Contract ID Number: E_____

2008

MEDICARE PRESCRIPTION DRUG BENEFIT

Solicitation for Applications for New Employer/Union Direct Contract Prescription Drug Plan (PDP) Sponsors

January ??, 2007

Contract ID Number: E_____

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1. GENERAL INFORMATION

1.1 Purpose of Solicitation

The Centers for Medicare & Medicaid Services (CMS) is seeking applications from entities that meet the requirements of 1860D-22(b) 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). Hereinafter, these entities will be referred to as "Direct Contract PDPs" or "Direct Contract PDP Sponsors". Please submit your applications according to the process described in Section 2.0.

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 1860D-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 its 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.

The MMA provides employers and unions with a number of options for providing prescription drug coverage to their Medicare-eligible retirees. Under the MMA, those options include making special arrangements with Medicare Advantage Organizations (MAOs) and Section 1876 Cost Plans to purchase customized benefits, including drug benefits, for their retirees; purchasing benefits from sponsors of prescription drug-only plans (PDPs); and directly contracting with CMS to become Part D plan sponsors themselves. Each of these approaches involves the use of CMS waivers authorized under Sections 1857(i) or 1860D-22(b) of the Social Security Act (SSA). Under this authority, CMS may waive or modify requirements that "hinder the design of, the offering of, or the enrollment in" employer-sponsored group plans.

This Solicitation applies to only the last option - the Direct Contract PDP employer or union sponsor who directly contracts with CMS to offer a standalone Prescription Drug Plan (PDP).

Please note this Solicitation is only to be used for Direct Contract PDPs. This solicitation is not to be used by existing Direct Contract PDP Sponsors seeking to renew their direct contracts with CMS for 2007. These entities should follow CMS renewal instructions.

In general, Part D plans can only cover beneficiaries in the service areas in which they operate. However, under our waiver authority, employers/unions which directly contract with CMS to sponsor their own PDPs can extend coverage to all of their retirees, regardless of where they reside in the nation. Also, Part D plans must meet minimum enrollment standards (42 CFR 423.512(a)). CMS has waived this requirement for all Direct Contract PDP Sponsors. (See Section 3.5 of the Solicitation.)

In addition, a Part D sponsor must be organized and licensed under State law as a risk-bearing entity eligible to offer health insurance or health benefits coverage in each State in which it offers its coverage (42 CFR 423.504(b)(2)). However, CMS has waived the state licensing requirement for all Direct Contract PDP Sponsors However, CMS will require such entities to certify that they meet solvency standards and/or have other safeguards as identified by CMS in Appendix VI of the Solicitation. (See Section 3.1.3 of the Solicitation.)

Additional relevant waivers that CMS has granted to Direct Contract PDP Sponsors are incorporated into this Solicitation.

1.4 Part D 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
June 4, 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: 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 Direct Contract PDP Sponsor's Role and Responsibilities

Key aspects of each PDP shall include the ability/responsibility to:

- Submit a formulary each year for CMS approval.

- Submit a PDP plan bid each year for CMS approval.

- Restrict enrollment to those Part D eligible individuals eligible for the employer's/union's employment-based retiree prescription drug coverage.

- 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 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 beneficiary dissemination 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 review 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 Part D bid submission on June 4, 2007. The second step involves the bid review and negotiations with plans 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: PDP sponsors, as covered entities under the Health Insurance Portability and Accountability Act Privacy Rule, are subject to investigation and penalties for findings of Health Insurance Portability and Accountability Act Privacy Rule 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, PDE claims data, cost data, benefit management data, marketing review information, and customer satisfaction and complaints data.

To monitor plan performance in the areas we have identified, 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.

Marketing Guidelines and Review
Marketing Guidelines are posted on the www.cms.hhs.gov/ website, and will be updated on a quarterly basis. The Direct Contract PDP Sponsor will be required to adhere to all CMS requirements concerning marketing and beneficiary dissemination unless these requirements have been specifically waived and/or modified for Direct Contract PDP Sponsors. Specific marketing requirements that are eligible for waiver are reflected in this application. Beneficiary dissemination requirements relevant to this Solicitation are incorporated herein. (See Section 3.13 of the Solicitation.)

Eligibility for the Low Income Subsidy Program
Low-income Medicare beneficiaries will receive full or partial subsidies of premiums and reductions in cost sharing under the Part D benefit. Certain groups of Medicare beneficiaries will automatically be 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 will apply for a low-income subsidy and have their eligibility determined by either the states 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 plan sponsors as part of the enrollment files from the enrollment processing system described below. For additional information regarding how low income subsidy eligibility determinations are made, 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 disenrollments 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.

Under Section 1860D-22(b) of the Social Security Act, Direct Contract PDP Sponsors may only offer "employment based retiree health coverage." Therefore, Direct Contract PDP Sponsors will be

required to restrict enrollment to those Part D eligible individuals eligible for their employment-based retiree prescription drug plans.

Direct Contract PDP Sponsors may enroll those Part D eligible individuals eligible for the employer's/union's employment-based retiree prescription drug coverage using a group enrollment process that includes providing CMS with any information it has on other insurance coverage for the purposes of coordination of benefits. Also, special enrollment periods exists for individuals enrolling in employer/union group-sponsored Part D plans, for individuals to disenroll from a Part D plan to take employer/union group-sponsored coverage of any kind, and for individuals disenrolling from employer/union group-sponsored coverage to enroll in a Part D plan. These special enrollment rules apply to Direct Contract PDP Sponsors. For additional information regarding enrollment and eligibility, refer to www.cms.hhs.gov/website

Payment to Direct Contract PDPs

Generally, CMS provides payment to Direct Contract PDP Sponsors in the form of advance monthly payments (consisting of the Part D standardized bid, risk adjusted for health status, minus the beneficiary monthly premium), and estimated low-income subsidies. After the end of the payment year, CMS reconciles the correct amounts of low-income subsidies against the amount paid as a part of the prospective monthly payments. A complete description of the bidding and payment process for Direct Contract PDP Sponsors will be included in future CMS guidance. 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

These are specific instructions on how employers or unions must complete an initial application to directly contract with CMS to offer a PDP for their Part D eligible individuals eligible for the employer's/union's employment-based retiree prescription drug coverage in 2008.

2.2 Other Technical Support

CMS conducts technical support calls, also known as User Group calls, for Applicants. CMS operational experts (e.g. 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.

2.3 Health Plan Management System (HPMS) Data Entry

Direct Contract PDP Applicants that submit a Notice of Intent to Apply form will be assigned a pending contract number (E number) to use throughout the application and subsequent operational processes. Once the contract number is assigned, Direct Contract PDP Applicants will receive their CMS User ID(s) and password(s) for HPMS access and will need to input contact and other related information into the Health Plan Management System (HPMS). Applicants will be 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 up until March 12, 2007. Applicants must use the 2008 Solicitation. CMS will not accept or review in any way those submissions using the 2007 Solicitation.

Instructions
Applicants must include the contract ID number in the heading on each page of the application submitted to CMS.

In preparing your application in response to the prompts in Section 3.0 of this solicitation, please mark "Yes" or "No" in sections organized with that format.

In many instances Applicants are directed to affirm 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.

There are certain attestations to which all applicants must attest 'Yes' in the Solicitation. However, in addition to attesting 'Yes,' an Applicant may request in writing a waiver or modification of additional requirements under this Part that hinder the design of, the offering of, or the enrollment in the Direct Contract PDP. Applicants who wish to request waivers in addition to those specified in the Solicitation must satisfy the requirements of Appendix XIV.

Where this application directs the Applicant to attest that it will meet a particular Part D requirement for which the Applicant has requested a waiver, the Applicant must check the "Yes" box. In the event that CMS does not approve a particular waiver, the Applicant will still have attested that it will meet all the applicable Part D program requirements and remain eligible to enter into a Direct PDP contract upon approval of its bids at the end of the summer of 2007. This process will prevent Applicants from having to submit additional application responses after the original March 12, 2007 deadline. If, as a result of CMS' denial of its waiver request, the Applicant no longer intends to offer a Direct PDP, the Applicant must notify CMS in writing. CMS will not execute a Direct PDP contract with Applicants that submit such a notice. This notice of withdrawal should be sent to:

Centers for Medicare & Medicaid Services (CMS)
Center for Beneficiary Choices
Attention: Application Withdrawal
7500 Security Boulevard
Mail Stop C1-22-06
Baltimore, Maryland 21244-1850

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 below the question. (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 the deadline for application submission. We will notify Applicants of any deficiencies and afford them the opportunity to amend their applications.

CMS has established that all aspects of program that the Direct Contract PDP Sponsor attests to must be ready for operation by the contract signature date. As with all aspects of a Direct Contract PDP 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 Direct Contract PDP Sponsor's

facilities as well as through other program monitoring techniques. Consequences of a failure to meet the requirements attested to in this Solicitation and failure to operate a Part D plan consistent with the requirements of the applicable statutes, regulations, call letter, and the Part D contract may delay the Direct Contract PDP's enrollment activities or, if corrections cannot be made in a timely manner, the Direct Contract PDP Sponsor may 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 must deliver a total of two (2) hard copies of the written application and supporting documentation.

- Applicant must include a cover letter with the following elements:

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

NOTE: It is important that Applicant **provides 2 separate contact persons** and applicable contact information for PDP Application submission(s). This will help to avoid delays in the processing of an application.

- All responses must be completed in Microsoft Word, Microsoft Excel, or PDF (in a version that is compatible with Office 2003).

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

- One application must be clearly marked, "Original" and contain all original signed certifications requested in the application.

- Additionally, the Applicant must submit the cover letter, written application, appendices, attachments and all supporting documentation electronically on 2 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) **NOTE:** If all of the application materials will not fit on a single CD, Applicant must submit multiple CDs and label them 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 an application consistent with these instructions may delay its review by CMS and could result in the sponsor receiving a notice of intent to deny.

- Applications must be sent to:

Centers for Medicare & Medicaid Services (CMS)
Mail Stop: C1-22-06
Attn: Direct Contract PDP Application
7500 Security Boulevard
Baltimore, Maryland 21244-1850

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

- CMS will not review applications received after 5:00 P.M. EST on March 12, 2007. CMS will not review any submissions based on the 2007 Solicitation. Applicants must complete the 2008 Solicitation in order to be considered for Part D sponsorship.

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.

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. **Direct Contract PDP s will be excluded**

from this automatic enrollment process (i.e., no dual eligible individuals will be automatically enrolled in these employer/union plans).

NOTE: Full-benefit dual eligible individuals not otherwise enrolled in a Part D plan initially will be automatically enrolled in a Part D plan. Direct Contract PDP s will be permitted to utilize the group enrollment process which will override any previous automatic enrollment of or individually elected enrollment in Part D by full-benefit dual eligible individuals.

Technical Assistance
For technical assistance in the completion of this Application, contact:
Marye Isaacs by email at Marye.Isaacs@cms.hhs.gov or by phone at 410-786-3276 or Julian Nadolny by email at Julian.Nadolny@cms.hhs.gov or by phone at 410-786-2274.

2.5 Submission Software Training

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

Applicants will be 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
PDP 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. Direct Contract PDP Applicants are required to secure access to HPMS in order to carry out these functions.

Enrollment and Payment

All PDP 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, PDP 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 will be the primary contact for all issues related to the physical submission of transaction files to CMS. PDPs that enter into a contract with CMS must also submit the *Banking Information Form* (Appendix II) so that payments can be transmitted to your account.

Each month, CMS will provide reports to each PDP sponsor for each of their plans with member and plan-level information by CMS. PDP 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 will be responsible for your geographic area and will help sponsors to 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 for Direct Contract PDP 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 will include premiums and subsidies CMS is paying on behalf of low-income individuals qualifying for the full and partial low-income subsidies. Estimated low-income subsidies will also be included.

2.7 Summary Instruction and Format for Bids

Each Direct Contract PDP Sponsor must submit to CMS a bid for each prescription drug plan it intends to offer. Further guidance for Direct Contract PDP Sponsors on bidding for 2007 contract year will be provided by CMS. Applicants must submit their formularies to HPMS on or before April 16, 2007 and the PBPs and BPTs on or before June 4, 2007.

2.7.1 Format of Bids

Bid Submission Sections Due Prior to June 4, 2007

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 evaluate 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 review of the formulary development 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 June 4, 2007, PBP and BPT submissions so that any modification may be reflected in those documents.

Bid Submission Due June 4, 2007

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. Generally, CMS requires that the bid represent a uniform benefit package based upon a uniform level of premium and cost sharing among all retirees enrolled in the plan. The benefit packages submitted must be cross walked appropriately from the formulary. Pursuant to 42 CFR 423.505(k)(4), the CEO, CFO, or a designee 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.

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 PDP sponsor is taking to control costs, such as through various programs to 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 PDP applicants 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. 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

CMS waived the specific Part D retail pharmacy access standards in 423.120(a)(1) ("TriCare" standards) for Employer/Union Direct Contract PDPs. Direct PDPs must agree that its retail pharmacy access will be sufficient to meet the needs of its population, including situations involving emergency access. CMS may review the adequacy of the plan's pharmacy networks and potentially require expanded access in the event of beneficiary complaints or for other reasons it determines in order to ensure that the plan's network is sufficient to meet the needs of its retiree population.

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 Direct PDP 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. 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.

2.9 Standard Contract with Direct Contract PDP Sponsors

Successful Applicants will be deemed qualified to enter into a Part D contract with CMS to operate a 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 can always 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 C.F.R. §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, except to the extent waivers and/or modifications to these requirements have been granted by CMS under section 1860D-22(b) of the Act. Failure to reference a regulatory requirement in this application does not affect the applicability of such requirement, and Direct Contract PDP Sponsors are required to comply with all applicable requirements of the regulations in Part 423 of 42 CFR.

For several 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, and Financial Stability

3.1.1 Management and Operations

A. Complete the tables below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING REQUIREMENTS TO BE APPROVED FOR A PDP CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN:	YES	NO
1. Applicant is applying to operate as a Direct Contract PDP Sponsor.	☐	☐
2. Applicant is an entity that meets the requirements under 1860D-22(b). (Applicant is an employer, labor union, or the trustees of a fund established by one or more employers or labor organizations (or combination thereof) to furnish benefits to the entity's employees, former employees (or combination thereof) or members or former members (or combination thereof) of the labor organizations.)	☐	☐
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 provides evidence of and maintains contracts or other legal arrangements between or among the entities combined to meet the functions identified in subsection 3.1.2 A.	☐	☐
APPLICANT MUST ATTEST 'YES' TO A5, A6, AND A7 OR APPLICANT MUST ATTEST 'YES' TO A8 TO BE APPROVED FOR A PDP CONTRACT.	**YES**	**NO**
5. 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	☐	☐
6. Applicant has administrative and management arrangements that feature personnel and systems sufficient for the Direct Contract PDP Sponsor to organize, implement, control and evaluate financial activities, the furnishing of prescription drug services, the quality assurance, medication therapy management, and drug utilization management programs, and the administrative aspects of the organization.	☐	☐
7. Applicant has administrative and management arrangements that feature an executive manager whose appointment and removal are under the control of the policy-making body.	☐	☐
8. Applicant (or to the extent applicable, the business associate with which it contracts for prescription drug services) is subject to other standards governing its management and operations, such as ERISA fiduciary requirements, state law standards, and certain oversight standards created under the Sarbanes Oxley Act. Please identify the other governing standards: _____	☐	☐
APPLICANT MUST ATTEST 'YES' OR 'NO' TO A9 AND A10. IF APPLICANT ATTESTS 'NO' TO EITHER PROVISION, THE REQUIREMENTS OF APPENDIX VI MUST BE COMPLETED AND SUBMITTED WITH THE SOLICITATION.	**YES**	**NO**
9. 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.	☐	☐
10. 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.	☐	☐

APPLICANT MUST ATTEST 'YES' OR 'NO' TO THE FOLLOWING REQUEST FOR INFORMATION TO BE APPROVED FOR A PDP CONTRACT. ATTEST 'YES' OR 'NO' TO BY PLACING A CHECKMARK IN THE RELEVANT COLUMN:	YES	NO
11. Applicant is applying to operate as a Direct Contract PDP Sponsor on a calendar-year basis. If 'No,' Applicant must insert the start and end date of the non-calendar year plan. (Start Date):_____ (End Date):_____	☐	☐

B. Complete the form below inserting 'N/A' if a line is not applicable:

IDENTIFY YOUR ORGANIZATION BY PROVIDING THE FOLLOWING INFORMATION	
Full Legal Organization's Name:	
Full Address of Your Organization's Headquarters *(Street, City, State, Zip):*	
Name of Chief Executive Officer/Trustee(s)/Equivalent Official:	
Name of Chief Operating Officer/Trustee(s)/Equivalent Official:	
Name of Chief Financial Officer/Trustee(s)/Equivalent Official:	
Type of Entity (place a checkmark in <u>all</u> applicable boxes): ☐ Employer ☐ Trust established by one or more employers or labor organizations ☐ Union ☐ Governmental ☐ Church Group ☐ Not-for-Profit ☐ Publicly-Traded Corporation ☐ Privately- Held Corporation ☐ Other (list type) _ _____	
Name of Your Organization's Parent Organization, if any:	
Is Applicant subject to ERISA? ☐ Yes ☐ No	
State in Which your Organization is Incorporated or Otherwise Organized to do Business:	
Federal Taxpayer Identification Number:	
PROVIDE NAME AND TITLE OF INDIVIDUAL WHO WILL SIGN THE MEDICARE PDP CONTRACT, IF APPLICATION AND BID ARE SUCCESSFUL. PLEASE SEE 42 CFR 423.502(b). THIS PERSON MUST BE AUTHORIZED TO ACT FOR THE ENTITY	
Name of Individual:	Title:
PROVIDE YOUR COMPANY'S CONTACT INFORMATION FOR AN INDIVIDUAL WHO CAN ANSWER QUESTIONS REGARDING YOUR ORGANIZATION'S APPLICATION	
Name of Individual:	Title:
Telephone Number:	Fax Number:
Email Address:	

C. Provide below, or as an attachment, a brief summary of the background, history, structure and ownership of Applicant's organization. Include a chart showing the structure of ownership, subsidiaries, and business affiliations. The organizational chart should depict the placement of the Medicare PDP operations within Applicant's organization as well as who within Applicant's organization will be managing/administering the PDP.

If Applicant is a state agency, instrumentality or subdivision, the organizational chart should indicate the relationship between the entity that is named as the PDP applicant and the state or commonwealth with respect to which Applicant is an agency, instrumentality or subdivision. The organizational chart also should indicate the source of Applicant's revenues including whether Applicant receives appropriations and/or has the authority to issue debt.

If Applicant is a labor organization including a fund or trust, the organizational chart should indicate the relationship (if any) between Applicant and any other related labor organizations such as regional, local or international unions, or welfare funds sponsored by such related labor organizations. If Applicant is a jointly trusteed Taft-Hartley fund, please include the names and titles of labor-appointed and management-appointed trustees.

If Applicant is a trust such as a voluntary employee beneficiary association under Sec. 501(c)(9) of the Internal Revenue Code, the organizational chart should include the names of the individual trustees and the bank, trust company or other financial institution that has custody of Applicant's assets.

D. Complete the form(s) below to identify the names of each of the entities with which you subcontract or will subcontract to serve the functions identified in Subsection 3.1.1E. If more than one subcontractor has been engaged to meet these functions, identify each of the subcontractors within the relevant requirement column. Copy and paste the form, if you need additional space:

IDENTIFY YOUR SUBCONTRACTOR BY PROVIDING THE FOLLOWING INFORMATION	
Full Legal Organization's Name of Subcontractor:	Function(s) Contracted for:
Full Address of Subcontractor's Headquarters *(Street, City, State, Zip):*	
Name of Chief Operating Officer of Subcontractor:	
Name of Chief Financial Officer of Subcontractor:	
Type of Ownership: ☐ Sole Proprietorship ☐ Partnership ☐ Publicly-Traded Corporation ☐ Privately- Held Corporation ☐ Other (list type)_ ___	
Name of Subcontractor's Parent Organization, if any:	
State in Which Your Subcontractor is Incorporated or Otherwise Organized to do Business:	
Federal Taxpayer Identification Number of Subcontractor	
PROVIDE INDIVIDUAL WHO WILL SIGN THE SUBCONTRACT WITH PDP APPLICANT. THIS PERSON MUST BE AUTHORIZED TO ACT FOR THE SUBCONTRACTOR ENTITY:	
Name of Individual:	Title:
Telephone Number:	

E. Subcontractor Function Chart

Identify the names of the subcontractors you will use to serve these functions (Indicate 'APPLICANT' if Applicant will perform the function). NOTE: Information for each identified subcontractor must be provided in 3.1.1D.	**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.	

F. Provide as attachments (as instructed in Section 2.4) copies of executed contracts and fully executed letters of agreement with each subcontractor identified in 3.1.1D and E. Each contract must contain each of the elements listed below.

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 Direct Contract 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 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 (e.g., 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 Direct Contract PDP Sponsor;

12. Contain language that if the Applicant, upon becoming a Direct Contract PDP Sponsor, delegates an activity or responsibility to the subcontractor, that such activity or responsibility may be revoked if CMS or the Direct Contract PDP 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 Direct Contract PDP Sponsor, will monitor the performance of the subcontractor on an ongoing basis; and

14. Contain language specifying that if the subcontractor will establish the pharmacy network or select the pharmacies to be included in the network, the Direct Contract PDP Sponsor retains the right to approve, suspend, or terminate any arrangement with a pharmacy.

15. Contain language to ensure that PBMs report 100% of any manufacturer rebates they receive for drugs provided under the sponsor's Part D plan, including the portion of such rebates retained by the PBM as part of the price concession for the PBM's services. (e.g. clause that provides for 100% reporting requirement with an auditing clause in any contract)

G. Provide as an attachment the signed certification in Appendix V. The certification allows the Applicant to verify that the subcontracts meet all of the requirements identified in 3.1.1F.

H. Provide electronic lists of the subcontract citations demonstrating that the requirements of Section 3.1.1F 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.

3.1.2 Experience and Capabilities

A. Complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PDP CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN.	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 operate 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 operate 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.		

3.1.3 Financial Solvency

A PDP generally must be licensed by at least one state as a risk-bearing entity (42 CFR 423.401(a)(1)). CMS has waived the requirement for Direct Contract PDP Sponsors. Direct Contract PDP Sponsors are not required to be licensed, but must demonstrate financial solvency through other CMS requirements. Each Direct Contract PDP Sponsor applicant must comply with the requirements set forth at Appendix IV and provide all required information.

3.1.4 Business Integrity

A. Complete the table below:

APPLICANT MUST ATTEST 'YES' TO THE FOLLOWING QUALIFICATION TO BE APPROVED FOR A PDP CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN.	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 3.1.4A2, 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); and**
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; and
5) Settlement agreements or corporate integrity agreements.

3.1.5 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. 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 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. 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. Complete the form below.

IF APPLICANT IS SUBMITTING 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 PHARMACY BENEFIT MANAGER'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.	YES	NO
1. Applicant is using either its own P&T committee or the P&T committee of its PBM for purposes of the Part D benefit.	☐	☐
2. If answered yes to A1, Applicant's PBM is operating under a confidentiality agreement for purposes of the P&T Committee. (If not applicable, check "NO.")	☐	☐
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 Applicant's P&T committee shall be practicing physicians and/or practicing pharmacists.		
10. The membership of Applicant's P&T committee will include at least one practicing physician and at least one practicing pharmacist who are free of conflict with respect to the Applicant organization and pharmaceutical manufacturers.		
11. The membership of 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 the Inspector General's Exclusion List. This list can be found at http://exclusions.oig.hhs.gov/search.html .		

B. 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 A9, 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 XII 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. 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 2.5					
	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. Complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PDP CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN.	**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 3.13 Reporting Requirements).	☐	☐

3.2.3 Quality Assurance and Patient Safety

A. Complete the table below:

APPLICANT MUST ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PDP CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN.	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 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 42 CFR 423.153 (c) (2) and (3).	☐	☐
4. Applicant will ensure patient counseling is offered to enrollees, when appropriate.	☐	☐
5. Applicant develops and implements internal medication error identification and reduction systems.	☐	☐
6. Applicant will report to CMS data for QA standards in the manner prescribed by CMS. (See Section 3.16 Reporting Requirements)	☐	☐
7. 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.	☐	☐
8. 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.		
9. 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	☐	☐
10. Applicant agrees to ensure that staff are trained on and information systems are in place to accommodate administration of the transition policy. This includes adoption of necessary information system overrides.	☐	☐
11. Applicant will establish policies and procedures for P & T committee involvement in reviewing non-formulary drug request 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.	☐	☐
12. 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.	☐	☐
13. Applicant will establish appropriate timeframes and "first fill" procedures to non-formulary Part D medications in long term care and retail setting.	☐	☐

3.2.4 Medication Therapy Management

A. Complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PDP CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN.	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 on March 12, 2007.	☐	☐
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 by those providing MTM services.	☐	☐
11. The Applicant agrees to submit a description 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 by 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

Contract ID Number: E_____

A. Complete the table below:

APPLICANT MUST ATTEST 'YES' TO THE FOLLOWING QUALIFICATION TO BE APPROVED FOR A PDP CONTRACT. ATTEST 'YES' OR 'NO' TO THE FOLLOWING QUALIFICATION BY PLACING A CHECKMARK IN THE RELEVANT COLUMN.	YES	NO
1. 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. Complete the table below:

APPLICANT MUST ATTEST 'YES' TO THE FOLLOWING QUALIFICATION TO BE APPROVED FOR A PDP CONTRACT. ATTEST 'YES' OR 'NO' TO THE FOLLOWING QUALIFICATION BY PLACING A CHECKMARK IN THE RELEVANT COLUMN.	YES	NO
Applicant agrees to comply with CMS bidding requirements.	☐	☐

3.3 Service Area/Regions

In general, Part D plans can only cover beneficiaries in the service areas in which they operate. CMS has waived this requirement for Direct Contract PDP Sponsors. Direct Contract PDP Sponsors can extend coverage to all of their retirees, regardless of whether they reside in one or more other PDP regions in the nation. Direct PDPs will automatically have set a national service area so they will have the ability to cover their retirees nationwide.

3.4 Pharmacy Access

A. Complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PDP CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN:	YES	NO
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 PDP'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 (i.e. web posting) 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(a) 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 VII-XI will be included in the respective downstream pharmacy network contracts.	☐	☐
9. Applicant agrees to notify CMS when the Applicant changes its pharmacy benefit management (PBM) subcontractor.	☐	☐
10. Applicant agrees to notify CMS about any substantive change in its organization's pharmacy network that may impact the organization's ability to maintain a Part D pharmacy network that meets CMS' requirements.	☐	☐

B. Provide as an attachment a contract template for each of the following types of pharmacies: Retail, Mail Order, Home Infusion, Long-Term Care and I/T/U. The mail order contract is only necessary if the plan is offering mail order. The I/T/U 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. For example, if different terms for retail pharmacies apply depending upon geographic location, all standard terms 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 through XI are included in such contracts. Submit this data by creating separate spreadsheets in Microsoft Excel that mimic Appendix VII through XI. Provide these attachments on each of the 2 CDs as instructed in Section 2.

3.4.1 Retail Pharmacy

CMS has waived the "Tricare" retail pharmacy access requirements set forth in 42 CFR 423.120(a)(1); they will not apply when the plan's pharmacy network is sufficient to meet the needs of its enrollee population, as determined by CMS. CMS may periodically review the adequacy of the plan's pharmacy network and require the plan to expand access if CMS determines that such expansion is necessary in order to ensure that the plan's network is sufficient to meet the needs of its enrollee population.

A. Complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PDP CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN:	YES	NO
1. Applicant agrees that its retail pharmacy access will be sufficient to meet the needs of its retiree population, including situations involving emergency access.	☐	☐
2. Applicant acknowledges that CMS may review the adequacy of the plan's pharmacy networks and potentially require expanded access in the event of beneficiary	☐	☐

	complaints or for other reasons it determines in order to ensure that the plan's network is sufficient to meet the needs of its retiree population.		
3.	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.	☐	☐
4.	Applicant agrees to use the CMS beneficiary counts in the data file "Medicare Beneficiaries by State, Region, Zip DATE" to prepare the retail network analyses.	☐	☐
5.	Applicant seeks to obtain a pharmacy access waiver of any willing pharmacy requirements. If YES, complete table C.	☐	☐

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 file templates "Retail Pharmacy List" for reference).

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.
   - When defining the service area for Applicant's geonetworks® reports, include any and all states where Applicant's current retirees reside.
   - Also, define the geonetworks® reports in accordance with the TriCare standards.. Even though your submission will not be held to the TriCare standards, the geonetworks® reports requires the use of these standards. Applicant is required to provide county and state specific reports as instructed..

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.

While the documentation that Applicant provides will represent the pharmacy networks for the service area where Applicant's current retirees reside, Direct Contract PDPs must ensure that they have adequate Part D pharmacy access sufficient to meet the needs of their retiree population wherever retirees may reside. This includes retail/mail order, home infusion, long-term care and I/T/U pharmacy access. These pharmacy access requirements will be included as terms in the CMS contract that will be made available to qualified applicants in September 2007. One way to ensure convenient access in service areas that you may cover but where your retirees presently do not reside would be to subcontract with a pharmacy benefit manager (PBM) that offers a national Part D pharmacy network.

3.4.2 Out-of-Network Pharmacy

A. Complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PDP CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN:	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 § 423.104(d)(2)(i)(B) and § 423.104(e).	☐	☐

3.4.3 Mail Order Pharmacy

A. Complete the table below:

APPLICANTS MAY OFFER A MAIL ORDER OPTION IN ADDITION TO THEIR CONTRACTED PDP PHARMACY NETWORK BUT MAIL ORDER PHARMACIES DO NOT COUNT IN MEETING NETWORK ADEQUACY STANDARDS. INDICATE '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 plan.	☐	☐
2. If Applicant attests 'Yes' to 3.4.3A1, mail order will 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 file templates "Mail Order Pharmacy List" for reference).

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

   - 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.

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 "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.

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 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. Complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PDP CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN:	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 beneficiaries' 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". (Appendix IX contains the template "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 your Medicare-eligible retirees.

3.4.5 Long -Term Care (LTC) Pharmacy

A. Complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PDP CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN:	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. (From Pharmacy Access Submission document)	☐	☐
4. Applicant agrees to recognize the CMS special election period (SEP) or open enrollment period for institutionalized individuals (OEPI) 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 file template "Long Term Care Pharmacy List" for reference).

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 your Medicare-eligible retirees.

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

A. Complete the table below:

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

Note: Information for Part D Sponsors on Contracting with Indian Health Care Providers is posted on the www.cms.hhs.gov/PrescriptionDrugCovContra/ website.

A. 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 file template "ITU Pharmacy List" for reference).

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. Complete the table below.

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PDP CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN:	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 it will not require pharmacies to accept different reimbursement rates for certain "specialty" drugs.	☐	☐
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. Complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PDP CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN:	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 the Creditable Coverage guidelines that are posted on the www.cms.hhs.gov/ website.	☐	☐
3. Applicant agrees to restrict enrollment to those Part D eligible individuals eligible for the employer's/union's employment-based retiree prescription drug coverage.	☐	☐
4. Applicant agrees not to enroll beneficiaries except during allowable enrollment periods, including Special Enrollment Periods.	☐	☐
5. Applicant will collect and transmit data elements specified by CMS for the purposes of enrolling and disenrolling beneficiaries in accordance with the CMS Eligibility and Enrollment and Disenrollment Guidance.	☐	☐
6. Applicant agrees to transmit enrollment and disenrollment transactions to CMS within 14 calendar days of receipt.	☐	☐
7. Applicant agrees that for enrollments, it will send individuals an acknowledgement notice within 7 calendar days of receiving an enrollment request from an individual and a confirmation notice within 7 calendar days of receiving confirmation of enrollment from CMS.	☐	☐
8. 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.		
9. Applicant will permit voluntary disenrollments only during allowable periods as specified in CMS requirements.	☐	☐
10. 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.	☐	☐
11. 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.		
12. Applicant will notify 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.	☐	☐
13. Applicant will follow policies and procedures established by CMS for addressing beneficiary requests for a Special Enrollment Period and verifying a beneficiary's eligibility for a Special Enrollment Period.	☐	☐
14. Applicant will develop and implement policies and procedures (including appropriate notice and due process requirements) for optional involuntary disenrollment as permitted by CMS.	☐	☐
15. 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.	☐	☐
16. Applicant will collect and transmit creditable coverage information in accordance with CMS guidance and policies	☐	☐
17. 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.	☐	☐
18. Applicant will query the Batch Eligibility Query (BEQ) or the Medicare Beneficiary Database User Interface (MBDUII) to receive: • the end date of the beneficiary's Part D IEP, • periods of enrollment in a Medicare plan that provides prescription drug coverage, and • periods of enrollment in a retiree prescription drug plan whose sponsor receives a retiree drug subsidy from Medicare	☐	☐
19. Applicant agrees to review creditable coverage evidence such as: a copy of a personalized disclosure notice from the covering entity; a copy of a generic creditable coverage disclosure notice from the covering entity, with some sort of proof of beneficiary coverage, such as an identification card, a bill, a summary of plan notice, etc; or a model Personalized Disclosure Form that allows beneficiaries to provide Part D plans with written confirmation of creditable coverage at the time of enrollment or upon appeal.	☐	☐
20. 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.	☐	☐
21. Applicant agrees to provide CMS with daily reports on the availability of 4 Rx data for all their enrollees. 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

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PDP CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN.	**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 Grievances

A. Complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PDP CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN.	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 Direct Contract 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 Direct Contract 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.

3.8 Exceptions and Appeals

A. Complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PDP CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN.	YES	NO
1. Applicant will adopt policies and procedures for beneficiary coverage determination, exceptions, and appeals consistent with 42 CFR Part 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 off-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.	☐	☐

3.9 Coordination of Benefits

A. Complete the table below:

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

QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN:		
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 from this requirement in accordance with CMS guidance (beneficiaries exempted would include, for example, auto-enrollees 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 (this may be combined with the working aged survey for MA sponsors).	☐	☐
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; • 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.	☐	☐

3.10 Tracking Out-of-Pocket Costs (TrOOP)

CMS has agreed that the disclosure requirements set forth in 42 CFR 423.128 and in marketing guidelines will not apply with respect to any employer/union-only group PDP when the Direct Contract PDP Sponsor is subject to alternative disclosure requirements (e.g., the Employee Retirement Income Security Act of 1974 ("ERISA")) and fully complies with such alternative requirements.

A. Complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PDP CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN:	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: a. Provide enrollees with a report on their TrOOP status at least monthly; **OR** b. If the employer/union is subject to alternative disclosure requirements (e.g., ERISA), Applicant fully complies with such alternative requirements. Please identify the other governing standards: _____	☐	☐
5. Applicant will: a. Provide enrollees daily access to their current TrOOP status through the organization's toll-free customer service phone number unless subject to alternative dissemination requirements; **OR** b. If the employer/union is subject to alternative disclosure requirements (e.g., ERISA), Applicant fully complies with such alternative requirements. Please identify the other governing standards: _____		
6. In the event of disenrollment, Applicant agrees to provide TrOOP status of the beneficiary as of the effective date of the disenrollment.	☐	☐
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 it receives notice that a beneficiary has disenrolled from the Applicant's Part D plan by enrolling 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.	☐	☐

Contract ID Number: E_____

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

3.11 Medicare Secondary Payer (MSP)

A. Complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PDP CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN:	YES	NO
1. Applicant will comply with the rules that determine when other payers are primary or secondary to Medicare as referenced in 42 CFR 423.462	☐	☐
2. Applicant will comply with 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.	☐	☐

3.12 Marketing/Beneficiary Communications

CMS will waive the disclosure requirements set forth in 42 CFR 423.128 and in marketing guidelines when a Direct Contract PDP Sponsor is subject to alternative disclosure requirements (e.g., the Employee Retirement Income Security Act of 1974 ("ERISA")) and fully complies with such alternative requirements.

A. Complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PDP CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN.	YES	NO
1. Applicant will comply with: a. Marketing guidelines that are updated on a quarterly basis and are posted on the www.cms.hhs.gov/ website. ; **OR** b. If the employer/union is subject to alternative disclosure requirements (e.g., ERISA), Applicant fully complies with such alternative requirements. Please identify the other governing standards: _____	☐	☐
2. Applicant agrees that: a. Annually and at the time of enrollment it will provide enrollees information about the following PDP features, as described in the marketing guidelines, except as modified by employer group waiver guidance: • 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; Applicant further agrees to provide general coverage information, as well as information concerning utilization, grievances, quality assurance, and sponsor financial information to any beneficiary upon request; **OR** b. If the employer/union is subject to alternative disclosure requirements (e.g., ERISA), Applicant fully complies with such alternative requirements. Please identify the other governing standards: _____		
3. The Applicant further agrees to provide general coverage information, as well as information concerning utilization, grievances, quality assurance and sponsor financial information to any beneficiary upon request.		
4. Applicant agrees that: a. 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 7 days a week, from 8 am to 8 pm according to the time zone for the regions in which the Applicant is offering a plan; • 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 PDP benefit plan, including co-payments, deductibles, and network pharmacies; • Call center features an explicit process for handling customer complaints; and • Call center shall provide service to non-English speaking and hearing impaired beneficiaries; **OR** b. If the employer/union is subject to alternative disclosure requirements (e.g., ERISA), Applicant fully complies with such alternative requirements. Please identify the other governing standards: _____	☐	☐
5. Applicant agrees that: a. Applicant will operate an Internet Web site that i) provides all the information described in Item #2 of this table, ii)describes the Applicant's PDP's formularies, and iii) 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; **OR** b. If the employer/union is subject to alternative disclosure requirements (e.g., ERISA), Applicant fully complies with such alternative requirements. Please identify the other governing standards: _____	☐	☐
6. Applicant agrees that: a. 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: i) the item or service for which payment was made; ii) notice of the enrollee's right to an itemized statement; iii) a year-to-date statement of the total Part D benefits provided in relation to deductibles, coverage limits, and annual out-of-pocket thresholds; iv) cumulative year-to-date total of incurred costs; and v) applicable formulary	☐	☐

changes; **OR** b. If the employer/union is subject to alternative disclosure requirements (e.g., ERISA), Applicant fully complies with such alternative requirements. Please identify the other governing standards: _____		
7. Applicant agrees not to include co-branding names and/or logos of providers or names and/or logos that are substantially similar to a provider's name and/or logo on member identification cards.		
8. Applicant agrees that the CY 2008 Annual Notice of Change (ANOC) / Summary of Benefits (SB) / Formulary will be provided to members.	☐	☐
9. Applicant agrees that the CY 2008 Evidence of Coverage (EOCs) will be provided to members.	☐	☐

3.13 Provider Communications

A. Complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PDP CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN:	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.	☐	☐
1. 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; and 3. Provides and follows a process for immediate access in situations where an enrollee's life or health is in serious jeopardy.	☐	☐

3.14 Compliance Plan

A. Complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PDP CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN:	YES	NO
1. Applicant will implement a compliance plan in accordance with all Federal and State regulations and guidelines, including Chapter 9 of the Part D Manual, "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 a 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.

3.15 Reporting Requirements

A. Complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PDP CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN:	YES	NO

Contract ID Number: E_____

REPORTING REQUIREMENTS GUIDANCE		
1. Applicant agrees to comply with the applicable Reporting Requirements Guidance that is posted on the **www.cms.hhs.gov/** website. NOTE: CMS has modified the reporting requirements under 42 CFR 423.514(a) to require information regarding such direct contract arrangements be reported to enrollees and to the general public to the extent required by other law (including ERISA or securities laws) or by contract.	☐	☐
BUSINESS TRANSACTIONS AND FINANCIAL REQUIREMENTS	**YES**	**NO**
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	**YES**	**NO**
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 third party administrator (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. 7. The Applicant or the Applicant's representative, such as a third party administrator (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 third party administrator (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 third party administrator (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 third party administrator (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 third party administrator (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	**YES**	**NO**

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.	☐	☐
UTILIZATION MANAGEMENT DATA	**YES**	**NO**
18. The Applicant will report quarterly the information needed to calculate the generic dispensing rate.	☐	☐
19. If formulary management tools include prior authorization the Applicant will report to CMS on a quarterly basis information about the use of that tool. Such information may include, but is not limited to: • The number of pharmacy transactions denied due to the need for prior authorization • The number of prior authorizations requested • The number of prior authorizations approved	☐	☐
EXCEPTIONS AND APPEALS	**YES**	**NO**
20. The Applicant will report at a frequency specified by CMS the following information related to exceptions and appeals that may include, but is not limited to: • # Step edits attempted • # Step edits failed • # Appeals • # Appeals overturned	☐	☐
MEDICATION THERAPY MANAGEMENT DATA	**YES**	**NO**
21. The Applicant will report semi-annually (by dates to be published by CMS each year) information related to the implementation of its Medication Therapy Management program that may include, but is not limited to: • # Beneficiaries targeted • # Beneficiaries participating • # Beneficiaries declined • Total drug cost for patients in MTM on a per enrolled MTM beneficiary per month basis	☐	☐
OTHER DATA	**YES**	**NO**
22. 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.		
23. 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.	☐	☐
CONFLICT OF INTEREST	**YES**	**NO**
24. 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.

3.16 Data Exchange Between PDP and CMS

A. Complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PDP CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN:	YES	NO
HPMS	**YES**	**NO**
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. PDPs are required to secure access to HPMS in order to carry out these functions.	☐	☐
ENROLLMENT & PAYMENT	**YES**	**NO**
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 PDP 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.	☐	☐

3.17 Upgrades of Health Information Technology

A. Complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PDP CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN:	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.	☐	☐

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

A. Complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PDP CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN:	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 Part 160.	☐	☐
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 subparts I *et seq*.	☐	☐
5. Applicant will comply with any other Administrative Simplification Provisions under 45 CFR Parts 160, 162, and 164 not specifically listed above.	☐	☐
6. Applicant agrees to issue payment and remittance notices consistent with the HIPAA-adopted ACS X12N 835, Version 4010/4010A1: Health Care Claim Payment and Remittance Advice Implementation Guide ("835").	☐	☐
7. Applicant will report to CMS any unauthorized public disclosures of protected health information within 48 hours of the Applicant's detection of such disclosure.	☐	☐
8. 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; and • The performance the work outside of the United States is in the best interests of the United States.	☐	☐
9. Applicant agrees, in accordance with CMS guidance, to 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 to obtain re-certification from a qualified reviewer once every two years.	☐	☐

3.19 Prohibition on Use of SSN or Medicare ID Number on Enrollee ID Cards

A. Complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PDP CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN:	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.	☐	☐

3.20 Record Retention

A. Complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PDP CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN:	YES	NO
1. 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 or other applicable law or regulation at the Applicant's discretion.	☐	☐

3.21 Claims Processing

A. Complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PDP CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN:	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. 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. 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 its 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.	☐	☐

Contract ID Number: E_____

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 as well as Part 423 of 42 CFR and all other applicable Federal statutes, regulations, and policies, including employer/union-only group waiver guidance, 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 requirements 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 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

Contract ID Number: E_____

Return Form to: MMAHelp@CMS.HHS.GOV by December XX, 2006
Subject: CMS Connectivity Request Form

APPENDIX I

CMS CONNECTIVITY REQUEST FORM
Prescription Drug Plan

THE FOLLOWING ORGANIZATION IS REQUESTING CONNECTIVITY TO CMS FOR THE PRESCRIPTION DRUG PLAN	
Name of Organization:	
Primary Contact Name:	Primary Contact Telephone Number:
Address *(Street, City, State, Zip)*:	
Telecommunications Contact Name:	
Telecommunications Contact Email:	
Physical Site Address (Must be the physical location for the T1 installation):	

1. Does your site have leased line IP connectivity into the MDCN (Medicare Data Communications Network) via AGNS (AT&T Global Network Services)? ☐ Yes. Please answer questions 2-13. ☐ No. Please answer questions 4-13.
2. What are the AGNS account names; i.e. BXKY, BXSC, CWF3, associated with the physical location to be used for transactions? (For example, the AGNS account for the IP connectivity into the CMS central office is HCFA).
3. Are there other locations networked to the physical site? ☐ Yes ☐ No If yes please list the city and state below.
4. What are the IP networks/sub-network masks that will be communicating with CMS? (This is required for both ends of the connectivity so routing can be put in place over the new PVC built across the AGNS.) Please note you may need to contact your network administrator for this information *NOTE: If the AGNS router is placed on a ring/segment upstream from the origination network(s), CMS will need to know what the next hop will be out of the AGNS router to get to the cascaded network(s)*.
5. Do you currently have Connect: Direct that you will use for the Medicare Prescription Drug Program within your system infrastructure? ☐ Yes. Please answer question a below. ☐ No. Please answer questions b and c below.
a. Which version of Connect: Direct do you currently have within your infrastructure; i.e. enterprise, workstation (runs on PC) or satellite (LAN/Server based)?
b. Please provide the following information for Connect: Direct software installation on the hardware resident within your infrastructure. Make & Model of Hardware Where Software Will Reside: Number of Processors Associated with this Hardware: Operating System Used on the Hardware:
c. Who is the contact person(s) who will be responsible for the Connect: Direct Software? Name: Phone Number: Email Address:
6. For T1 installation, what type of LAN will connect to the CMS router; i.e. ethernet, token ring?

Contract ID Number: E_____

7. Will this new site require non-portable registered IP addresses from AGNS? ☐ Yes ☐ No. If yes, how many? If no, what addresses will be used at this site (sub-network/mask) and what IP address/sub-network mask should be used as the LAN interface address on the AGNS router?
8. What protocols will need to be enabled for this site; i.e. IP, SNA?
9. Will this site require the use of a dynamic routing protocol to advertise/learn routes to/from the AT&T Business Services network; i.e. IGRP, EIGRP, OSPF, BGP? ☐ Yes ☐ No If no, CMS will assume static routes should be used on the router placed at the new site.
10. What IP network(s) or host(s) at this site, including sub-network mask(s), will need to be able to communicate with what IP network(s) or host(s) at other sites and vice versa? Please include subnetwork masks for the destination network(s) as well *NOTE: If the AGNS router is placed on a ring/segment upstream from the origination network(s), CMS will need to know what the next hop will be out of the AGNS router to get to the cascaded network(s).*
11. Does this site have connectivity out to the Internet?
12. If there is connectivity out to the Internet, please describe the firewall used at the site for which this is applicable. Socks or proxy: Firewall software/hardware:
13. Is there any unsolicited inbound traffic permitted from the Internet through the firewall?
14. Will AGNS MDCN WAN be connected to the secure side of the firewall?
15. Are there any dial-up connectivity requirements to the sub-network(s) at this site?

Questions about completing the CMS Connectivity Request form should be direct to the MMAHelp Desk at MMAHelp@CMS.HHS.GOV with Part D Benefit as the subject line or call 1-800-927-8069.

Contract ID Number: E_____

APPENDIX II
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 & 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 OF ORGANIZATION'S AUTHORIZED REPRESENTATIVE

Signature: _____

Date: _ _____

Title: _ _____

Print Name: _ _____

Phone Number: _ _____

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)* 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 report and reply 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 Direct Contract PDP Sponsor Applicants

I. FINANCIAL DOCUMENTATION

A. **Net Worth - Minimum Net Worth: $1.5 million -**
Documentation of Minimum Net Worth

The Direct Contract PDP Sponsor must demonstrate financial solvency through furnishing two years of independently audited financial statements to CMS. If the potential Direct Contract PDP Sponsor has not been in operation at least twelve months, it may choose to: 1) obtain independently audited financial statements for a shorter time period; or 2) demonstrate that it has the minimum net worth through presentation of un-audited financial statements that contain sufficient detail to allow CMS to verify the validity of the financial presentation. The un-audited financial statement must be accompanied by an actuarial opinion from a qualified actuary regarding the assumptions and methods used in determining loss reserves, actuarial liabilities and related items.

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

If the potential Direct Contract PDP Sponsor's auditor is not one of the 10 largest national accounting firms in accordance with the list of the 100 largest public accounting firms published by the CCH Public Accounting Report, the applicant should enclose proof of the auditor's good standing from the relevant state board of accountancy.

B. **Liquidity**

The Direct Contract PDP Sponsor must have sufficient cash flow to meet its financial obligations as they become due. The amount of the 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, investments must have a maturity date not longer than 3 months from the date of purchase.

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

1. The timeliness of payment,
2. 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
3. The availability of outside financial resources.

CMS may apply the following corresponding corrective remedies:

1. If a 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.
2. CMS may require the PDP Sponsor to initiate corrective action if any of the following are evident:

a) The current ratio declines significantly; or
b) 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.

3. If there is a change in the availability of outside resources, CMS will require the PDP Sponsor to obtain funding from alternative financial resources.

C. **Methods of Accounting**

The Direct Contract PDP Sponsor generally must use the standards of Generally Accepted Accounting Principles (GAAP). Generally Accepted Accounting Principles (GAAP) are those accounting principles or practices prescribed or permitted by the Financial Accounting Standards Board. However, a PDP Sponsor whose audited financial statements are prepared using accounting principles or practices other than GAAP, such as a governmental entity that reports in accordance with the principles promulgated by the Governmental Accounting Standards Board (GASB), may utilize such alternative standard.

D. **Bonding and Insurance**

A Direct Contract PDP Sponsor may request a waiver in writing of the bonding and/or insurance requirements set forth at 42 CFR 423.504(b)(4)(iv) and (v) in accordance with Appendix XVII to this application. Relevant considerations will include demonstration that either or both of the foregoing requirements are unnecessary based on the entity's individualized circumstances, including maintenance of similar coverage pursuant to other law, such as the bonding requirement at ERISA Sec. 412.

E. **Additional Information**

A potential Direct Contract PDP Sponsor must furnish the following financial information to CMS to the extent applicable:

1. **Self-Insurance/Self Funding-** If the potential Direct Contract PDP Sponsor's health plan(s) are self-insured or self-funded, it must forward proof of stop-loss coverage (if any) through copies of policy declarations.
2. **Trust-** If the potential Direct Contract PDP Sponsor maintains one or more trusts with respect to its health plan(s), a copy of the trust documents, and if the trust is intended to meet the requirements of Section 501(c)(9) of the Internal Revenue Code, the most recent IRS approval letter.
3. **Forms 5500 and M-1-** The two most recent annual reports on Forms 5500 and M-1 (to the extent applicable) for the potential Direct Contract PDP Sponsor's health plans that cover prescription drugs for retirees that are PDP eligible individuals.
4. **ERISA Sec. 411(a) Attestation-** Each applicant (including an applicant that is exempt from ERISA) must provide a signed attestation that no person serves as a fiduciary, administrator, trustee, custodian, counsel, agent, employee, consultant, adviser or in any capacity that involves decision-making authority, custody, or control of the assets or property of any employee benefit plan sponsored by the potential Direct Contract PDP Sponsor if he or she has been convicted of, or has been imprisoned as a result of his or her conviction of, one of the felonies set forth in ERISA Sec. 411(a), for 13 years after such conviction or imprisonment (whichever is later).

5. **Defined Benefit Pension Plan-** If the potential Direct Contract PDP Sponsor sponsors one or more defined benefit pension plans (within the meaning of ERISA Sec. 3(35)) that is subject to the requirements of Title IV of ERISA, the latest actuarial report for each such plan.
6. **Multi-Employer Pension Plan-** If the potential Direct Contract PDP Sponsor is a contributing employer with respect to one or more multi-employer pension plans within the meaning of ERISA Sec. 3(37), the latest estimate of contingent withdrawal liability.
7. **Tax-Exempt Applicants Only**- A copy of the most recent IRS tax-exemption.

II. INSOLVENCY REQUIREMENTS

A. Hold Harmless and Continuation of Coverage/Benefits

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

B. Insolvency Deposit

A Direct Contract PDP Sponsor generally must forward confirmation of its establishment and maintenance of an insolvency deposit of at least $100,000, to be 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 the U.S. Federal or State authorities having regulatory authority over banks and trust companies.

A Direct Contract PDP Sponsor may request a waiver in writing of this requirement in accordance with Appendix XVII to this application.

III. GUARANTEES (this Section only applies to an Applicant that utilizes a Guarantor)

A. General policy

A Direct Contract PDP Sponsor, or the legal entity of which the Direct Contract 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 Direct Contract PDP Sponsor set forth above. CMS has the sole discretion to approve or deny the use of a Guarantor.

B. Request to Use a Guarantor

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

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

ii. 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. Is 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 a 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 or other State official with authority for risk-bearing entities regulates the Guarantor, it must meet the net worth requirement in Section I.A above 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 net worth requirement in Section I.A above 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.

D. Guarantee Document

If the guarantee request is approved, a Direct Contract 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 any other conditions as CMS may establish from time to time.

E. Ongoing Reporting Requirements

A Direct Contract 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 requires.

F. Modification, Substitution, and Termination of a Guarantee

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

1. Requests CMS's approval at least 90 days before the proposed effective date of the modification, substitution, or termination;
2. Demonstrates to CMS's satisfaction that the modification, substitution, or termination will not result in insolvency of the Direct Contract PDP Sponsor; and
3. Demonstrates how the Direct Contract 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 Direct Contract PDP Sponsor that it ceases to recognize the guarantee document. In the event of this nullification, a Direct Contract 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 15 business days in paragraph (G.1.) of this section.

IV. ONGOING REPORTING REQUIREMENTS

An approved Direct Contract PDP Sponsor is required to update financial information set forth in Sections I and II above to CMS on an ongoing basis. The schedule, manner, and form of reporting will be in accordance with CMS requirements.

Contract ID Number: E_____

APPENDIX V

CERTIFICATION BY DIRECT CONTRACT PDP SPONSOR THAT SUBCONTRACTS MEET THE REQUIREMENTS OF SECTION 3.1.1F

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 3.1.1:

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 3.1.1B 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 Direct Contract 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 (e.g.., 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; and
    E. Contain language that the Direct Contract PDP Sponsor retains the right to approve, suspend, or terminate any arrangement with a pharmacy if the subcontract contains language specifying that the subcontractor will establish the pharmacy network or select pharmacies to be included in the network.

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

2. I understand that CMS will review the submitted contracts to ensure that they comply with the contracting requirements stated in Section 3.1.1F 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

Contract ID Number: E_____

_____	_____
Authorized Representative Signature	Date (MM/DD/YYYY

Appendix VI

Crosswalk of Section 3.1.1F Requirements to Location in Subcontracts Submitted as Attachments to Section 3.1.1

INSTRUCTIONS: Applicants must complete the following chart for each subcontract submitted under Section 3.1.1F. Applicants must identify where specifically in each contract the following elements are found.

Section	Requirement	Location in Subcontract by Page number and Section
3.1.1F1	The parties to the contract	
3.1.1F2	The functions to be performed by the subcontractor, as well as any reporting requirements the subcontractor has to the Applicant identified in Section 3.1.1B of the application.	
3.1.1F3	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.	
3.1.1F4	Language describing the services to be performed in a manner that encompasses the services required to support the Medicare Prescription Drug Benefit program.	
3.1.1F5	The payment the subcontractor will receive for performance under the contract, if applicable.	
3.1.1F6	Are for a term of at least the one-year contract period for which application is submitted.	
3.1.1F7	Are signed by a representative of each party with legal authority to bind the entity.	
3.1.1F8	Language obligating the subcontractor to abide by all applicable Federal and State laws and regulations and CMS instructions.	
3.1.1F9	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.	
3.1.1F10	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.	
3.1.1F11	Language stating that the subcontractor will ensure that beneficiaries are not held liable for fees that are the responsibility of the Applicant.	
3.1.1F12	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.	
3.1.1F13	Language specifying that the Applicant, upon becoming a Part D sponsor, will monitor the performance of the subcontractor on an ongoing basis.	
3.1.1F14	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.	
3.1.1F15	Language to ensure that subcontractor reports 100% of any manufacturer rebates paid for drugs provided under the Applicant's Part D plan.	

APPENDIX VII
Crosswalk for Retail Pharmacy Access Contracts

INSTRUCTIONS: Applicants must complete the following chart (which contains applicable Section 3.1.1 F 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 this Appendix for each contract template.

The provisions listed below must be in all retail 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
3.1.1F2	The functions to be performed by the subcontractor, as well as any reporting requirements the subcontractor has to the Applicant identified in Section 3.1.1B of the application.	
3.1.1F4	Language describing the services to be performed in a manner that encompasses the services required to support the Medicare Prescription Drug Benefit program.	
3.1.1F8	Language obligating the subcontractor to abide by all applicable Federal and State laws and regulations and CMS instructions.	
3.1.1F9	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.	
3.1.1F10	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.	
3.1.1F11	Language stating that the subcontractor will ensure that beneficiaries are not held liable for fees that are the responsibility of the Applicant.	
3.1.1F12	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.	
3.1.1F13	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 may offer a Mail Order option. Applicants who choose to offer Mail Order pharmacy services must complete the following chart (which contains applicable Section 3.1.1 F 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 this Appendix for each contract template.

The provisions listed below must be in all mail order 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
3.1.1F2	The functions to be performed by the subcontractor, as well as any reporting requirements the subcontractor has to the Applicant identified in Section 3.1.1B of the application.	
3.1.1F4	Language describing the services to be performed in a manner that encompasses the services required to support the Medicare Prescription Drug Benefit program.	
3.1.1F8	Language obligating the subcontractor to abide by all applicable Federal and State laws and regulations and CMS instructions.	
3.1.1F9	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.	
3.1.1F10	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.	
3.1.1F11	Language stating that the subcontractor will ensure that beneficiaries are not held liable for fees that are the responsibility of the Applicant.	
3.1.1F12	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.	
3.1.1F13	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 3.1.1 F 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 this Appendix for each contract template.		
The provisions listed below must be in all home infusion 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**
3.1.1F2	The functions to be performed by the subcontractor, as well as any reporting requirements the subcontractor has to the Applicant identified in Section 3.1.1B of the application.	
3.1.1F4	Language describing the services to be performed in a manner that encompasses the services required to support the Medicare Prescription Drug Benefit program.	
3.1.1F8	Language obligating the subcontractor to abide by all applicable Federal and State laws and regulations and CMS instructions.	
3.1.1F9	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.	
3.1.1F10	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.	
3.1.1F11	Language stating that the subcontractor will ensure that beneficiaries are not held liable for fees that are the responsibility of the Applicant.	
3.1.1F12	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.	
3.1.1F13	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	3.4A4
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.	
????	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 3.1.1 F 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 this Appendix for each contract template.		
The provisions listed below must be in all long-term care 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**
3.1.1F2	The functions to be performed by the subcontractor, as well as any reporting requirements the subcontractor has to the Applicant identified in Section 3.1.1B of the application.	
3.1.1F4	Language describing the services to be performed in a manner that encompasses the services required to support the Medicare Prescription Drug Benefit program.	
3.1.1F8	Language obligating the subcontractor to abide by all applicable Federal and State laws and regulations and CMS instructions.	
3.1.1F9	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.	
3.1.1F10	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.	
3.1.1F11	Language stating that the subcontractor will ensure that beneficiaries are not held liable for fees that are the responsibility of the Applicant.	
3.1.1F12	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.	
3.1.1F13	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 3.1.1 F 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 this Appendix for each contract template.

The provisions listed below must be in all I/T/U 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
3.1.1F2	The functions to be performed by the subcontractor, as well as any reporting requirements the subcontractor has to the Applicant identified in Section 3.1.1B of the application.	
3.1.1F4	Language describing the services to be performed in a manner that encompasses the services required to support the Medicare Prescription Drug Benefit program.	
3.1.1F8	Language obligating the subcontractor to abide by all applicable Federal and State laws and regulations and CMS instructions.	
3.1.1F9	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.	
3.1.1F10	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.	
3.1.1F11	Language stating that the subcontractor will ensure that beneficiaries are not held liable for fees that are the responsibility of the Applicant.	
3.1.1F12	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.	
3.1.1F13	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: Sections referenced are the provisions listed in the model I/T/U Addendum, located at** www.cms.hhs.gov/10_RxContracting_SpecialGuidance.asp#TopOfPage The I/T/U Contracts must contain language consistent with the model addendum that address the following.		
Item 1	Supercession 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 must 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 2 CD's 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.

Contract ID Number: E_____

Mail the CD's and hard copy material via courier to:
Centers for Medicare and Medicaid Services
ATTN: Kimberly Spurgeon/Addendum to Generalist Review Section/ (P&T Member List) and/or (P&T Certification)
Mail Stop C1-22-06
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: ___ _____

Complete either Part A or the Certification (Parts B, C, and D, below).

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	Practicing Physician	Practicing Pharmacist	Elderly/Disabled Expert	With You're Organization?	With Pharmaceutical Manufacturers?

1Complete the table below if a PBM submitting on behalf of Part D plan
2

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)**

Contract ID Number: E_____

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

B. 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.

C. 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.

D. 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

CMS has waived the "TriCare" retail pharmacy access requirements set forth in 42 CFR 423.120(a)(1); they will not apply when the plan's pharmacy network is sufficient to meet the needs of its enrollee population, as determined by CMS. CMS may periodically review the adequacy of the plan's pharmacy network and require the plan to expand access if CMS determines that such expansion is necessary in order to ensure that the plan's network is sufficient to meet the needs of its enrollee population.

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. 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 chapter. If this is not possible then Applicant must contact Dennis Hodges at dennis.hodges@cms.hhs.gov (410.786.3048) by no later than _____to 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 part of the chapter is not intended to provide step-by-step instructions for the use of GeoNetworks®. It is the responsibility of Applicant to ensure that their submission provides adequate information for CMS to determine if each of their plan offerings meets the retail pharmacy access submission requirements.

1. Defining the Medicare Beneficiary File in GeoNetworks®:

The Medicare Beneficiary File ("Medicare Beneficiaries by State, Region, ZIP _____") is provided by CMS.

The Medicare Beneficiary File referenced above contains ZIP Codes and beneficiary counts for Applicants as of_____. 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. Applicants may not use beneficiary counts from other sources in their accessibility analyses.

Applicants should import the data sub-file 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 resident 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 employer 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 not 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 of each of your plans. 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 (i.e., the ZIP+ 4 Centroid Method, the ZIP+2 Centroid Method, or address-based geocoding).

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, 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. CMS also recognizes that these PBM contracts are to the benefit or the beneficiary. 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

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.

Please note that it is not a requirement for PDP Applicants to provide summary statistics related to the TRICARE standard at the region level (even in the case where the region covers multiple states). PDPs are required to adhere to the TRICARE access 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 TRICARE access 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 III,D.4.b.1 Example PDP Contractor PBP Offerings

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

Applicant should define one service area (labeled PDP Region 05: Exxxx 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 chapter, 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 applicants 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.***[2] For each accessibility analysis, separate reports are required for (a) beneficiaries meeting the applicable access requirement ("with access") and (b) beneficiaries not meeting the applicable access requirement ("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 with access in the service area for Exxxx 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 Retail Network A", set Access Standard to be "Urban: 1 provider within 2 miles", set Access filter to "with", and set Service Area to Exxxx
- 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): Part D Retail List -- A "

The steps to define the service area report for all beneficiaries with access in the region for Exxxx 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 A", set Service Area to Exxxx.

- 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 "Exxxx, PDP Region 05: Mid-Atlantic ".

- 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 nine (9) page report will be generated using the CMS example, for Exxxx, 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 both "with" and "without" specifications. An overview of this report is specified in Table III5.b.1. A sample of the actual reports entitled, "Sample_PDP Accessibility Analyses" can be found in this appendix.

Table III 5.a.1:: Example Exxxx 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	Exxxx	With
4	Accessibility Detail	County	Urban PDP Region 05 Beneficiaries	PDP Region 05 Part D Retail Pharmacy Network	Urban: 1 provider within 2 miles	Exxxx	Without
5	Accessibility Detail	County	Suburban PDP Region 05 Beneficiaries	PDP Region 05 Part D Retail Pharmacy Network	Suburban: 1 provider within 5 miles	Exxxx	With
6	Accessibility Detail	County	Suburban PDP Region 05 Beneficiaries	PDP Region 05 Part D Retail Pharmacy Network	Suburban: 1 provider within 5 miles	Exxxx	Without
7	Accessibility Detail	County	Rural PDP Region 05 Beneficiaries	PDP Region 05 Part D Retail Pharmacy Network	Rural: 1 provider within 15 miles	Exxxx	With
8	Accessibility Detail	County	Rural PDP Region 05	PDP Region 05 Part D Retail Pharmacy Network	Rural: 1 provider within 15 miles	Exxxx	Without

Table III 5.a.1:: Example Exxxx Report Pages Specification							
Rpt #	**Page**	**Summarized by**	**Employee Group**	**Provider Group**	**Access Standard**	**Service Area / Title 1**	**Access Filter**
			Beneficiaries				
9	Service Area	State	All Beneficiaries	Part D Retail Pharmacy Network		Exxxx	
10	GeoNetworks Report (auto generated summary information report to be included in submission)						

Contract ID Number: E_____
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.

Sample PDP reports are provided in this Appendix.

> ✓***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.

APPENDIX XIV

Instructions for Additional Employer/Union-Only Group Waiver/Modification Requests

As part of the application process, Direct Contract PDP Sponsors may submit individual waiver/modification requests to CMS. These requests must be identified as requests for additional waivers/modifications and must fully address the following items:

- Provisions of existing statutory and/or regulatory requirement(s) the entity is requesting to be waived/modified (please be explicit as to whether you are requesting a waiver or a modification of these requirements);
- How the particular requirements hinder the design of, the offering of, or the enrollment in, the employer-sponsored group plan;
- Executive summary of the requested waiver/modification;
- Detailed description of the waiver/modification requested including how the waiver/modification will remedy the impediment (i.e., hindrance) to the design of, the offering of, or the enrollment in, the employer-sponsored group prescription drug plan;
- Other details specific to the particular waiver/modification that would assist CMS in the evaluation of the request; and
- Contact information (contract number, name, position, phone, fax and email address) of the person who is available to answer inquiries about the waiver/modification request.