complete application. 42 CFR 423. 410(b) (1).
2. The State does not have a licensing process in effect with respect to PDP sponsors. 42 CFR 423.410(c).

3. The State has denied the license application on the basis of one of the following: (a) material requirements, procedures, or standards (other than solvency requirements) not generally applied by the State to other entities engaged in a substantially similar business; or (b) the State requires, as a condition of licensure, the Applicant to offer any product or plan other than a PDP. 42 CFR 423.410(b)(2).
4. The State has denied the licensure application, in whole or in part, for one of the following reasons: (a) on the basis of the Applicant's failure to meet solvency requirements that are different from the solvency standards developed by CMS; or (b) the State has imposed, as a condition of licensing, any documentation or information requirements relating to solvency that are different from the information or documentation requirements in the solvency standards developed by CMS. 42 CFR 423.410(b)(3).
5. The State has denied the licensure application on the basis of grounds other than those required under Federal law. 42 CFR 423.410(b)(4).

NOTE: To meet the conditions for CMS to grant a state licensure waiver pursuant to 42 CFR §423.410(b), the waiver applicant must demonstrate that by the time the waiver application is submitted to CMS, either:

1) The State has already had a substantially complete license application for 90 days and has not made a determination, or
2) The State has denied the license application for one of the reasons specified in 42 CFR §423.410 (b)(2) through (b)(4).

In order to apply for a CMS waiver based on the ground that a State did not act within 90 days of receiving a substantially complete application, the State must have had a substantially complete application for 90 days at the time the waiver applicant applies to CMS for a waiver. Therefore, in order to use this ground as a basis for a waiver, any new State license application must be received by a State(s) no later than December 1, 2006. This will help insure that the State has time to confirm "the receipt and completeness of the application" which is necessary to establish that the 90-day period has been met. It may be prudent to file the State application sooner than December 1, 2006 in case a State does not accept an application as being substantially complete. Furthermore, filing the application no later than December 1, 2006 will allow the State time to process the application and either approve or deny it.

B. REGIONAL PLAN WAIVERS

The Applicant is State-licensed in the State(s) of _____ and is applying for a regional plan waiver in the following region(s): _____ as provided under 42 CFR 423.415(a). The Applicant must demonstrate that it submitted a substantially complete licensure application in each State in the region for which it does not already have State licensure, except that no such application is necessary if CMS determines that the State does not have a licensing process for potential PDP sponsors.

III. WAIVER DURATION

A. SINGLE STATE WAIVER

The Single State waiver listed in II.A is effective for up to 36 months only and cannot be renewed unless CMS determines that the State in question does not have a licensing process in effect with respect to PDP sponsors. Thus, by the end of the three-year waiver period the PDP sponsor must be State-licensed if it wishes to continue as a PDP sponsor, unless CMS determines that the State in question has chosen not to create a licensing process for PDP sponsors – in which case the

waiver can continue until CMS determines that a licensure process has been created. Single State waivers automatically terminate if the PDP sponsor obtains State licensure.

B. REGIONAL PLAN WAIVERS

The Regional Plan waivers expire at the end of the time period the Secretary determines is appropriate for timely processing of the licensure application, but in no case will a waiver extend beyond the end of the calendar year. For both Single State and Regional Plan waivers, the waiver will terminate if the contract with Medicare terminates.

IV. INFORMATION TO BE INCLUDED IN THIS REQUEST

While the applicant should provide information concerning each of the following areas, the specific information and documentation requested below are not necessarily all inclusive for CMS to approve or deny the request. Applicants should provide any information and all documentation necessary to substantiate their request.

a) Provide a narrative of the circumstances leading to the PDP's eligibility for a waiver based on one of the grounds listed in section II. Include information about the State risk-bearing entity license for which the PDP applied, the application process that the PDP followed, and any relevant interaction with the State.

b) Provide documentation to substantiate the narrative required in (a). Depending on the grounds for waiver eligibility, this documentation should include but is not necessarily limited to the list below. For Regional Plan Waivers, group response to numbers 1-6, as they apply, by state:

1. Evidence of State's failure to act on a licensure application on a timely basis

Copy of the dated cover sheet to the application submitted to the State, State confirmation of the receipt and completeness of the application, State requests for additional information, and all pertinent correspondence with the State relating to the status of the application, etc.

2. Evidence of denial of the application based on discriminatory treatment

Copy of denial letter from the State, copy of "discriminatory" material requirements (including, State laws and regulation), procedures or standards to which the PDP was required to comply that are not generally applicable to other entities engaged in a substantially similar business, a copy of State licensure requirements that the PDP offer a particular product or plan in addition to a Medicare plan, and any supplemental material received from the State explaining their rationale for the denial, etc.

PDPs seeking a waiver on the grounds that they are subject to requirements, procedures and standards not applicable to entities

engaged in a "substantially similar business" must demonstrate through submission of these and other appropriate materials:

a) The types of entities subject to the different requirements, procedures and standards are engaged in a "substantially similar business".

b) The State requirements, procedures and standards imposed on the PDP entity are not applicable to other "substantially similar business" entities.

3. Evidence of denial of the application based on solvency requirements
Copy of denial letter from the State, copy of State solvency requirements, demonstration of the difference between State solvency requirements, procedures and standards and Federal PDP solvency requirements, procedures and standards, any other State information regarding documentation, information, and other material requirements, procedures or standards relating to solvency, or any correspondence detailing the reason the application was denied, etc.

4. Evidence of State licensure standards other than those required by Federal law
Memo identifying the State licensure standards by reference to relevant State law, regulation, or policy guidance and describing the how those standards differ from those required by Federal law.

5. Regional Plan Waiver
Evidence of licensure in one State within a regional plan and evidence that a substantially complete application has been submitted to the other States in the region – unless CMS determines that there is no PDP licensing process in effect in a State.

c) Provide the name, address and telephone number of all State regulatory officials involved in the State application and/or denial proceedings.

d) Provide any other information that you believe supports your request for a waiver under Section II.

V. OVERVIEW OF WAIVER REQUEST PROCESS

For single-state waivers, section 1860D-12(c) and section 1855(a)(2) of the Act requires the Secretary to grant or deny this waiver request within 60 days after the date the Secretary determines that a substantially complete application has been filed. Upon receipt of a waiver request, CMS will review it to determine whether it contains sufficient information to approve or deny the request. The 60-day review period begins at the time CMS determines that the applications is substantially complete. For those applications deemed incomplete, CMS will work with the applicant to identify the remaining information necessary to either approve or deny the request.

APPENDIX III

CERTIFICATION OF MONTHLY ENROLLMENT AND PAYMENT DATA RELATING TO CMS PAYMENT TO A PDP

Pursuant to the contract(s) between the Centers for Medicare & Medicaid Services (CMS), and _____ *(name of PDP Organization Applicant)* hereafter referred to as the "Organization" governing the operation of the following PDPs _____ *(plan identification numbers)*, the PDP hereby requests payment under the contract, and in doing so, makes the following certifications concerning CMS payments to the Organization. The Organization acknowledges that the information described below directly affects the calculation of CMS payments to the Organization and that misrepresentations to CMS about the accuracy of such information may result in Federal civil action and/or criminal prosecution. This certification shall not be considered a waiver of the Organization's right to seek payment adjustments from CMS based on information or data that does not become available until after the date the PDP submits this certification.

1. The Organization has reported to CMS for applications received in the month of_____ *(month and year)* all new enrollments, disenrollments, and changes in Plan Benefit Packages with respect to the above-stated PDP plans. Based on best knowledge, information, and belief, all information submitted to CMS in this report is accurate, complete, and truthful.

2. The Organization has reviewed the CMS monthly membership transaction report and reply (TRR) listing for the month of _____ *(month and year)* for the above-stated PDP plans and has submitted requests to the IntegriGuard, under separate cover, for retroactive adjustments to correct payment data when the Organization has more accurate information. This may include enrollment status and State and County Code related to a specific beneficiary. For those portions of the monthly membership report and the reply listing to which the Organization raises no objection, the Organization, through the certifying CEO/CFO, will be deemed to have attested, based on best knowledge, information, and belief, to their accuracy, completeness, and truthfulness.

NAME: _____
TITLE: _____
On behalf of: _____ *(Organization)*

NOTE: The person signing this form must be the CEO, CFO, or an individual delegated the authority to sign on behalf of on of the CEO or CFO and who reports to the CEO or CFO. Otherwise the certification will be considered invalid, per 42 CFR §423.505(k).

APPENDIX IV
Financial Solvency Documentation
For Applicant Not Licensed as a Risk-bearing Entity in Any State

I. DOCUMENTATION

A. Net Worth - Minimum Net Worth: $1.5 million

1. Documentation of Minimum Net Worth

At the time of application, the potential PDP Sponsor not licensed in any state must show evidence of the required minimum net worth. The PDP Sponsor must demonstrate this through an independently audited financial statement if it has been in operation at least twelve months.

If the organization has not been in operation at least twelve months it may choose to 1) obtain an independently audited financial statement for a shorter time period; or 2) demonstrate that it has the minimum net worth through presentation of an unaudited financial statement that contains sufficient detail that CMS may verify the validity of the financial presentation. The unaudited financial statement must be accompanied by an actuarial opinion by a qualified actuary regarding the assumptions and methods used in determining loss reserves, actuarial liabilities and related items.

A qualified actuary for the purposes of this application means a member in good standing of the American Academy of Actuaries or a person recognized by the Academy as qualified for membership, or a person who has otherwise demonstrated competency in the field of actuarial determination and is satisfactory to CMS.

B. Financial Plan

1. Plan Content and Coverage

At the time of application, the PDP Sponsor must submit a business plan (with supporting financial projections and assumptions, satisfactory to CMS), covering the first twelve months of operation under the Medicare contract and meeting the requirements stated below. If the plan projects losses, the business plan must cover the period for twelve months past the date of projected break-even.

The business plan must include a financial plan with:

a. A detailed marketing plan;
b. Statements of revenue and expense on an accrual basis;
c. A cash flow statement;
d. Balance sheets;
e. The assumptions in support of the financial plan;
f. If applicable, availability of financial resources to meet projected losses; (if no projected losses this does not preclude applicant from calculating projected losses as prescribed by CMS in 2. b. below)and
g. Independent actuarial certification of business plan assumptions and plan feasibility by a qualified actuary.

2. Funding for Projected Losses

(a) Allowable sources of funding:

In the financial plan, the PDP Sponsor must demonstrate that it has the resources available to meet the projected losses for time-period to breakeven. Except for the use of guarantees as provided in section (a) below, letters of credit as provided in section (b) below, and other means as provided in section (c) below, the resources must be assets on the balance sheet of the PDP Sponsor in a form that is either cash or is convertible to cash in a timely manner (i.e. cash or cash equivalents), pursuant to the financial plan.

(i) Guarantees will be acceptable as a resource to meet projected losses under the conditions detailed in Section III, Guarantees.

(ii) An irrevocable, clean, unconditional, evergreen letter of credit may be used in place of cash or cash equivalents if prior approval is obtained from CMS. It must be issued or confirmed by a qualified United States financial institution as defined in Section II.B, Insolvency, below. The letter of credit shall contain an issue date and expiration date and shall stipulate that the beneficiary need only draw a sight draft under the letter of credit and present it to obtain funds and that no other document need be presented.

“Beneficiary” means the PDP sponsor for whose benefit the credit has been established and any successor of the PDP sponsor by operation of law. If a court of law appoints a successor in interest to the named beneficiary, then the named beneficiary includes the court appointed bankruptcy trustee or receiver.
The letter of credit also shall indicate that it is not subject to any condition or qualifications any other agreement, documents or entities.

CMS must be notified in writing thirty days prior to the expiration without renewal or the reduction of a proposed or existing letter of credit or replacement of a letter of credit by one for a reduced amount.

Prior written approval of CMS should be secured by the PDP sponsor of any form of proposed letter of credit arrangements before it is concluded for purposes of funding for projected losses.

(iii) If approved by CMS, based on appropriate standards promulgated by CMS, a PDP sponsor may use the following to fund projected fund losses for periods after the first year: lines of credit from regulated financial institutions, legally binding agreements for capital contributions, or other legally binding contracts of a similar level of reliability.

NOTE: A plan needs to maintain its $1.5 million in net worth to meet the net worth standard (Section A, above) and may not use any portion of the $1.5 million in net worth to fund the projected losses. Net worth in excess of $1.5 million, which is funded through the forms allowable for meeting projected losses (i.e., cash, or cash equivalents,.,) may be counted in the projected losses funding however the minimum $750,000 liquidity requirement (Section C, below) must still be met and may not be used to meet the projected losses.

(b) Calculation of projected losses:

An applicant that has had state licensure waived must demonstrate that in order to cover projected losses, the applicant possesses allowable sources of funding sufficient to cover the greater of:

(i) 7.5 percent of the aggregated projected target amount for a given year (aggregated projected target amount is calculated by estimating the average monthly per capita cost of benefits (excluding administrative costs) and multiplying that amount by member months for a 12 month period), or

(ii) Resources to cover 100% of any projected losses, if the business plan projects losses greater than 7.5% of the aggregated projected target amount.

The applicant must include with the application, a worksheet calculating the aggregated projected target amount as defined above.

Enrollment projections, once submitted to CMS as part of the Applicant's originally submitted financial solvency documentation, may be revised only when accompanied by supporting documentation providing an explanation for the revision along with a revised financial plan. CMS will not accept revisions made solely to ensure that the calculation of required funding for projected losses results in an amount less than or equal to the Applicant's available financial resources. Additionally, the Applicant must submit an attestation signed by the CEO, CFO, or an individual designated to sign on his or her behalf and who reports directly to the officer, describing the basis for the changes in enrollment projections (e.g., updated Medicare Part D market analysis information).

C. Liquidity

The PDP Sponsor must have sufficient cash flow to meet its financial obligations as they become due. The amount of minimum net worth requirement to be met by cash or cash equivalents is $750,000. Cash equivalents are short term highly liquid investments that can be readily converted to cash. To be classified as cash equivalents these investments must have a maturity date not longer than 3 months from the date of purchase

In determining the ability of a PDP Sponsor to meet this requirement, CMS will consider the following:

(a) The timeliness of payment,
(b) The extent to which the current ratio is maintained at 1:1 or greater, or whether there is a change in the current ratio over a period of time, and
(c) The availability of outside financial resources.

CMS may apply the following corresponding corrective action remedies:

(a) If the PDP Sponsor fails to pay obligations as they become due, CMS will require the PDP Sponsor to initiate corrective action to pay all overdue obligations.
(b) CMS may require the PDP Sponsor to initiate corrective action if any of the following are evident:
(1) the current ratio declines significantly; or
(2) a continued downward trend in the current ratio. The corrective action may include a change in the distribution of assets, a reduction of liabilities or alternative arrangements to secure additional funding to restore the current ratio to at least 1:1.
(c) If there is a change in the availability of the outside resources, CMS will require the PDP Sponsor to obtain funding from alternative financial resources.

D. Methods of Accounting

The PDP Sponsor may use the standards of Generally Accepted Accounting Principles (GAAP) or it may use the standards of Statutory Accounting Principles (SAP) applicable to the type of organization

it would have been licensed as at the state level if a waiver were not granted by CMS. Whether GAAP or SAP is utilized however, there are certain additional differences cited below for waivered PDP Sponsors.

Generally Accepted Accounting Principles (GAAP) are those accounting principles or practices prescribed or permitted by the Financial Accounting Standards Board.
Statutory Accounting Principles are those accounting principles or practices prescribed or permitted by the domiciliary State insurance department in the State that the PDP Sponsor operates.

Waivered organizations should note that the maximum period of waiver is limited by Federal regulation. At such time as the waiver expires, the PDP Sponsor would have to obtain a risk bearing license.

Waivered PDP Sponsors should adjust their balance sheets as follows:

1. Calculation-Assets

   The following asset classes will not be admitted as assets:

   - Good will
   - Acquisition costs
   - Other similar intangible assets

2. Calculation- Liabilities

   Net worth means the excess of total admitted assets over total liabilities, but the liabilities shall not include fully subordinated debt.

   Subordinated debt means an obligation that is owed by an organization, that the creditor of the obligation, by law, agreement, or otherwise, has a lower repayment rank in the hierarchy of creditors than another creditor. The creditor would be entitled to repayment only after all higher ranking creditor's claims have been satisfied. A debt is fully subordinated if it has a lower repayment rank than all other classes of creditors and is payable out of net worth in excess of that required under Section IA, Net Worth and under Section IC, Liquidity above.

   In order to be considered fully subordinated debt for the purpose of calculating net worth, the subordinated debt obligation must be a written instrument and include:

   a) The effective date, amount, interest and parties involved.
   b) The principal sum and/or any interest accrued thereon that are subject to and subordinate to all other liabilities of the PDP sponsor, and upon dissolution or liquidation, no payment of any kind shall be made until all other liabilities of the PDP sponsor have been paid.
   c) The instrument states that the parties agree that the PDP sponsor must obtain written approval from CMS prior to the payment of interest or repayment of principal.

E. Financial Indicators and Reporting

The PDP Sponsor must file a Health Blank Form (in the same format as utilized by the National Association of Insurance Commissioners) to CMS. The portion of the Health Blank Form submitted to CMS will be limited to the following pages:

- Jurat Page
- Assets
- Liabilities, Capital and Surplus
- Statement of Revenue and Expenses

- Capital and Surplus Account
- Cash Flow
- Actuarial Opinion (the actuarial opinion is required only of annual report filings). In addition, the PDP Sponsor shall submit an annual independently audited financial statement with management letter.

Note: Future frequency of reporting will be both quarterly (first, second, and third quarters only) and annually to CMS. CMS may choose to initiate monthly reporting from certain PDP Sponsors who because of their financial status CMS deems may require additional monitoring.

Reporting shall be on the following schedule:

Quarterly reporting PDP sponsors shall report within 45 days of the close of a calendar quarter ending on the last day of March, June and September. No separate quarterly report shall be required for the final quarter of the year.

Annually reporting and quarterly reporting PDP sponsors shall report annually within 120 days of the close of the calendar year i.e. by April 30th or within 10 days of the receipt of the annual audited financial statement, whichever is earlier.

Financial reporting may be the under the principles of General Accepted Accounting Principles (GAAP) or under Statutory Accounting Principles (SAP) applicable to similar organizations of similar type within the state where the organization is based. However, if an organization chooses to report under GAAP, it may not report under GAAP for a period longer than 36 months unless a state has chosen to not license such organizations.

II. INSOLVENCY

A. Hold Harmless and Continuation of Coverage/Benefits

PDP Sponsors shall be subject to the same hold harmless and continuation of coverage/benefit requirements as Medicare Advantage contractors.

B. Insolvency Deposit $100,000 held in accordance with CMS requirements by a qualified U. S. Financial Institution. A qualified financial institution means an institution that:

1. Is organized or (in the case of a U. S. office of a foreign banking organization) licensed, under the laws of the United States or any state thereof; and
2. Is regulated, supervised and examined by U. S. Federal or State authorities having regulatory authority over banks and trust companies.

III. GUARANTEES

A. General policy.

A PDP Sponsor, or the legal entity of which the PDP Sponsor is a Component, may apply to CMS to use the financial resources of a Guarantor for the purpose of meeting the requirements of a PDP Sponsor. CMS has the discretion to approve or deny approval of the use of a Guarantor.

B. Request to use a Guarantor.

To apply to use the financial resources of a Guarantor, a PDP Sponsor must submit to CMS:

1. Documentation that the Guarantor meets the requirements for a Guarantor under paragraph (C) of this section; and

2. The Guarantor's independently audited financial statements for the current year-to-date and for the two most recent fiscal years. The financial statements must include the Guarantor's balance sheets, profit and loss statements, and cash flow statements.

C. Requirements for Guarantor.

To serve as a Guarantor, an organization must meet the following requirements:

1. Be a legal entity authorized to conduct business within a State of the United States.
2. Not be under Federal or State bankruptcy or rehabilitation proceedings.
3. Have an adjusted net worth (not including other guarantees, intangibles and restricted reserves) equal to three times the amount of the PDP Sponsor guarantee.
4. If a State insurance commissioner regulates the Guarantor, or other State official with authority for risk-bearing entities, it must meet the adjusted net worth requirement in this document with all guarantees and all investments in and loans to organizations covered by guarantees excluded from its assets.
5. If the Guarantor is not regulated by a State insurance commissioner, or other similar State official it must meet the adjusted net worth requirement in this document with all guarantees and all investments in and loans to organizations covered by a guarantee and to related parties (subsidiaries and affiliates) excluded from its assets and determination of adjusted net worth.

D. Guarantee document.

If the guarantee request is approved, a PDP Sponsor must submit to CMS a written guarantee document signed by an appropriate Guarantor. The guarantee document must:

1. State the financial obligation covered by the guarantee;
2. Agree to:
    a. Unconditionally fulfill the financial obligation covered by the guarantee; and
    b. Not subordinate the guarantee to any other claim on the resources of the Guarantor;
3. Declare that the Guarantor must act on a timely basis, in any case not more than 5 business days, to satisfy the financial obligation covered by the guarantee; and
4. Meet other conditions as CMS may establish from time to time.

E. Reporting requirement.

A PDP Sponsor must submit to CMS the current internal financial statements and annual audited financial statements of the Guarantor according to the schedule, manner, and form that CMS requests.

F. Modification, substitution, and termination of a guarantee.

A PDP Sponsor cannot modify, substitute or terminate a guarantee unless the PDP Sponsor:

1. Requests CMS' approval at least 90 days before the proposed effective date of the modification, substitution, or termination;
2. Demonstrates to CMS' satisfaction that the modification, substitution, or termination will not result in insolvency of the PDP Sponsor; and
3. Demonstrates how the PDP Sponsor will meet the requirements of this section.

G. Nullification.

If at any time the Guarantor or the guarantee ceases to meet the requirements of this section, CMS will notify the PDP Sponsor that it ceases to recognize the guarantee document. In the event of this nullification, a PDP Sponsor must:

1. Meet the applicable requirements of this section within 15 business days; and
2. If required by CMS, meet a portion of the applicable requirements in less than the time period granted in paragraph (G.1.) of this section.

APPENDIX V

CERTIFICATION BY PERSCRIPTION DRUG PLAN ORGANIZATION THAT SUBCONTRACTS MEET THE REQUIREMENTS OF SECTION 3.1.2E

A. I, the undersigned, certify, on behalf of NAME OF LEGAL ENTITY CONTRACTING AS A PRESCRIPTION DRUG PLAN ORGANIZATION, to the following:

The contracts submitted as attachments to Section 3.1.2:

1. Clearly identify the parties to the contract (or letter of agreement).
2. Describe the functions to be performed by the subcontractor, as well as any reporting requirements the subcontractor has to the Applicant identified in Section 3.1.2B of the application.
3. Contain language clearly indicating that the subcontractor has agreed to perform functions required under the Applicant's Medicare Prescription Drug Plan contract (except for a network pharmacy if the existing contract would allow participation in this program), and flow-down clauses requiring the subcontractor's activities to be consistent and comply with the Applicant's contractual obligations as a PDP sponsor.
4. Contain language describing the services to be performed in a manner that encompasses the services required to support the Medicare Prescription Drug Plan contract.
5. Describe the payment the subcontractor will receive for performance under the contract, if applicable;
6. Are for a term of at least a year (i.e., January 1, 2008 through December 31, 2008).
7. Are signed by a representative of each party with legal authority to bind the entity.
8. Contain language obligating the subcontractor to comply with all applicable Federal and State laws and regulations and CMS instructions.
9. Contain language obligating the subcontractor to comply with State and Federal privacy and security requirements, including the confidentiality and security provisions stated in the regulations at 42 CFR §423.136.
10. Contain language that specifies all requirements set forth in 42 CFR §423.505(i), including
    a. requiring the subcontractor to agree to make its books and other records available to HHS, the Comptroller General, or their designees in accordance with 42 CFR §423.505(i)(2), including the right to inspect, evaluate and audit books and other records and that these rights continue for a period of 10 years from the final date of the contract period or the date of audit completion, whichever is later.
    b. Contain language stating that the subcontractor will ensure that beneficiaries are not held liable for fees that are the responsibility of the Applicant.
    c. Contain language stating that if the Applicant, upon becoming a Part D sponsor, delegates an activity or responsibility to the subcontractor, that such activity or responsibility may be revoked if CMS or the Part D sponsor determines the subcontractor has not performed satisfactorily. The subcontract may include remedies in lieu of revocation to address this requirement.
    d. Contain language specifying that the Applicant, upon becoming a Part D sponsor, will monitor the performance of the subcontractor on an ongoing basis.
    e. Contain language that the Part D sponsor retains the right to approve, suspend, or terminate any arrangement with a pharmacy if the subcontractor will establish the pharmacy network or select pharmacies to be included in the network.

B. I certify that I am authorized to sign on behalf of the Applicant.

C. I understand that CMS will review the submitted contracts to ensure that they comply with the contracting requirements stated in Section 3.1.2E of the Solicitation for Application for New Prescription Drug Plans (PDP) Sponsors. When a submitted contract does not meet a requirement, CMS will ask the Applicant to resubmit the contract in question. I understand the Applicant's failure to provide in a timely manner fully executed contracts that meet CMS requirements may affect CMS' decision to allow the Applicant to accept enrollment into its PDP plan(s) on November 15, 2007.

_____ _____

Authorized Representative Name (printed) Title

Authorized Representative Signature	Date (MM/DD/YYYY

Appendix VI

Crosswalks of Section 3.1.2E Requirements in Subcontracts submitted as Attachments to Section 3.1.2

INSTRUCTIONS: Applicants must complete the following chart for each subcontract submitted under Section 3.1.2E. Applicants must identify where specifically in each contract the following elements are found.

Section	Requirement	Location in Subcontract by Page number and Section
3.1.2E1	The parties to the contract	
3.1.2E2	The functions to be performed by the subcontractor, as well as any reporting requirements the subcontractor has to the Applicant identified in Section 3.1.2B of the application.	
3.1.2E3	Language clearly indicating that the subcontractor has agreed to participate in your Medicare Prescription Drug Benefit program (except for a network pharmacy if the existing contract would allow participation in this program), and flow-down clause.	
3.1.2E4	Language describing the services to be performed in a manner that encompasses the services required to support the Medicare Prescription Drug Benefit program.	
3.1.2E5	The payment the subcontractor will receive for performance under the contract, if applicable.	
3.1.2E6	Are for a term of at least the one-year contract period for which application is submitted.	
3.1.2E7	Are signed by a representative of each party with legal authority to bind the entity.	
3.1.2E8	Language obligating the subcontractor to abide by all applicable Federal and State laws and regulations and CMS instructions.	
3.1.2EF9	Language obligating the subcontractor to abide by State and Federal privacy and security requirements, including the confidentiality and security provisions stated in the regulations for the program at 42 CFR §423.136.	
3.1.2E10	Language ensuring that the subcontractor will make its books and other records available in accordance with 42 CFR §423.505(i)(2), which generally states these regulations give HHS, the Comptroller General, or their designees the right to inspect.	
3.1.2E11	Language stating that the subcontractor will ensure that beneficiaries are not held liable for fees that are the responsibility of the Applicant.	
3.1.2E12	Language stating that if the Applicant, upon becoming a Part D sponsor, delegates an activity or responsibility to the subcontractor, that such activity or responsibility may be revoked if CMS or the Part D sponsor determines the subcontractor has not performed satisfactorily. The subcontract may include remedies in lieu of revocation to address this requirement.	
3.1.2E13	Language specifying that the Applicant, upon becoming a Part D sponsor, will monitor the performance of the subcontractor on an ongoing basis.	
3.1.2E14	Language that the Part D sponsor retains the right to approve, suspend, or terminate any arrangement with a	

	pharmacy if the subcontractor will establish the pharmacy network or select pharmacies to be included in the network.	

APPENDIX VII

Crosswalk for Retail Pharmacy Access Contracts

INSTRUCTIONS: Applicants must complete the following chart (which contains applicable Section 3.1.2E requirements AND additional requirements specific to Pharmacy Access) for each Retail pharmacy contract template submitted under Section 3.4. Applicants must identify where, in each contract template, the following elements reside. If multiple retail contract templates exist, applicant must provide a 'Citations for Retail Pharmacy Access Contracts' document (Appendix VII) for each contract template.

The provisions listed below must be in all pharmacy contracts. If contracts reference policies and procedures to with which the pharmacy must comply, provide the relevant documentation as evidence and cite this documentation accordingly.

Section	Requirement	Citation
3.1.2E2	The functions to be performed by the subcontractor, as well as any reporting requirements the subcontractor has to the Applicant identified in Section 3.1.2B of the application.	
3.1.2E4	Language describing the services to be performed in a manner that encompasses the services required to support the Medicare Prescription Drug Benefit program.	
3.1.2E8	Language obligating the subcontractor to abide by all applicable Federal and State laws and regulations and CMS instructions.	
3.1.2E9	Language obligating the subcontractor to abide by State and Federal privacy and security requirements, including the confidentiality and security provisions stated in the regulations for the program at 42 CFR §423.136.	
3.1.2E10	Language ensuring that the subcontractor will make their books and other records available in accordance with 42 CFR §423.505(i)(2), which generally states these regulations give HHS, the Comptroller General, or their designees the right to inspect.	
3.1.2E11	Language stating that the subcontractor will ensure that beneficiaries are not held liable for fees that are the responsibility of the Applicant.	
3.1.2E12	Language stating that if the Applicant, upon becoming a Part D sponsor, delegates an activity or responsibility to the subcontractor, that such activity or responsibility may be revoked if CMS or the Part D sponsor determines the subcontractor has not performed satisfactorily. The subcontract may include remedies in lieu of revocation to address this requirement.	
3.1.2E13	Language specifying that the Applicant, upon becoming a Part D sponsor, will monitor the performance of the subcontractor on an ongoing basis.	
3.4A3	Provisions governing submitting claims to a real-time claims adjudication system. Note: Applicant may indicate for I/T/U pharmacies and for certain pharmacies that are allowed to submit claims in the X 12 format that these may be batch processed.	
3.4A4	Provisions governing providing Part D enrollees access to negotiated prices as defined in 42 CFR 423.100	

3.4A5	Provisions regarding charging/applying the correct cost-sharing amount	
3.4A6	Provisions governing informing the Part D enrollee at the point of sale (or at the point of delivery for mail order drugs) of the lowest-priced, generically equivalent drug, if one exists for the beneficiary's prescription, as well as any associated differential in price.	

APPENDIX VIII

Crosswalk for Mail Order Pharmacy Access Contracts

INSTRUCTIONS: Applicants must complete the following chart (which contains applicable Section 3.1.2E requirements AND additional requirements specific to Pharmacy Access) for each Mail Order pharmacy contract template submitted under Section 3.4. Applicants must identify where, in each contract template, the following elements reside. If multiple retail contract templates exist, applicant must provide a 'Citations for Mail Order Pharmacy Access Contracts' document (Appendix VIII) for each contract template.		
The provisions listed below must be in all pharmacy contracts. If contracts reference policies and procedures with which the pharmacy must comply, provide the relevant documentation as evidence and cite this documentation accordingly.		
Section	**Requirement**	**Citation**
3.1.2E2	The functions to be performed by the subcontractor, as well as any reporting requirements the subcontractor has to the Applicant identified in Section 3.1.2B of the application.	
3.1.2E4	Language describing the services to be performed in a manner that encompasses the services required to support the Medicare Prescription Drug Benefit program.	
3.1.2E8	Language obligating the subcontractor to abide by all applicable Federal and State laws and regulations and CMS instructions.	
3.1.2E9	Language obligating the subcontractor to abide by State and Federal privacy and security requirements, including the confidentiality and security provisions stated in the regulations for the program at 42 CFR §423.136.	
3.1.2E10	Language ensuring that the subcontractor will make their books and other records available in accordance with 42 CFR §423.505(i)(2), which generally states these regulations give HHS, the Comptroller General, or their designees the right to inspect.	
3.1.2E11	Language stating that the subcontractor will ensure that beneficiaries are not held liable for fees that are the responsibility of the Applicant.	
3.1.2E12	Language stating that if the Applicant, upon becoming a Part D sponsor, delegates an activity or responsibility to the subcontractor, that such activity or responsibility may be revoked if CMS or the Part D sponsor determines the subcontractor has not performed satisfactorily. The subcontract may include remedies in lieu of revocation to address this requirement.	
3.1.2E13	Language specifying that the Applicant, upon becoming a Part D sponsor, will monitor the performance of the subcontractor on an ongoing basis.	
3.4A3	Provisions governing submitting claims to a real-time claims adjudication system.	
3.4A4	Provisions governing providing Part D enrollees access to negotiated prices as defined in 42 CFR 423.100	

3.4A5	Provisions regarding charging/applying the correct cost-sharing amount	
3.4A6	Provisions governing informing the Part D enrollee at the point of sale (or at the point of delivery for mail order drugs) of the lowest-priced, generically equivalent drug, if one exists for the beneficiary's prescription, as well as any associated differential in price.	

APPENDIX IX
Crosswalk for Home Infusion Pharmacy Access Contracts

INSTRUCTIONS: Applicants must complete the following chart (which contains applicable Section 3.1.2E requirements AND additional requirements specific to Pharmacy Access) for each Home Infusion pharmacy contract template submitted under Section 3.4. Applicants must identify where, in each contract template, the following elements reside. If multiple retail contract templates exist, applicant must provide a 'Citations for Home Infusion Pharmacy Access Contracts' document (Appendix IX) for each contract template.

The provisions listed below must be in all pharmacy contracts. If contracts reference policies and procedures with which the pharmacy must comply, provide the relevant documentation as evidence and cite this documentation accordingly.

Section	Requirement	Citation
3.1.2E2	The functions to be performed by the subcontractor, as well as any reporting requirements the subcontractor has to the Applicant identified in Section 3.1.2B of the application.	
3.1.2E4	Language describing the services to be performed in a manner that encompasses the services required to support the Medicare Prescription Drug Benefit program.	
3.1.2E8	Language obligating the subcontractor to abide by all applicable Federal and State laws and regulations and CMS instructions.	
3.1.2E9	Language obligating the subcontractor to abide by State and Federal privacy and security requirements, including the confidentiality and security provisions stated in the regulations for the program at 42 CFR §423.136.	
3.1.2E10	Language ensuring that the subcontractor will make their books and other records available in accordance with 42 CFR §423.505(i)(2), which generally states these regulations give HHS, the Comptroller General, or their designees the right to inspect.	
3.1.2E11	Language stating that the subcontractor will ensure that beneficiaries are not held liable for fees that are the responsibility of the Applicant.	
3.1.2E12	Language stating that if the Applicant, upon becoming a Part D sponsor, delegates an activity or responsibility to the subcontractor, that such activity or responsibility may be revoked if CMS or the Part D sponsor determines the subcontractor has not performed satisfactorily. The subcontract may include remedies in lieu of revocation to address this requirement.	
3.1.2E13	Language specifying that the Applicant, upon becoming a Part D sponsor, will monitor the performance of the subcontractor on an ongoing basis.	
3.4A3	Provisions governing submitting claims to a real-time claims adjudication system. Note: Applicant may indicate for I/T/U pharmacies and for certain pharmacies that are allowed to submit claims in the X 12 format that these may be batch processed	
3.4A4	Provisions governing providing Part D enrollees access to negotiated prices as defined in 42 CFR 423.100	

3.4A5	Provisions regarding charging/applying the correct cost-sharing amount	
3.4A6	Provisions governing informing the Part D enrollee at the point of sale (or at the point of delivery for mail order drugs) of the lowest-priced, generically equivalent drug, if one exists for the beneficiary's prescription, as well as any associated differential in price.	
3.4.4A5	Provisions ensuring that before dispensing home infusion drugs, pharmacy ensures that the professional services and ancillary supplies are in place.	

APPENDIX X
Crosswalk for Long-Term Care Pharmacy Access Contracts

INSTRUCTIONS: Applicants must complete the following chart (which contains applicable Section 3.1.2E requirements AND additional requirements specific to Pharmacy Access) for each Long-Term Care pharmacy contract template submitted under Section 3.4. Applicants must identify where, in each contract template, the following elements reside. If multiple retail contract templates exist, applicant must provide a 'Citations for Long-Term Care Pharmacy Access Contracts' document (Appendix X) for each contract template.		
The provisions listed below must be in all pharmacy contracts. If contracts reference policies and procedures with which the pharmacy must comply, provide the relevant documentation as evidence and cite this documentation accordingly.		
Section	**Requirement**	**Citation**
3.1.2E2	The functions to be performed by the subcontractor, as well as any reporting requirements the subcontractor has to the Applicant identified in Section 3.1.2B of the application.	
3.1.2E4	Language describing the services to be performed in a manner that encompasses the services required to support the Medicare Prescription Drug Benefit program.	
3.1.2E8	Language obligating the subcontractor to abide by all applicable Federal and State laws and regulations and CMS instructions.	
3.1.2E9	Language obligating the subcontractor to abide by State and Federal privacy and security requirements, including the confidentiality and security provisions stated in the regulations for the program at 42 CFR §423.136.	
3.1.2E10	Language ensuring that the subcontractor will make their books and other records available in accordance with 42 CFR §423.505(i)(2), which generally states these regulations give HHS, the Comptroller General, or their designees the right to inspect.	
3.1.2E11	Language stating that the subcontractor will ensure that beneficiaries are not held liable for fees that are the responsibility of the Applicant.	
3.1.2E12	Language stating that if the Applicant, upon becoming a Part D sponsor, delegates an activity or responsibility to the subcontractor, that such activity or responsibility may be revoked if CMS or the Part D sponsor determines the subcontractor has not performed satisfactorily. The subcontract may include remedies in lieu of revocation to address this requirement.	
3.1.2E13	Language specifying that the Applicant, upon becoming a Part D sponsor, will monitor the performance of the subcontractor on an ongoing basis.	
3.4A3	Provisions governing submitting claims to a real-time claims adjudication system. Note: Applicant may indicate for I/T/U pharmacies and for certain pharmacies that are allowed to submit claims in the X 12 format that these may be batch processed.	

3.4A4	Provisions governing providing Part D enrollees access to negotiated prices as defined in 42 CFR 423.100	
3.4A5	Provisions regarding charging/applying the correct cost-sharing amount	

Elements Specific to Long-Term Care Contracts

Note: CMS released Long-Term Care Guidance in early March 2005 that can be found at www.cms.hhs.gov/pdps/LTC_guidance.pdf . This document contains an updated list of performance and service criteria for contracting with long-term care pharmacies. Applicants should, at a minimum, incorporate these criteria in ALL LTC pharmacy network contracts. Applicant must list the criteria below, and then identify where the elements reside in the contract template(s) submitted.

Performance and Service Criteria	Citation
1. *Comprehensive Inventory and Inventory Capacity* – Network Long Term Care Pharmacies [NLTCPs] must provide a comprehensive inventory of Plan formulary drugs commonly used in the long term care setting. In addition, NLTCPs must provide a secured area for physical storage of drugs, with necessary added security as required by federal and state law for controlled substances. This is not to be interpreted that the pharmacy will have inventory or security measures outside of the normal business setting.	
2. *Pharmacy Operations and Prescription Orders* -- NLTCPs must provide services of a dispensing pharmacist to meet the requirements of pharmacy practice for dispensing prescription drugs to LTC residents, including but not limited to the performance of drug utilization review (DUR). In addition, the NLTCP pharmacist must conduct DUR to routinely screen for allergies and drug interactions, to identify potential adverse drug reactions, to identify inappropriate drug usage in the LTC population, and to promote cost effective therapy in the LTC setting. The NLTCP must also be equipped with pharmacy software and systems sufficient to meet the needs of prescription drug ordering and distribution to an LTC facility. Further, the NLTCP must provide written copies of the NLTCP's pharmacy procedures manual and said manual must be available at each LTC facility nurses' unit. NLTCPs are also required to provide ongoing in-service training to assure that LTC facility staff are proficient in the NLTCP's processes for ordering and receiving of medications. NLTCP must be responsible for return and/or disposal of unused medications following discontinuance, transfer, discharge, or death as permitted by State Boards of Pharmacy. Controlled substances and out of date substances must be disposed of within State and Federal guidelines.	
3. *Special Packaging* -- NLTCPs must have the capacity to provide specific drugs in Unit of Use Packaging, Bingo Cards, Cassettes, Unit Dose or other special	

packaging commonly required by LTC facilities. NLTCPs must have access to, or arrangements with, a vendor to furnish supplies and equipment including but not limited to labels, auxiliary labels, and packing machines for furnishing drugs in such special packaging required by the LTC setting.	
4. *IV Medications* -- NLTCPs must have the capacity to provide IV medications to the LTC resident as ordered by a qualified medical professional. NLTCPs must have access to specialized facilities for the preparation of IV prescriptions (clean room). Additionally, NLTCPs must have access to or arrangements with a vendor to furnish special equipment and supplies as well as IV trained pharmacists and technicians as required to safely provide IV medications.	
5. *Compounding /Alternative Forms of Drug Composition* -- NLTCPs must be capable of providing specialized drug delivery formulations as required for some LTC residents. Specifically, residents unable to swallow or ingest medications through normal routes may require tablets split or crushed or provided in suspensions or gel forms, to facilitate effective drug delivery.	
6. *Pharmacist On-call Service* -- NLTCP must provide on-call, 24 hours a day, 7 days a week service with a qualified pharmacist available for handling calls after hours and to provide medication dispensing available for emergencies, holidays and after hours of normal operations.	
7. *Delivery Service* -- NLTCP must provide for delivery of medications to the LTC facility up to seven days each week (up to three times per day) and in-between regularly scheduled visits. Emergency delivery service must be available 24 hours a day, 7 days a week. Specific delivery arrangements will be determined through an agreement between the NLTCP and the LTC facility. NLTCPs must provide safe and secure exchange systems for delivery of medication to the LTC facility. In addition, NLTCP must provide medication cassettes, or other standard delivery systems, that may be exchanged on a routine basis for automatic restocking. The NLTCP delivery of medication to carts is a part of routine “dispensing”.	
8. *Emergency Boxes* -- NLTCPs must provide “emergency” supply of medications as required by the facility in compliance with State requirements.	
9. *Emergency Log Books* -- NLTCP must provide a system for logging and charging medication used from emergency/first dose stock. Further, the pharmacy must maintain a comprehensive record of a resident’s medication order and drug administration.	
10. *Miscellaneous Reports, Forms and Prescription Ordering Supplies* -- NLTCP must provide reports, forms and prescription ordering supplies necessary for the delivery of quality pharmacy care in the LTC setting. Such reports, forms and prescription ordering supplies may include, but will not necessarily be limited to, provider order forms, monthly management reports to assist the LTC facility in managing orders, medication administration records, treatment administration records, interim order forms for new prescription orders, and boxes/folders for order storage and reconciliation in the facility.	

APPENDIX XI

Crosswalk for Indian Tribe and Tribal Organization, and Urban Indian Organization (I/T/U) Pharmacy Access Contracts

INSTRUCTIONS: Applicants must complete the following chart (which contains applicable Section 3.1.2E requirements AND additional requirements specific to Pharmacy Access) for each I/T/U pharmacy contract template submitted under Section 3.4. Applicants must identify where, in each contract template, the following elements reside. If multiple I/T/U contract templates exist, applicant must provide a 'Citations for I/T/U Pharmacy Access Contracts' document (Appendix XI) for each contract template.

The provisions listed below must be in all pharmacy contracts. If contracts reference policies and procedures with which the pharmacy must comply, provide the relevant documentation as evidence and cite this documentation accordingly.

Section	Requirement	Citation
3.1.2E2	The functions to be performed by the subcontractor, as well as any reporting requirements the subcontractor has to the Applicant identified in Section 3.1.2B of the application.	
3.1.2E4	Language describing the services to be performed in a manner that encompasses the services required to support the Medicare Prescription Drug Benefit program.	
3.1.2E8	Language obligating the subcontractor to abide by all applicable Federal and State laws and regulations and CMS instructions.	
3.1.2E9	Language obligating the subcontractor to abide by State and Federal privacy and security requirements, including the confidentiality and security provisions stated in the regulations for the program at 42 CFR §423.136.	
3.1.2E10	Language ensuring that the subcontractor will make their books and other records available in accordance with 42 CFR §423.505(i)(2), which generally states these regulations give HHS, the Comptroller General, or their designees the right to inspect.	
3.1.2E11	Language stating that the subcontractor will ensure that beneficiaries are not held liable for fees that are the responsibility of the Applicant.	
3.1.2E12	Language stating that if the Applicant, upon becoming a Part D sponsor, delegates an activity or responsibility to the subcontractor, that such activity or responsibility may be revoked if CMS or the Part D sponsor determines the subcontractor has not performed satisfactorily. The subcontract may include remedies in lieu of revocation to address this requirement.	
3.1.2E13	Language specifying that the Applicant, upon becoming a Part D sponsor, will monitor the performance of the subcontractor on an ongoing basis.	
3.4A3	Provisions governing submitting claims to a real-time claims adjudication system. Note: Applicant may indicate for I/T/U pharmacies and for certain pharmacies that are allowed to submit claims in the X 12 format that these may be batch processed.	
3.4A4	Provisions governing providing Part D enrollees access to negotiated prices as defined in 42 CFR 423.100	

3.4A5	Provisions regarding charging/applying the correct cost-sharing amount.	
3.4A6	Provisions governing informing the Part D enrollee at the point of sale (or at the point of delivery for mail order drugs) of the lowest-priced, generically equivalent drug, if one exists for the beneficiary's prescription, as well as any associated differential in price.	
Elements Specific to Indian Tribe and Tribal Organization, and Urban Indian Organization (I/T/U) Pharmacy Contracts **Note: Provisions listed below are in the model I/T/U Addendum, located at** www.cms.hhs.gov/10_RxContracting_SpecialGuidance.asp#TopOfPage **and all** I/T/U Contracts must contain language consistent with the model addendum that address the following.		
Item 1	Supersession of the addendum from underlying agreement.	
Item 3	The description of the provider.	
Item 4	Counting of costs paid for by provider toward any deductibles.	
Item 5	Persons eligible for services of the provider.	
Item 6	The applicability of certain Federal law.	
Item 7	The non-taxable status of the provider.	
Item 8	Insurance and indemnification.	
Item 9	Applicability of state licensing law to provider's employees.	
Item 10	Provider eligibility for payments	
Item 11	Dispute resolution.	
Item 12	Federal law as the governing law.	
Item 13	The contract will apply to all pharmacies and dispensaries operated by the provider.	
Item 14	The contract will not affect the provider's acquisition of pharmaceuticals.	
Item 15	The provider's point of sale processing capabilities.	
Item 16	Claims processing.	
Item 17	Reasonable and appropriate payment rates.	
Item 18	Any information, outreach or enrollment materials prepared by the Applicant will be supplied at no cost to the provider.	
Item 19	The provider determines the hours of service for the pharmacies or dispensaries of the provider.	
Item 20	Endorsement	

Item 21	Term and Termination of Pharmacy Agreement	

APPENDIX XII
Applicant Submission of P&T Committee Member List and Certification Statement

This appendix summarizes CMS policy on Part D Applicant/Sponsor and PBM submission of P&T Committee membership, and the accountability that each Part D Applicant/Sponsor holds regarding the integrity of the P&T Committee whose membership is submitted either directly by the Part D Applicant/Sponsor or by the applicant/sponsor's PBM. This appendix also instructs Part D Applicants (or their PBM's) on how to submit the Applicant's P&T Committee membership list, and a Certification of P&T Integrity and Quality in the event the Applicant is planning to operate under a confidentiality agreement with its PBM (such that the PBM does not disclose the membership to the Applicant).

P&T Committee Member Disclosure to CMS

As provided in the regulation at CFR 423.120 (b)(1), a Part D Sponsor's P&T Committee list must contain a majority of members who are practicing physicians and/or pharmacists, include at least one practicing physician and one practicing pharmacist who are experts regarding care of the elderly or disabled individuals, and includes at least one practicing physician and one practicing pharmacist who are independent and free of conflict relative to the Part D Sponsor or Plan and pharmaceutical manufacturers.

In the event the Part D Applicant/Sponsor has entered into a confidential agreement such that the PBM will not disclose its P&T Committee membership to the Part D Applicant/Sponsor, then it is the Part D Sponsor's responsibility to notify CMS that this information will be submitted by the Sponsor's PBM. Moreover, the Part D Applicant/Sponsor must ensure that the PBM notifies CMS of the P&T Committee membership. Also, the Part D Applicant/Sponsor should ensure that the PBM notifies the Sponsor that this information has been successfully submitted to CMS.

Instructions to Plans and PBMs

A. If the Part D Applicant sub-contracts with a PBM for its P&T Committee and operates under a Confidentiality Agreement (such that its members are not disclosed to the Part D Applicant) then the Applicant must (1) complete the attached Certification, and (2) forward the attached P&T Committee Member Disclosure from to the sub-contracted PBM and direct the PBM to submit the form to CMS By March 12, 2007. The PBM should follow the mailing instructions below.

B. In the event of any future changes to the membership of the Part D Sponsor's P&T Committee or the PBM's P&T Committee, Part D Sponsors must (or in the case of a confidential agreement the Part D Sponsor) assure that the PBM will notify the appropriate CMS account manager (to be assigned at a future date) within 30 days of the effective date of such change.

Mailing Instructions

1. Provide a signed cover sheet indicating that the information being sent to CMS is an addendum to the Plan's Part D Application.
2. Please mail 4 CDs containing both the completed P&T Committee Member Disclosure form and the completed Certification for Part D Sponsors Using a Pharmacy Benefit Manager's Pharmacy and Therapeutics Committee under a Confidentiality Agreement form.
3. Please mail 2 hard copies, including one original, of both the completed P&T Committee Member Disclosure form and the completed Certification for Part D Sponsors Using a Pharmacy Benefit Manager's Pharmacy and Therapeutics Committee under a Confidentiality Agreement form.

Mail the CDs and hard copy material via courier to:
Centers for Medicare & Medicaid Services

ATTN: P&T Member List and/or P&T Certification
Mail Stop C1-26-12
7500 Security Boulevard
Baltimore, MD 21244-1850

PHARMACY AND THERAPEUTICS COMMITTEE MEMBER DISCLOSURE

Name of Part D Plan or PBM: _____

If Part D Plan, provide Part D Contract number(s):_____

Contact Person: _____

Phone Number: _____

Email: _____

A. Complete the table below.

PROVIDE THE NAMES OF THE MEMBERS OF YOUR ORGANIZATION'S P&T COMMITTEE. INDICATE WHICH MEMBERS ARE PRACTICING PHYSICIANS OR PRACTICING PHARMACISTS. FURTHER, INDICATE WHICH MEMBERS ARE EXPERTS IN THE CARE OF THE ELDERLY OR DISABLED, AND FREE OF ANY CONFLICT OF INTEREST WITH YOUR ORGANIZATION AND PHARMACEUTICAL MANUFACTURERS. (APPLICANTS SHOULD MARK THE INFORMATION AS PROPRIETARY.) SUBMIT THIS DATA BY CREATING A SPREADSHEET IN MICROSOFT EXCEL THAT MIMICS THE TABLE BELOW. PROVIDE THIS ATTACHMENT ON A CD AS INSTRUCTED IN SECTION 2.4.

	Practice/Expertise *Mark an 'X' in Appropriate Column*			**Free of Any Conflict of Interest** *Type Yes or No*	
Full Name of Member Start Date and End Date	Practicing Physician	Practicing Pharmacist	Elderly/Disabled Expert	With Your Organization?	With Pharmaceutical Manufacturers?

B. Complete the table below if a PBM submitting on behalf of Part D plan.

PROVIDE THE NAMES OF THOSE APPLICANTS FOR THE PART D BENEFIT FOR WHICH YOUR ORGANIZATION IS PROVIDING PHARMACY BENEFIT MANAGEMENT SERVICES, THE TYPE OF APPLICATION, AND THE CONTRACT NUMBER(S). ADD ADDITIONAL ROWS AS NECESSARY.

Organization Name	**Type of Application**	**Contract Number(s)**

CERTIFICATION FOR PART D SPONSORS USING A PHARMACY BENEFIT MANAGER'S PHARMACY& THERAPEUTICS COMMITTEE UNDER A CONFIDENTIALITY AGREEMENT

A. I, the undersigned, certify, on behalf of LEGAL NAME OF PART D SPONSOR APPLICANT ("Applicant"), to the following:

1) I certify that APPLICANT has entered into a contract with LEGAL NAME OF PBM ("PBM") to perform pharmacy benefit management services related to the operation of a Medicare Part D benefit plan(s) on behalf of APPLICANT.

2) I agree, to the best of my knowledge, that "PBM," has a Pharmacy and Therapeutics (P&T) Committee that contains a majority of members who are practicing physicians and/or pharmacists, includes at least one practicing physician and one practicing pharmacist who are experts regarding the care of the elderly or disabled individuals, and includes at least one practicing physician and one practicing pharmacist who are independent and free of conflict relative to my plan and organization and pharmaceutical manufacturers.

3) I agree that the PBM will supply to CMS the following information, including but not limited to, the full legal name of each member of its P&T Committee designated as a practicing physician or pharmacist specializing in elderly and/or disabled care. Each member must also disclose any conflict of interest with my organization, and/or pharmaceutical manufacturers.

4) I agree that my organization will establish policies and procedures to ensure and confirm the ongoing integrity, qualifications and expertise of the PBM's P&T Committee.

5) I agree that in the event CMS identifies a PBM's P&T Committee member is listed on the OIG exclusion list, my organization will be notified by CMS of such a problem. In such an instance, my organization must assure that the PBM takes appropriate steps to correct the problem or my organization will be at risk of being subject to a corrective action plan and sanctions, depending on the nature of the problem.

B. I agree that CMS may inspect the records and premises of my organization or my subcontractor to ensure compliance with the statements to which I have attested above.

C. I certify that I am authorized to sign on behalf of the Applicant.

Part D Applicant's Contract Number: _____

_____ _____

Authorized Representative Name (printed) Title

_____ _____

Authorized Representative Signature Date (MM/DD/YYYY)

Appendix XIII
Retail Pharmacy Network Access Instructions

By contract, Part D sponsors are required to meet the access standards in 42 CFR §423.120(a)(1). Applicants should note that the Retail access standard requirement is applied at the Plan Benefit Package (PBP) level. *It is important to note the reference to plan (and not contract ID) in the requirements defined in* 42 CFR §423.120 (a)(1). As part of routine monitoring and audit processes, CMS will review retail pharmacy access at the PBP level.

Note: While CMS realizes that contracts with Indian Health Services, Indian Tribes and Tribal organizations and Urban Indian Organization (I/T/U), Federally Qualified Health Centers (FQHC) and Rural Health Centers (RHC) may be counted for purposes of meeting the pharmacy access standards, it should be noted that contracts with these pharmacies may not be used as a substitute for including retail pharmacies in plan networks.

Information Required to Qualify As Part D Sponsor

CMS recognizes that the deadline for submission of the Part D application (March) precedes the plan bidding and finalization process (June). Further, CMS recognizes that many (if not most) Part D sponsors continue work on defining their PBP service areas throughout their Bid formulation process. Therefore, it is difficult for applicants to submit final pharmacy accessibility analyses for each PBP, and we will only require a contract-level submission at this time. The impact on PDPs is minimal since those types of contracts must offer all PBPs with Part D throughout each specific PDP Region (PDPs).

Geographic Accessibility Analysis Instructions

All Applicants are strongly encouraged to use GeoNetworks® to compile the reports as outlined in this appendix. If this is not possible then Applicant must contact Dennis Hodges at dennis.hodges@cms.hhs.gov (410.786.3048) no later than February 1, 2007to determine if analyses provided by an alternative method are acceptable. Please note that alternative methods must produce analyses that will result in data directly comparable to the results produced by GeoNetworks®**.** Applicants that wish to use alternative methods will be required to demonstrate how their analysis is comparable to results produced by GeoNetworks®.

Though in many instances CMS provides specific instructions for formatting and compiling plan accessibility reports, this appendix is not intended to provide step-by-step instructions for the use of GeoNetworks®. The instructions and examples provided here were developed using GeoNetworks version 7.5.2.[1] It is the responsibility of Applicant to ensure that their submission provides adequate information for CMS to determine if each of their offerings meets the retail pharmacy access submission requirements. Detailed descriptions of the information needed by CMS are provided below.

[1] Systems files for CDF, DPF, PPF, RPF, ZDF are version 6.20. System file for Qms is version 17.00.

*1. Defining the Medicare Beneficiary File in **GeoNetworks®***

The Medicare Beneficiary File "Medicare Beneficiaries by State, Region, ZIP 09302006.xls" is provided by CMS as an attached document.

The Medicare Beneficiary File referenced above contains ZIP Codes and beneficiary counts for Applicants as of September 30, 2006. Use of this file is required for the accessibility analysis submission. Applicants should download this census file and create a sub-file(s) specific to their service area and/or region(s) and/or state as needed to support the level of analyses required (specified below). Applicants may not use beneficiary counts from other sources in their accessibility analyses.

Applicants should import the data sub-file into GeoNetworks® to create a geo-coded population file based on the Census data sub-file. A population file is created by navigating to Data > Populate > From File> "select and open the file". Applicants may geocode by selecting the "geocode after populate" check box during this step, or they may geocode the population file in a later step outlined below.

> ✓***Quality Check:*** *Applicant should verify that the beneficiary (employee) count in the population file is consistent with the total beneficiary census for the sub-file used as the basis for the analyses. CMS will check the count of beneficiaries provided in the reports against the count of beneficiaries residing in the plan's service area.*

Applicants should assign an Urban, Suburban, or Rural indicator to each Medicare beneficiary record in the Population file using the GeoNetworks® function, "Assign Place Names." Place names may be assigned by navigating to Data > Assign Place Names > Selecting and open the file. The Input field should be set to "ZIP". The default place name classification "STD_CLASS" will assign a Urban (U), Suburban (S), or Rural (R) designation to ZIP codes consistent with the definitions specified in 42 CFR § 423.100.

If geocodes are not assigned when the population file is created, Applicant may assign geocodes by navigating to Data > Assign Geocodes > Select and open file > Click OK. Applicants must use "representative" geocoding as the method to assign locations to each record in the Population file. This is the default GeoNetworks® method of assignment of geocodes when no address information is provided in the file (i.e., in this instance).

Applicants must define one employee group for all beneficiaries using the Medicare Beneficiary File Extract used in their analyses. The all beneficiaries file is used in the service area report.

- To define all beneficiaries, navigate to Define > Employee Groups > Add > on the Connection tab, select the data source > on the Filter Tab **no** tests should be set > Under the Options tab, enter the label of "All Beneficiaries" in the Description field and specify that Service Area Restriction is set to "inside"> click OK.

Applicants must define three subsets of the Medicare Beneficiary File Extract used in their analyses. These subsets are based on filtering on the designation of urban/suburban/rural assigned in the step above. These three subsets are used in the accessibility reports.

- To define the subset of Urban beneficiaries, navigate to Define > Employee Groups > Add > on the Connection tab, select the data source > on the Filter Tab, select "*filename*.STD_CLASS" as the field > "Test" should be "=" (equal to) > Value should be 'U' (Note: the single quotes signify a text field) > Under the Options tab, enter the label of "Urban Beneficiaries" in the Description field and specify that Service Area Restriction is set to "inside"> click OK.

- To define the subset of Suburban beneficiaries, navigate to Define > Employee Groups > Add > on the Connection tab, select the data source > on the Filter Tab, select "filename.STD_CLASS" as the field > "Test" should be "=" (equal to) > Value should be 'S' (Note: the single quotes signify a text field) > Under the Options tab, enter the label of "Suburban Beneficiaries" in the Description field and specify that Service Area Restriction is set to "inside"> click OK.

- To define the subset of Rural beneficiaries, navigate to Define > Employee Groups > Add > on the Connection tab, select the data source > on the Filter Tab, select "filename.STD_CLASS" as the field > Test should be "=" (equal to) > Value should be 'R' (Note: the single quotes signify a text field) > Under the Options tab, enter the label of "Rural Beneficiaries" in the Description field and specify that Service Area Restriction is set to "inside"> click OK.

  ✓***Quality Check:*** *Applicant should verify that the urban, suburban, and rural definitions are defined appropriately for each page of the report. These (filtered) sub-populations are used to verify access compliance. CMS will compare the total of urban, suburban, and rural beneficiaries for specific counties to totals derived from the Medicare Beneficiary File. Additionally, Applicant should verify that only beneficiaries within their service area are included in the report. This setting can be checked under the Options tab, in the Service Area Restriction box. The "within" radio button should be selected.*

  2. Defining the Provider File in GeoNetworks®

Applicants must use their listing of contracted Part D retail pharmacies. The listing used in these analyses must be consistent with the pharmacy listing provided under the instructions in Section 3.4.1C of this solicitation that includes address information to define their provider file. If an Applicant used more than one retail pharmacy network to provide the Part D benefit, the network must be combined in the GeoNetworks® analysis (and the submission provided under Section 3.4.1B of this solicitation to represent one complete Part D network).

Applicant may use representative ZIP Geocoding or the more precise geocoding methods for pharmacy providers (i.e., the ZIP+ 4 Centroid Method, the ZIP+2 Centroid Method, or address-based geocoding). CMS strongly encourages the use of more precise methods for geocoding. Use of address-based geocoding will prevent, in some market areas, false indications that access standards are not met.

Applicant must define Geocodes for their provider file by navigating to Data > Assign Geocodes > Select and open the provider file > Click OK. To the extent possible, CMS recommends that

Applicants use "address-based" geocoding as to assign locations to pharmacies as it is more precise. If this function is not available on your version of GeoNetworks®, the default, representative geocoding, methodology is acceptable.

Next, the Applicant shall define the Provider Group by navigating to Define > Provider Groups > Add > on the Connection tab, select the data source > on the Options tab, enter the label of "Part D Retail Pharmacy Network" in the Description field > Select OK.

> ✓***Quality Check:*** *Applicant should verify that the total counts for pharmacy providers match the counts in the Part D contracted retail pharmacy listing that must also be provided to CMS in accordance with the instructions in Section 3.4.1C of this solicitation. CMS will check total counts of pharmacies provided in the service area against the record count from submitted pharmacy listings.*
>
> *CMS recognizes that some regional PDPs contract with PBMs to provide national networks. Our review testing will reject instances where the total number of pharmacies in the GeoNetworks® analysis is greater than the number of retail pharmacies provided in the retail Pharmacy listing provided in Section 3.4.1C of this solicitation.*

3. Defining Access Criteria Consistent with Part D requirements

The Applicant must define access standards in accordance with the Part D standards, as defined in 42 CFR § 423.120 (a)(1).

- To define the Urban access standard, navigate to Define > Access Standards > Add > in the Description field, type "Urban: 1 provider within 2 miles" > Ensure that the Number of Providers is 1, the Test is within, and Miles is 2 > Click OK.

- To define the Suburban access standard, navigate to Define > Access Standards > Add > in the Description field, type "Suburban: 1 provider within 5 miles" > Ensure that the Number of Providers is 1, the Test is within, and Miles is 5 > Click OK.

- To define the Rural access standard, navigate to Define > Access Standards > Add > in the Description field, type "Rural: 1 provider within 15 miles" > Ensure that the Number of Providers is 1, the Test is within, and Miles is 15 > Click OK.

4. Defining the Plan Service Area(s)

PDP Applicants

For PDP Applicants, one service area may be defined to include all states that the organization intends to serve under a contract number. Separate accessibility analyses are required for each state if the contract number includes plans within that state that vary by the provider network. (i.e., Plan 001 has preferred providers only and Plan 002 includes preferred and non-preferred).

Please note that it is not a requirement for PDP Applicants to provide summary statistics related to the accessibility standards at the region level (even in the instance where the PDP region

covers multiple states). PDPs are required to adhere to the accessibility standards at the state level, although Applicant must also present access statistics at the county level. This will help CMS determine, for example, if there are particular geographic areas in the country where attaining the rural access requirement is difficult.

> ✓***Quality Check:*** *Applicants must verify that the reports provided to CMS include totals and summary statistics for each individual state within the PDP regions.*

Because the accessibility standard applies to PDPs, at state-level, their specification is straightforward. As outlined in Table below most PDPs will have multiple plan offerings in a region with each plan using the same network(s).

Table I

Example PDP Contractor PBP Offerings

Contract	**Contract Service Area**	**Pharmacy Network**
S0000	PDP Region 5: Maryland, Delaware and the District of Columbia	Part D Pharmacy Network 1

In this example, Applicant should define one service area (labeled PDP Region 05: S0000 in the description field) that includes the three states in the PDP region.

> *5. Accessibility Analyses -- Generating the Title, Table of Contents, Accessibility Detail and Service Area Detail Reports:*

The following two sub-parts provide instructions for PDP plans separately. Sub-part (b.) provides instructions for the completion of reports for PDP.

a. PDP Reports

Applicant reports must include a title page and a table of contents. To add a title page, navigate to Page > Add > Title Page. To add a table of contents, navigate to Page > Add > Table of Contents. Double click on the new Table of Contents page. Under the Options tab select Tab leaders, Page specifications, and Roman page numbers to be included in the report.

Accessibility Detail pages should be generated to represent urban/suburban/rural beneficiaries with and without access in each of the service area(s) defined. There should be six reports for each unique combination of a contract service area(s) and pharmacy network(s).

As stated earlier in this appendix, a PDP's service area is defined by the PDP region(s) that it serves. Accessibility analyses may vary based on the specific plan's pharmacy provider network (i.e., preferred only, preferred and non-preferred). Applicant should provide reports for each unique combination of contract and network. Reports should be provided that include each state in the applicant's PDP service area. ***The title in the accessibility detail report should specify the network represented in the pharmacy list. The network reference should match the "List Identifier" entry in your submission of the "Retail Pharmacy List.xls" file.*** For each accessibility analysis, a report is created that provides the percentage of beneficiaries with access and the percentage of beneficiaries without access. As specified in the instructions below, statistics for **each individual county** within the service area and statistics for **each State** (in total) must be provided.

Using the example outlined in Part 4.b., the steps to define the accessibility detail report for urban beneficiaries in the service area for S0000 requires the following steps:

- Navigate to Page > Add > Accessibility Detail > Double click on the page that appears
- Under the Specifications tab for the new Accessibility Detail Page set Employee Group to be your urban beneficiaries, set Provider Group to be "Part D Pharmacy Network 1", set Access Standard to be "Urban: 1 provider within 2 miles", set Access filter to "all", and set Service Area to S0000
- Under the Options tab for the new Accessibility Detail Page, select to summarize by county, and under show, ensure that the following options are checked: state, percent in filter, number in filter, number of providers, subtotals and totals.
- Under the Titles Page, uncheck the default Title 1 and specify a title that describes the unique service area. In this instance the title would be "PDP Region 05: Mid-Atlantic (DE, DC, MD)"

The steps above are repeated, with appropriate modifications, for suburban and rural beneficiaries.

The steps to define the service area report for all beneficiaries with access in the region for S0000 are as follows:

- Navigate to Page > Add > Service Area Detail> Double click on the page that appears.
- Under the Specifications tab for the new Service Area Detail Page set Employee Group to be all beneficiaries, set Provider Group to be "Part D Retail Network 1", set Service Area to S0000.
- Under the Options tab for the new Service Area Detail Page, select to summarize by state, set service area filter to inside, ensure that the following options are checked: number of employees, number of providers, and totals.
- Under the Titles tab, uncheck the default Title 1 and specify a title that describes the service area. In this instance the title would be "PDP Region 05: Mid-Atlantic (DE, DC, MD) ".

- Ensure that no specifications are indicated under the Include tab.

- Under the Sort tab ensure that sort order is State (ascending), then County (ascending).

Including the title and table of contents, a six (6) page report will be generated using the CMS example, for S0000, and following all of the specifications including: (1) use of the appropriate employee group, (2) correct definition of the access standards, (3) correct definition of the service area; and (4) provide analyses with "all" beneficiary specification. An overview of this report is specified in Table II. CMS also requests the inclusion of the summary report that provides information about the set-up and run date of the analysis. An example of the PDP GeoAccess reports with the file name, "Example PDP GeoNetworks Analysis.tif" accompanies this document.

Table II

Example S0000 Report Pages Specification

Rpt #	Page	Summarized by	Employee Group	Provider Group	Access Standard	Service Area / Title 1	Access Filter
1	Title						
2	Table of Contents						
3	Accessibility Detail	County	Urban PDP Region 05 Beneficiaries	PDP Region 05 Part D Retail Pharmacy Network	Urban: 1 provider within 2 miles	S0000	All
4	Accessibility Detail	County	Suburban PDP Region 05 Beneficiaries	PDP Region 05 Part D Retail Pharmacy Network	Suburban: 1 provider within 15 miles	S0000	All
5	Accessibility Detail	County	Rural PDP Region 05 Beneficiaries	PDP Region 05 Part D Retail Pharmacy Network	Rural: 1 provider within 15 miles	S0000	All
6	Service Area	State	All Beneficiaries	Part D Retail Pharmacy Network		S0000	

Table II

Example S0000 Report Pages Specification

Rpt #	Page	Summarized by	Employee Group	Provider Group	Access Standard	Service Area / Title 1	Access Filter
7	GeoNetworks Report (auto generated summary information report to be included in submission)						

As part of the submission for each contract report Applicants should include the "Report Information" page. This page is generated automatically when the GeoNetworks® report is run.

An example of the PDP GeoAccess report with the file name, "Example PDP GeoNetworks Analysis.tif " accompanies this document.

> ✓***Quality Check:*** *Applicants must verify that accessibility detail reports are provided for each unique combination of service area and pharmacy network consistent with the example table above. Additionally, each submission should include the report information page for each report.*

6. Providing copies of the GeoNetworks® Analysis to CMS for review

Applicants must provide both a single hardcopy of their GeoNetworks® reports as well as Adobe Acrobat readable (*.pdf) versions of the reports. These reports must be submitted as attachments pursuant to the instructions in Section 2.4 of this solicitation.