

**2010 PART D SERVICE AREA EXPANSION
APPLICATION**

FOR

PRESCRIPTION DRUG PLAN (PDP) SPONSORS

AND

**MEDICARE ADVANTAGE PRESCRIPTION DRUG PLAN
(MA-PD) SPONSORS**

Department of Health and Human Services
Centers for Medicare and Medicaid Services (CMS)
Center for Beneficiary Choices (CBC)
Medicare Drug Benefit Group (MDBG)

2010 Contract Year

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1. General Information

1.1 Purpose of Solicitation

The Centers for Medicare & Medicaid Services is seeking applications from existing Part D Benefit organizations seeking to expand the current service area to which they are offering qualified prescription drug coverage. Please submit your service area applications (SAEs) according to the process described below.

This solicitation represents an abbreviated version of the Part D Sponsor Application that is used for organizations seeking to participate in the Part D benefit for the first time. The sections below must be completed for the new service area for which your organization is seeking to expand the Part D benefit under an existing contract. Existing Part D Sponsors who offer either a PDP or MA-PD plan may expand their regional coverage. CMS has identified 26 MA Regions and 34 PDP Regions; in addition, each territory is its own PDP region. Additional information about the regions can be found on the www.cms.hhs.gov/ website.

While CMS approval of a service area expansion requires completion of the sections below, Part D Sponsors are assumed to be able to maintain all requirements for the new service area related to Part D as included in their existing Part D contract or contract addendum. For instance, Part D sponsors are held to the attestations made for their existing contract for the new service area. In addition, Part D sponsors are still required to provide to CMS formulary and bid submissions on the appropriate dates.

1.2 Part D Schedule

<i>APPLICATION REVIEW PROCESS</i>	
Date	Milestone
November 18, 2008	Organizations: Submit notice of intent to apply to CMS
December 3, 2008	CMS User ID forms due to CMS
January 6, 2009	Final Applications Posted by CMS
February 26, 2009	Applications due
March 30, 2009	Release of Health Plan Management System (HPMS) formulary submissions module.
April 10, 2009	Plan Creation module, Plan Benefit Package (PBP) and Bid Pricing Tool (BPT) available on HPMS
April 20, 2009	Formulary Submissions due to CMS Transition Policies and Procedures due to CMS
May 2009	CMS sends Part D contract eligibility determination to Applicants, based on review of application. Applicant's bids must still be negotiated (see below)
May 15, 2009	PBP/BPT Upload Module available on HPMS
June 1, 2009	All bids due.
July 15, 2009	Any contract determination, including an appeal, must be resolved to

	participate as a Part D sponsor in 2010.
Early August 2009	CMS publishes national average Part D premium
September 2009	CMS completes review and approval of bid data. CMS executes Part D addenda to MA contract with MA-PD organizations who submit an acceptable bid.
November 15, 2009	2010 Annual Coordinated Election Period begins

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

2. INSTRUCTIONS

2.1 Overview

This application is to be completed by those Part D Sponsors that intend to expand their Part D coverage during 2010. Please refer to the guidance for MA and Cost Plan sponsors posted on the CMS web site for instructions on the type of MA documentation your organization must provide to CMS to qualify to expand an MA plan during 2010.

2.2 Other Technical Support

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

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

2.3 Health Plan Management System (HPMS) Data Entry

Part D sponsors are assigned a contract number (H/R/S number) to use throughout the application and subsequent operational processes. All Service Area Expansion (SAE) Applicants have their CMS User ID(s) and password(s) for HPMS access and need to maintain contact and other related information into HPMS. Applicants are required to provide prompt entry and ongoing maintenance of data in HPMS. By keeping the information in HPMS current, the Applicant facilitates the tracking of their application throughout the review process and ensures that CMS has the most current information for application updates, guidance and other types of correspondence.

In the event that an Applicant is awarded an addendum to their existing 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 February 26, 2009. Applicants must use the 2010 solicitation. CMS will not accept or review in anyway those submissions using the prior versions of the solicitation (e.g. 2009 and earlier).

Instructions

Applicants will complete the entire solicitation via HPMS.

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

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

CMS will not accept any information in hard copy. If an Applicant submits the information via hard copy, the application will not be considered received.

CMS will check the application for completeness shortly after its receipt. We will notify Applicants of any deficiencies and afford them a courtesy opportunity to amend their applications. CMS will only review the last submission provided during this courtesy cure period.

CMS has established that all aspects of the program that the Applicant attests to must be ready for operation by the contract signature date. As with all aspects of a Part D sponsor’s operations under its contract with CMS, we may verify a sponsor’s compliance with qualifications it attests it will meet, through on-site visits at the Part D sponsor’s facilities as well as through other program monitoring techniques. Failure to meet the requirements attested to in the Applicant’s response to this solicitation and failure to operate its Part D plan(s) consistent with the requirements of the applicable statutes, regulations, call letter, and the Part D contract may delay a Part D sponsor’s marketing and enrollment activities, or, if corrections cannot be made timely, the Part D sponsor will be disqualified it from participation in the Part D program.

An individual with legal authority to bind the Applicant shall attest to 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. The end of the 10 day period is the last opportunity an Applicant has to provide CMS with clarification or corrections. CMS will only review the last submission provided during this cure period. Such materials will not be accepted after this 10-day time period.

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

- CMS will not review applications received after 11:59 P.M. on February 26, 2009. CMS will lock access to application fields within HPMS as of this time. . CMS will not review any submissions based on earlier versions of the solicitation. Applicants must complete the 2010 solicitation in order to be considered for Part D sponsorship.

Separate entries **MUST** be submitted through HPMS for each pending contract number/application.

If a subsidiary, parent, or otherwise related organization is also applying to offer Part D benefits, these entities **MUST** submit separate applications. There are four types of Part D solicitations for which applications are due on February 26, 2009; they are PDP, MA-PD, Cost Plan solicitations and the Service Area Expansion Application. Organizations that intend to offer a combination of these types of Part D plans must submit a separate application for each type. (Employer and PACE plan sponsors will also have separate solicitations.) **For example, an MA-PD and PDP product may not be represented in the same application.** Also, entities intending to offer both local MA-PD and Regional PPO plans must submit separate MA-PD applications.

Applicant Entity Same as Contracting Entity

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

Technical Assistance

For technical assistance in the completion of this application, contact: Marla Rothouse by email at marla.rothouse@cms.hhs.gov or by phone at 410-786-8063 or Linda Anders by email at linda.anders@cms.hhs.gov or by phone at 410-786-0459.

2.5 Submission Software Training

Applicants use the CMS Health Plan Management System (HPMS) during the application, formulary, and bid processes. Applicants are required to enter contact and

other related information collected in HPMS in order to facilitate the application review process.

Applicants are required to upload their plan formularies to HPMS using a pre-defined file format and record layout. The formulary upload functionality will be available on March 30, 2009. The deadline for formulary submission to CMS is 11:59 PM EDT on April 20, 2009. CMS will use the last successful upload received for an Applicant as the official formulary submission.

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 15, 2009 and the CY 2010 bid deadline of June 1, 2009. 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 2009.

2.6 Summary Instruction and Format for Part D Bids

Each Part D Sponsor must submit to CMS a bid for each prescription drug plan it intends to offer. Applicants using this solicitation must apply to offer full risk Part D plans. Applicants must submit their formularies to HPMS on or before April 20, 2009 and the PBPs and BPTs on or before the bid submission date.

2.6.1 Format of Part D Bids

Bid-Related Sections Due Prior to Bid Submission Date

To facilitate the timely review of all the bid submissions, CMS requires Applicants to submit the portion of their bid related to formulary and covered drugs from March 30-April 20, 2009. 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 evaluation of the formulary review process prior to CMS approval of the bid.

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

Bid Submission

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

In order to encourage successful bid submissions, CMS limits multiple bids to ensure that each bid submitted represents a meaningful variation based on plan characteristics that will provide beneficiaries with substantially different options. CMS expects that more than two (2) bids from a sponsoring organization would not provide meaningful variation, unless one (1) of the bids is an enhanced alternative plan that provides coverage in the coverage gap. CMS reviews multiple bids received from a Part D Applicant as a whole and applies a reasonableness test to determine examples of a strong likelihood of incompetence and/or 'gaming', including, but not limited to: a) multiple bid submissions that would fail a reasonableness test; b) multiple bid submissions based on different formulary drug lists; c) multiple bid submissions based on different levels of utilization management control; and d) multiple bid submissions that reflect a significant unexplained variation in costs between the plans, particularly between plans offered to the group versus the individual market.

2.6.2 CMS Review of Bids

CMS evaluates the bids based on four broad areas: 1) administrative costs, 2) aggregate costs, 3) benefit structure, and 4) plan management. CMS evaluates the

administrative costs for reasonableness in comparison to other bidders. CMS also examines aggregate costs to determine whether the revenue requirements for qualified prescription drug coverage are reasonable and equitable. In addition, CMS reviews the steps the Part D sponsor is taking to control costs, such as through various programs 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).

2.6.3 Overview of Part D Bid Negotiation

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

2.7 Pharmacy Access

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

2.7.1 Retail Pharmacy Access

Applicants must ensure that their retail pharmacy network meets the criteria established under 42 CFR §423.120. Applicants must ensure the pharmacy network

has a sufficient number of pharmacies that dispense drugs directly to patients (other than by mail order) to ensure convenient access to Part D drugs. CMS rules require Applicants establish retail pharmacy networks in which:

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

Section 3.5 of this Solicitation includes a reference to the Appendix entitled *Retail Pharmacy Network Access Instructions* that provides Applicants with detailed instructions to complete the retail pharmacy network access portion of this submission. For purposes of meeting the 2010 Pharmacy Access requirements, Applicants may use their contracted PBM's existing 2009 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 2010. CMS conducts the review of Retail Pharmacy Access based on the service area that the Applicant has provided in HPMS by February 26, 2009. To the extent that the service area is reduced during the application review process, the pharmacy access submission reports must pass a full and complete CMS review, including a review that ensures the access submission matches the service area in HPMS at one of the following points in time:

- a) **initial application submission** (a fully passing retail access review at this point in the application process will not require a subsequent review even if the service area is later reduced), or
- b) **at the time of the courtesy submission window after CMS has issued an interim deficiency notice**, if the initial application retail submission is found to contain retail access related deficiencies of any type (a fully passing retail access review at this point in the application process will not require a subsequent review even if the service area is later reduced), or
- c) **at the time of the final submission window after CMS has issued a Notice of Intent to Deny (see Section 2.4)**, if the courtesy retail submission is found to contain retail access related deficiencies of any type.

If none of the submissions includes a service area that perfectly matches HPMS at that exact point in time, CMS will conclude that the Applicant is itself unclear about its service area intentions, will find the submission deficient, and will deny the application for (at a minimum) being unable to demonstrate that it meets the retail access requirements.

While Applicants are required to demonstrate that they meet the Part D pharmacy access requirements at the time this solicitation is submitted to CMS, CMS expects that pharmacy network contracting will be ongoing in order to maintain compliance with our retail pharmacy access requirements. See the Appendix entitled *Retail Pharmacy Network Access Instructions* for detailed instructions for the retail pharmacy network analysis.

2.7.2 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 3.5.4). 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 to identify outliers amongst all Applicants.

2.7.3 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 3.5.5). 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.

2.7.4 Waivers Related to Pharmacy Access

Waivers for MA-PD Plans. CMS guidance regarding pharmacy access and any willing pharmacy requirements for certain MA-PD sponsors is contained at sections 50.7 and 50.8.1 of Chapter 5 of the Prescription Drug Benefit Manual. These waivers are described below. If an Applicant believes that any waiver described below applies to a specific contract/plan number then please complete the documentation identified.

Waiver of Retail Convenient Access Standards for MA-PDs

As described in section 50.7.1 of Chapter 5 of the Prescription Drug Benefit Manual, the requirement that MA-PD or Cost plan sponsors must offer their Part D plan benefit through a contracted retail pharmacy network that meets CMS convenient access standards is waived for MA-PD or Cost plan sponsors that operate their own pharmacies. MA-PD or Cost plan sponsors must demonstrate at the plan level that a majority (50%) of the prescriptions are filled at retail pharmacies owned and operated by the organization in order to be granted the waiver.

Waiver of Convenient Access Standards for MA-PFFS

As described in section 50.7.2 of Chapter 5 of the Prescription Drug Benefit Manual, the requirement that MA-PD sponsors must offer Part D plan benefits through a contracted pharmacy network that meets CMS convenient access standards is waived for MA-PFFS plans that meet the criteria in table 3.4.

Waiver of Any Willing Pharmacy Requirements for MA-PD

As described in section 50.8.1 of Chapter 5 of the Prescription Drug Benefit Manual, the requirement that MA-PD or Cost plan sponsors must offer a network pharmacy contract to any willing pharmacy that agrees to accept MA-PD or Cost plan sponsor's standard terms and conditions is waived for MA-PD or Cost plan sponsors that own and operate the pharmacies in their network. MA-PD or Cost plan sponsors must demonstrate at the plan level that at least 98% of prescriptions are filled through pharmacies that are owned and operated by plan sponsor in order to be granted the waiver.

Waivers for Plans in the Territories

To ensure access to coverage in the territories, §1860D-42(a) of the MMA grants CMS the authority to waive the necessary requirements to secure access to qualified prescription drug coverage for Part D eligible individuals residing in the territories. The regulations for the MMA under §423.859(c) allow access to coverage in the territories to be waived or modified either through an Applicant's request or at CMS's own determination. Under that authority, CMS will consider waiving the convenient access requirements for a plan's Part D contracted retail pharmacy network, found in §423.120(a)(1) of the Part D Final Regulation for the territories, if Applicant requests such a waiver, and demonstrates that it has made a good faith effort to meet the requirements described in Section 3.5.1C.

2.8 Standard Contract with MA-PD Sponsors

Successful Applicants will be deemed qualified to enter into a Part D addendum to their Medicare Advantage contract after CMS has reviewed the Applicant's entire submission. Under this addendum the MA-PD sponsor will be authorized to operate one or more Medicare prescription drug plans. 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 addendum.

2.9 Protection of Confidential Information

Applicants may 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. This designation must be in writing. When there is a request for information that is designated by the Applicant as confidential or that could reasonably be considered exempt under Exemption 4, CMS is required by its FOIA regulation at 45 CFR §5.65(d) and by Executive Order 12,600 to give the submitter notice before the information is disclosed.

To decide whether the Applicant's information is protected by Exemption 4, CMS must determine whether the Applicant has shown that— (1) disclosure of the information might impair the government's ability to obtain necessary information in the future; (2) disclosure of the information would cause substantial harm to the competitive position of the submitter; (3) disclosure would impair other government interests, such as program effectiveness and compliance; or (4) disclosure would impair other private interests, such as an interest in controlling availability of intrinsically valuable records, which are sold in the market. 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.

2.10 Waivers

CMS is authorized to grant waivers of Part D program requirements where such a requirement conflicts with or duplicates a Part C requirement, or where granting such a waiver would improve the MA-PD sponsor's coordination of Part C and Part D benefits.

Applicant Requests for Additional Waivers: CMS may grant additional waivers upon an MA-PD sponsor's request, provided that the waivers may be justified because the Part D requirement is duplicative of or conflicting with Part C requirements or the waiver will improve the coordination of Part C and Part D benefits. Any waiver granted by CMS will apply to all similarly situated MA-PD sponsors.

For each waiver request, the Applicant must upload in HPMS a statement that includes:

1. The Part D regulation reference.
2. The appropriate waiver criteria (e.g., duplicative, conflicts, improves benefit coordination).
3. A discussion of how the requested waiver meets at least one of the three waiver criteria.

CMS will notify Applicants whether their requests were approved via a CMS web posting of all approved waivers. As noted above, waivers granted will be reflected in each MA-PD sponsor's Part D addendum.

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 should check the "Yes, and Waiver Requested" within HPMS. 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 Part D addendum upon approval of its bids. This process will prevent Applicants from having to submit additional application responses after the original February 26, 2009 deadline. If, as a result of CMS' denial of its waiver request, the Applicant no longer intends to offer a Part D benefit plan, the Applicant must notify CMS in writing on or before June 30,

2009. CMS will not execute a Part D addendum 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 C1-26-12
Baltimore, Maryland 21244-1850

3. Application

NOTE: All uploads and templates will be accessed in HPMS through the HPMS Contract Management Module. Applicants should refer to the *Contract Management – Online Application User’s Guide Version 2.0* for further instructions.

3.1 Service Area 42 CFR 423.112; Prescription Drug Benefit Manual, Chapter 5

A. Complete in HPMS, in the Contract Management/Contract Service Area/Service Area Data page, the service area information indicating the regions (including territories) you plan to serve. Information on PDP and MA-PD regions and Territories may be found on the www.cms.hhs.gov/ website. Be sure to list both the region/territory name and associated number. Note: CMS bases its pharmacy network analyses on the service area your organization inputs into HPMS. Please make sure that the service area information you input into HPMS corresponds to the pharmacy lists and geo-access reports that are provided under the Pharmacy Access section of the application.

3.2 Licensure and Solvency 42 CFR 423.401; 42 CFR 423.410; 2008 Call Letter

Note: MA-PD Sponsors seeking to expand into another MA region may skip this section and proceed directly to Section 3.3--Pharmacy Access.

A. Only PDP Sponsors seeking to expand into another PDP region must complete the table below in HPMS:

ATTEST 'YES' OR 'NO' TO THE FOLLOWING STATE LICENSURE REQUIREMENTS IN HPMS.	YES	NO	DOES NOT APPLY
1. Applicant is licensed under State law as a risk-bearing entity eligible to offer health insurance or health benefits coverage in each State in which the Applicant proposes to offer Part D drug benefits. <ul style="list-style-type: none"> • If the answer to this attestation is “YES,” then upload in HPMS the documentation (e.g. licensing certificate or letter) from each State licensing authority of your organization’s status as an entity entitled to bear risk. • If the answer to this attestation is “NO,” see Attestation #2. 			
2. If the Applicant is not State licensed as a risk-bearing entity eligible to offer health insurance or health benefits coverage in each State in which the Applicant proposes to offer Part D benefits, is the Applicant State licensed as a risk-bearing entity in at least one State? <ul style="list-style-type: none"> • If the answer to this attestation is “YES,” then upload in HPMS the documentation (e.g., licensing certificate or letter), from each state licensing authority of your organization’s status as an entity entitled to bear risk. • If the answer to this attestation is “NO,” the Applicant must submit via HPMS the Appendix entitled <i>Financial Solvency Documentation</i>. 			
3. If the Applicant does not meet Requirement #1, then the Applicant has completed and provided, or will within the requisite time period, to CMS via HPMS the Appendix entitled <i>State Licensure Waiver Request Form</i> for each State in the expansion area in which it is not licensed but seeks to offer Part D drug benefits.			
4. If Applicant is seeking a waiver of the licensure requirement, the Applicant meets the CMS-published financial solvency and capital adequacy requirements.			
5. Applicant is currently under supervision, corrective action plan or special monitoring by the State licensing authority in any State.			

<ul style="list-style-type: none"> If the answer to this attestation is "YES", upload in HPMS an explanation of the specific actions taken by the State license regulator. In these cases, CMS reserves the right to require the Applicant to demonstrate that it meets the CMS-published financial solvency and capital adequacy requirements. 			
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3.3 Private Fee-For-Service Pharmacy Access 42 CFR 423.120(a)(7); Prescription Drug Benefit Manual, Chapter 5

A. In HPMS, complete the table below ONLY if you are a Private Fee For Service Applicant. Otherwise, proceed directly to 3.4.1.

<p>APPLICANT MUST ATTEST 'YES' OR 'NO' 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:</p>	YES	NO
<p>1. Applicant intends to use a contracted network of pharmacies and therefore will meet the retail pharmacy convenient access standards; LTC and IT/IO pharmacy convenient access standards; and home infusion pharmacy adequate access standards. Note: If answer Yes, Applicant must complete all of Section 3.4.</p>		
<p>2. If Applicant attests 'NO' to 3.3A1, Applicant agrees to provide coverage for drugs purchased from all pharmacies, regardless of whether they are network pharmacies.</p>		
<p>3. If Applicant attests 'NO' to 3.3A1, Applicant agrees not to charge additional cost-sharing to beneficiaries for obtaining their drugs at a non-network pharmacy.</p>		
<p>4. If Applicant attests 'NO' to 3.3A1, Applicant agrees that providing access at non-network pharmacies is provided by reimbursing the pharmacy its Usual and Customary price (defined as the price an out of network pharmacy charges a customer who does not have any form of prescription drug coverage for a covered Part D drug) minus any applicable beneficiary cost sharing.</p>		
<p>5. If Applicant attests 'NO' to 3.3A1, Applicant agrees it will not routinely rely on billing practices that require an enrollee to pay the usual and customary price upfront and then submit a paper claim to the applicant for reimbursement.</p>		
<p>6. If Applicant attests 'NO' to 3.3A1, Applicant agrees to establish policies and procedures appropriately restricting the use of paper claims only to the situations in which online claims processing is not available at the point of sale in order to promote accurate TrOOP accounting, as well as to minimize administrative costs to the Part D plans and the Medicare program and opportunities for fraudulent duplicate claims reimbursement.</p>		
<p>7. If Applicant attests 'NO' to 3.3A1, Applicant agrees to arrange for automated, online billing at non-network pharmacies (similar to the way in which our point-of-sale contractor has allowed for online billing by non-contracted pharmacies.)</p>		

Note: Only if SAE Applicant attests No to 3.3A1, and Yes to 3.3A2-7, SAE Applicant may move directly to Section 4.0 and will be granted a waiver of convenient access.

3.4 General Pharmacy Access 42 CFR 423.120(a); Prescription Drug Benefit Manual, Chapter 5

3.4.1 Retail Pharmacy Access 42 CFR 423.120(a); 42 CFR 423.859(c); Prescription Drug Benefit Manual, Chapter 5

A. In HPMS, complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PART D CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN IN HPMS:	YES	NO	Requesting Waiver? Yes or No
1. Applicant agrees to meet the CMS Standards for Convenient Access [§423.120 (a)(1) and (2)] (See Appendix entitled <i>Retail Pharmacy Network Access Instructions</i>).			
2. Applicant agrees that when Applicant is offering extended supplies via mail order, it also has to contract with a sufficient number of network retail pharmacies so as to ensure that enrollees have reasonable access to the same extended day supply benefits at retail that are available at mail-order.			
3. Applicant agrees to use the CMS beneficiary counts in the data file "Medicare Beneficiaries by State, Region, Zip 09242007v1" to prepare the retail network analyses.			
4. Applicant seeks to obtain a waiver of retail pharmacy convenient access standards. If YES, complete table G below in HPMS.			
5. Applicant seeks to obtain a waiver of any willing pharmacy requirements. If YES, complete table H below in HPMS.			

B. Upload in HPMS the Pharmacy Network Access Reports as described in the Appendix entitled *Retail Pharmacy Network Access Instructions*.

C. Upload in HPMS the Retail Pharmacy List:

To submit retail pharmacy listings to CMS, Applicants must download the Microsoft Excel worksheet from HPMS that is located specifically on the Pharmacy Upload page, complete the worksheet and upload the finished document back into HPMS.

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

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

Upload in HPMS, in pdf format, the following information to demonstrate that meeting the access standard within the service area is not practical or impossible.

1. Indicate the geographic area(s) in which the applicant cannot demonstrate that it meets the retail pharmacy convenient access standards as defined in the Appendix entitled *Retail Pharmacy Network Access Instructions*.
2. Explain why these standards cannot be met. Include in the discussion relevant information such as geographic barriers, pharmacy infrastructure barriers, and/or market barriers.
3. Describe how the pharmacies in the Applicant's retail contracted network will provide access to all eligible Part D individuals enrolled in the Applicant's plan(s) in each of the geographic areas defined in item 1 above.

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

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

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

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

G. In HPMS complete the table below:

Waiver of Retail Convenient Access Standards for MA-PDs	
Provide the number of prescriptions provided in 2008 by retail pharmacies owned and operated by Applicant.	
Provide the number of prescriptions provided in 2008 at all retail pharmacies contracted by Applicant.	

NOTE: CMS will determine the percentage of prescriptions at provided at retail pharmacies owned and operated by Applicant over total prescriptions provided at all retail pharmacies contracted by the Applicant.

H. In HPMS complete the table below:

Waiver of Any Willing Pharmacy Requirements for MA-PDs	
Provide the number of prescriptions provided in 2008 by all pharmacies owned and operated by Applicant.	
Provide the number of prescriptions provided in 2008 at all pharmacies contracted by Applicant.	

NOTE: CMS will determine the percentage of prescriptions at provided at all pharmacies owned and operated by Applicant over total prescriptions provided at all pharmacies contracted by the Applicant.

3.4.2 Mail Order Pharmacy 42 CFR 423.120(a)(10); Prescription Drug Benefit Manual, Chapter 5

A. In HPMS, complete the table below:

APPLICANTS <u>MAY</u> OFFER A MAIL ORDER OPTION <u>IN ADDITION TO THEIR CONTRACTED PART D 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 IN HPMS.</u>	YES	NO	Requesting Waiver? Yes or No
1. Applicant will offer mail order pharmacy as a part of its Part D plan(s).			
2. If Applicant attests 'YES' to 3.4.3A1 will Applicant's mail order contract include an extended (e.g., 90) day supply?			
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 an 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. Applicant must ensure that the availability of an extended day supply at retail does not increase the costs to the government and that enrollee cost-sharing for an extended day supply never exceeds what the enrollee would have paid had he/she filled his/her prescription in multiple 30-day supply increments at retail pharmacy rates.			

B. Mail Order Pharmacy List

To submit mail order pharmacy listings to CMS, Applicants must download the Microsoft Excel worksheet from HPMS that is specifically located on the Pharmacy Upload page, complete the worksheet and upload the finished document back into HPMS.

3.4.3 Home Infusion Pharmacy 42 CFR 423.120(a)(4); Prescription Drug Benefit Manual, Chapter 5

A. In HPMS, complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PART D CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN IN HPMS:	YES	NO	Requesting Waiver? Yes or No
1. Applicant agrees to provide adequate access to home infusion pharmacies.			
2. Applicant agrees that its network contracts will address Part D drugs delivered in the home setting.			
3. Applicant agrees that its contracted home infusion pharmacies will deliver home infused drugs in a form that can be administered in a clinically appropriate fashion in the beneficiary's 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 their 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

To submit home infusion pharmacy listings to CMS, Applicants must download the Microsoft Excel worksheet from HPMS that is located specifically on the Pharmacy Upload page, complete the worksheet and upload the finished document back into HPMS.

3.4.4 Long -Term Care (LTC) Pharmacy 42 CFR 423.120(a)(5); Prescription Drug Benefit Manual, Chapter 5

A. In HPMS, complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PART D CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN IN HPMS:	YES	NO	Requesting Waiver? Yes or No
1. 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 section 50.2 of Chapter 5 of the Prescription Drug Benefit Manual.			
2. 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.			
3. Applicant agrees to recognize the CMS special election period (SEP) or open enrollment period for institutionalized individuals for Part D drug plan enrollment and disenrollment for beneficiaries entering, living in, or leaving a long-term care facility.			
4. 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.			
5. Applicant agrees that it will contract with a sufficient number of LTC pharmacies to provide all of the plan's institutionalized enrollees' convenient access to their LTC pharmacies.			
6. 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 served by those LTC pharmacies relative to those residing in LTC facilities serviced by network LTC pharmacies whose contracts with the Applicant may not include the same provisions.			

B. LTC Pharmacy List

To submit LTC pharmacy listings to CMS, Applicants must download the Microsoft Excel worksheet from HPMS that is located specifically on the Pharmacy Upload page, complete the worksheet and upload the finished document back into HPMS.

3.4.5 Indian Health Service, Indian Tribe and Tribal Organization, and Urban Indian Organization (I/T/U) Pharmacy 42 CFR 423.120(a)(6); Prescription Drug Benefit Manual, Chapter 5

A. In HPMS, complete the table below:

APPLICANT MUST ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN IN HPMS TO BE APPROVED FOR A PART D CONTRACT :	YES	NO	N/A	Requesting Waiver? Yes or No

1. Using the list of I/T/U pharmacies provided on the www.cms.hhs.gov/ website, indicate whether your service area includes at least one I/T/U pharmacy.				
NOT ALL PART D REGIONS HAVE I/T/U PHARMACIES. IF THE APPLICANT'S SERVICE AREA COVERS ANY REGION THAT INCLUDES I/T/U PHARMACIES, THEN THE APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PART D CONTRACT. IF ALL OF THE APPLICANT'S SERVICE AREA DOES NOT INCLUDE I/T/U PHARMACIES, THEN THE APPLICANT MAY ANSWER 'NO' or N/A AND STILL BE APPROVED FOR A PART D CONTRACT SINCE THESE REQUIREMENTS DO NOT APPLY. ATTEST 'YES,' 'NO,' OR N/A TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN IN HPMS:	YES	NO	N/A	Requesting Waiver? Yes or 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. The model contract addendum is posted on the www.cms.hhs.gov/ 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 made by proof of fax or U.S. postage mail receipt of delivery.				

B. I/T/U Pharmacy List

To submit I/T/U pharmacy listings to CMS, Applicants must download the Microsoft Excel worksheet from HPMS that is located specifically on the Pharmacy Upload page, complete the worksheet and upload the finished document back into HPMS.

Upload in HPMS, in a pdf format, the following certification:

4. CERTIFICATION

I, NAME, TITLE, attest 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 for the expanded service area, I will abide by the requirements contained in this Application and provide the services outlined in my application.
- 4) I agree that CMS may inspect any and all information necessary including inspecting of the premises of the Part D Sponsor'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, 2009 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 business organization that is applying for qualification to enter into a Part D contract with CMS.
- 7) I acknowledge that I am aware that there is operational policy guidance, including the forthcoming 2010 Call Letter, relevant to this application that is posted on the CMS website and that 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 SAE to their existing contract.

Authorized Representative Name (printed)

Title

Authorized Representative Signature

5. Appendices

Date (MM/DD/YYYY)

Section B

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

Section C

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

If you have any questions regarding this form please contact:

Joseph Millstone
410-786-2976

INSTRUCTIONS FOLLOW

(THIS SECTION FOR OFFICIAL USE ONLY)

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

I. BACKGROUND AND PURPOSE

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

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

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

Waiver requests should be submitted to CMS using the criteria described below.

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

Waiver Applicants must also comply with CMS standards for financial solvency and capital adequacy.

II. WAIVER ELIGIBILITY

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

A. SINGLE STATE WAIVER

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

1. The State has failed to complete action on a licensing application within 90 days of the date of the State's receipt of a substantially complete application. 42 CFR 423.410(b) (1).
2. The State does not have a licensing process in effect with respect to PDP sponsors. 42 CFR 423.410(c).
3. The State has denied the license application on the basis of one of the following:
 - (a) material requirements, procedures, or standards (other than solvency

requirements) not generally applied by the State to other entities engaged in a substantially similar business; or (b) the State requires, as a condition of licensure, the Applicant to offer any product or plan other than a PDP. 42 CFR 423.410(b)(2).

4. □ The State has denied the licensure application, in whole or in part, for one of the following reasons: (a) on the basis of the Applicant's failure to meet solvency requirements that are different from the solvency standards developed by CMS; or (b) the State has imposed, as a condition of licensing, any documentation or information requirements relating to solvency that are different from the information or documentation requirements in the solvency standards developed by CMS. 42 CFR 423.410(b)(3).
5. □ The State has denied the licensure application on the basis of grounds other than those required under Federal law. 42 CFR 423.410(b)(4).

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

- 1) The State failed to complete the action on the licensing application within 90 days of the date that the state received a substantially complete application. States must confirm the receipt and completeness of the application, which is necessary to establish that the 90-day period has been met; or
- 2) The State denied the substantially complete license application for one of the reasons specified in 42 CFR §423.410(b)(2) through (b)(4), relating to Single-State Waivers.

In order to apply for a CMS waiver based on the ground that a State did not act within 90 days of receiving a substantially complete application, the State must have had a substantially complete application for at least 90 days at the time the waiver applicant applies to CMS for a waiver. Therefore, in order to use this ground as a basis for a waiver, any new State license application must be received by a State(s) no later than November 1, 2008. This will help insure that the State has time to confirm "the receipt and completeness of the application" which is necessary to establish that the 90-day period has been met. It may be prudent to file the State application sooner than November 1, 2008 in case a State does not accept an application as being substantially complete. Furthermore, filing the application no later than November 1, 2008 will allow the State time to process the application and either approve or deny it. A state's denial of an application that was not complete does not create grounds for waiver approval.

B. REGIONAL PLAN WAIVERS

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

III. WAIVER DURATION

A. SINGLE STATE WAIVER

The Single State waiver listed in II.A is effective for up to 36 months only and cannot be renewed unless CMS determines that the State in question does not have a licensing process in effect with respect to PDP sponsors. Thus, prior to the CMS renewal notice deadline for the fourth year the PDP sponsor must be State-licensed if it wishes to continue as a PDP sponsor and receive a

contract for the subsequent year, unless CMS determines that the State in question has chosen not to create a licensing process for PDP sponsors – in which case the waiver can continue until CMS determines that a licensure process has been created. Single State waivers automatically terminate if the PDP sponsor obtains State licensure.

B. REGIONAL PLAN WAIVERS

The Regional Plan waivers expire at the end of the time period the Secretary determines is appropriate for timely processing of the licensure application, but in no case will a waiver extend beyond the end of the calendar year.

C. ALL WAIVERS

For both Single State and Regional Plan waivers, the waiver will terminate if the contract with Medicare terminates.

IV. INFORMATION TO BE INCLUDED IN THIS REQUEST

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

SINGLE-STATE WAIVER:

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

b) Provide documentation to substantiate the narrative required in (a). Depending on the grounds for waiver eligibility, this documentation should include but is not necessarily limited to the list below:

1. Evidence of state’s failure to act on a licensure application on a timely basis

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

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

Documentation in b.1 above, and,

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

PDPs seeking a waiver on the grounds that they are subject to requirements, procedures and standards not applicable to entities engaged in a “substantially similar business” must demonstrate through submission of these and other appropriate materials:

- i) The types of entities subject to the different requirements, procedures and standards are engaged in a “substantially similar business”.
- ii) The state requirements, procedures and standards imposed on the PDP entity are not applicable to other “substantially similar business” entities.

3. Evidence of denial of the application based on solvency requirements

Documentation in b.1 above, and,

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

4. Evidence of State denial of the application based on licensure standards other than those required by Federal law

Documentation in b.1 above, and,

Copy of denial letter from the state, memo identifying the state licensure standards by reference to relevant state law, regulation, or policy guidance and describing the how those standards differ from those required by Federal law.

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

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

REGIONAL PLAN WAIVERS

a) Evidence of licensure in one state within the region and

b) Copy of the dated cover sheet to the application(s) submitted to the unlicensed state(s), state confirmation of the receipt and completeness of each application, state requests for additional information, and all pertinent correspondence with the state(s) relating to the status of the application, etc. – unless CMS determines that there is no PDP licensing process in effect in a state.

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

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

V. OVERVIEW OF WAIVER REQUEST PROCESS

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

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

Upload all appropriate documentation in HPMS on the Part D Financial Solvency Upload Page.

I. DOCUMENTATION

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

1. Documentation of Minimum Net Worth

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

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

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

B. Financial Plan

1. Plan Content and Coverage

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

The business plan must include a financial plan with:

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

- g. Independent actuarial certification of business plan assumptions and plan feasibility by a qualified actuary.

2. Funding for Projected Losses

(a) Allowable sources of funding:

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

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

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

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

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

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

(iii) If approved by CMS, based on appropriate standards promulgated by CMS, a PDP sponsor may use the following to fund projected fund losses for periods after the first year: lines of credit from regulated financial institutions, legally binding

agreements for capital contributions, or other legally binding contracts of a similar level of reliability.

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

(b) Calculation of projected losses:

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

- (i) 7.5 percent of the aggregated projected target amount for a given year (aggregated projected target amount is calculated by estimating the average monthly per capita cost of benefits (excluding administrative costs) and multiplying that amount by member months for a 12 month period), or
- (ii) Resources to cover 100% of any projected losses, if the business plan projects losses greater than 7.5% of the aggregated projected target amount.

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

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

C. Liquidity

The PDP Sponsor must have sufficient cash flow to meet its financial obligations as they become due. The amount of minimum net worth requirement to be met by cash or cash equivalents is \$750,000. Cash equivalents are short term highly liquid investments that

can be readily converted to cash. To be classified as cash equivalents these investments must have a maturity date not longer than 3 months from the date of purchase.

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

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

CMS may apply the following corresponding corrective action remedies:

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

D. Methods of Accounting

The PDP Sponsor may use the standards of Generally Accepted Accounting Principles (GAAP) or it may use the standards of Statutory Accounting Principles (SAP) applicable to the type of organization it would have been licensed as at the state level if a waiver were not granted by CMS. Whether GAAP or SAP is utilized however, there are certain additional differences cited below for waived PDP Sponsors.

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

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

Waivered PDP Sponsors should adjust their balance sheets as follows:

1. Calculation-Assets

The following asset classes will not be admitted as assets:

- Good will
- Acquisition costs
- Other similar intangible assets

2. Calculation- Liabilities

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

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

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

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

E. Financial Indicators and Reporting

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

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

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

Reporting shall be on the following schedule:

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

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

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

II. INSOLVENCY

A. Hold Harmless and Continuation of Coverage/Benefits

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

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

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

III. GUARANTEES

A. General policy.

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

B. Request to use a Guarantor.

To apply to use the financial resources of a Guarantor, a PDP Sponsor must upload in HPMS:

1. Documentation that the Guarantor meets the requirements for a Guarantor under paragraph (C) of this section; and
2. The Guarantor's independently audited financial statements for the current year-to-date and for the two most recent fiscal years. The financial statements must include the Guarantor's balance sheets, profit and loss statements, and cash flow statements.

C. Requirements for Guarantor.

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

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

D. Guarantee document.

If the guarantee request is approved, a PDP Sponsor must upload in HPMS a written guarantee document signed by an appropriate Guarantor. The guarantee document must:

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

E. Reporting requirement.

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

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

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

1. Requests CMS'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 PDP Sponsor; and
3. Demonstrates how the PDP Sponsor will meet the requirements of this section.

G. Nullification.

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

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

Appendix III Retail Pharmacy Network Access Instructions

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

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

Information Required to Qualify As Part D Sponsor

CMS recognizes that the deadline for submission of the Part D application (March) precedes the plan bidding and finalization process (June). Further CMS recognizes that many (if not most) Part D sponsors continue work on defining their PBP service areas throughout their Bid formulation process. Therefore, it is difficult for Applicants to submit final pharmacy accessibility analyses for each PBP, and we will require a contract-level submission at this time. This circumstance is especially problematic for MA-PD sponsors that may choose to offer a PBP to a subset of their Contract Service Area. The impact on PDPs, RPPOs, and Cost Plans is minimal since those types of contracts must offer all PBPs with Part D throughout each specific PDP Region (PDPs), MA Region (RPPOs) or geographic area (Cost Plans).

Local MA-PD Service Area Expansion (SAE) Applicants for Part D should submit their pharmacy access analyses at the contract level, including the entire service area for the contract.

GeoNetworks® reports provided at the contract level must include detail on the number of beneficiaries and the number of contracted pharmacies at the county level. MA-PD SAE Applicants for Part D are not required to submit separate geographic accessibility analyses for each unique PBP service area or each unique combination of PBPs offered in the same service area.

PDP or Regional MA-PD (RPPO) SAE Applicants, possessing a current contract, that are applying for a Service Area Expansion are required to submit GeoAccess Analyses for the new proposed service area only. For example, if PDP sponsor currently provides services in PDP Regions 01, 02, 03, and 04, and applies for a Service Area Expansion into Region 05, the PDP SAE Applicant is only required to provide GeoAccess reports for Region 05 (the area of expansion). Similarly, if a RPPO currently provides services in MA Regions 01, 02, 03, and 04 and applies for a Service Area Expansion into Region 05, the RPPO SAE Applicant is only required to provide GeoAccess reports for Region 05 (the area of expansion).

Geographic Accessibility Analysis Instructions

All SAE Applicants are strongly encouraged to use The Quest Analytics Suite™ or GeoNetworks® software to compile the reports as outlined in this appendix. If this is not possible then SAE Applicants must contact Dennis Hodges, at dennis.hodges@cms.hhs.gov (410.786.3048), no later than February 4, 2009 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 The Quest Analytics Suite™ or GeoNetworks®. SAE Applicants that wish to use alternative methods will be required to demonstrate how their analysis is comparable to results produced by either The Quest Analytics Suite™ or GeoNetworks®.

Though in many instances CMS provides specific instructions for formatting and compiling plan accessibility reports, this appendix is not intended to provide step-by-step instructions for the use of either software. Instructions and examples provided here were developed using The Quest Analytics Suite version 2007.3 and GeoNetworks version 7.5.2.¹ It is the responsibility of the SAE Applicant to ensure that their submission provides adequate information for CMS to determine if their offerings meet the retail pharmacy access submission requirements. Detailed descriptions of the information needed by CMS are provided below.

I. Instructions for Part D Applicants using The Quest Analytics Suite™

1. Defining the Medicare Beneficiary File

The Medicare Beneficiary File “**Medicare Beneficiaries by State, Region, ZIP 09242007v1.xls**” is provided by CMS and can be accessed at the following URL: www.cms.hhs.gov/PrescriptionDrugCovContra/. The Medicare Beneficiary File referenced above contains ZIP Codes and beneficiary counts for Applicants as of September, 2008. ***Use of this file is required for the accessibility analysis submission.***

- Download this file and create a sub-file(s) specific to their service area and/or region(s) and/or state as needed to support the level of analyses required (specified below). Applicants may not use beneficiary counts from other sources in their accessibility analyses.
- Open the Quest Analytics Project file you downloaded and link to the data sub-file in The Quest Analytics Suite by adding an Employee Group and name it “All Beneficiaries”. Applicants may geocode by selecting the “Geocoding Tab” and select “Geocode Now” during this step, or they may defer geocoding the population file until run time.
- Verify that the beneficiary (employee) count in the population file is consistent with the total beneficiary census for the sub-file used as the basis for the analyses. CMS will check the count of beneficiaries provided in the reports against the count of beneficiaries residing in the plan’s service area.
- The most recent version of The Quest Analytics Suite™ assigns an Urban, Suburban, or Rural classification for each Medicare beneficiary record consistent with the definitions specified in 42 CFR §423.100. Select the appropriate options under project preferences.
- 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 Employee Groups resource and Copy the All Beneficiaries group. Change the name to “Urban Beneficiaries” and on the zip code filter, turn off the suburban and rural check boxes.

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

- To define the subset of Suburban beneficiaries, navigate to Employee Groups resource and Copy the All Beneficiaries group. Change the name to “Suburban Beneficiaries” and on the zip code filter, turn off the urban and rural check boxes.
- To define the subset of Rural beneficiaries, navigate to Employee Groups resource and Copy the All Beneficiaries group. Change the name to “Rural Beneficiaries” and on the zip code filter, turn off the urban and suburban check boxes.
- Verify that the urban, suburban, and rural definitions are defined appropriately for each page of the report. CMS will compare the total of urban, suburban, and rural beneficiaries for specific counties to totals derived from the Medicare Beneficiary File.
- The Quest Analytics Suite™ default restricts beneficiaries inside your service area.
- Applicants may specify that contracted providers outside their service area (e.g., across state or county lines) be included in their accessibility analyses. The most recent release of The Quest Analytics Suite™ allows for inclusion of providers outside the specified service area under the report area options.

2. Defining the Provider File

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 analysis (and the submission provided under Section 3.4.1B of this solicitation to represent one complete Part D network).

- Applicant may use representative ZIP Geocoding or the more precise geocoding methods for pharmacy providers (i.e., the ZIP+ 4 Centroid Method, the ZIP+2 Centroid Method, or address-based geocoding). CMS strongly encourages the use of more precise methods for geocoding. Use of address-based geocoding will prevent, in some market areas, false indications that access standards are not met.
- The Quest Analytics Suite™ will automatically geocode your provider file using an “address-based” method (if licensed). If this function is not available on your version of Quest Analytics Suite™, the default, distributive geocoding methodology, is acceptable.
- Define the Provider Group by navigating to Add Provider Groups. Select the data source on the Source Table button. On the Name enter the label of “Part D Retail Pharmacy Network”, select OK.
- Verify that the total counts for pharmacy providers in the report do not exceed the count of pharmacies in your Part D contracted retail pharmacy listing that must also be provided using the retail listing template provided in HPMS.

3. Defining Access Criteria

- The Applicant must define access standards in accordance with the Part D standards, as defined in 42 CFR § 423.120(a)(1).
- The Urban access standard of 1 provider within 2 miles is predefined within the Quest project file that you downloaded.
- The Suburban access standard of 1 provider within 5 miles is predefined within the Quest project file that you downloaded.
- The Rural access standard of 1 provider within 15 miles is predefined within the Quest project file that you downloaded.

4. Defining the Plan Service Area

Applicants should define their service area based on the service area for the entire contract. The service area defined in your report must EXACTLY match the service area you have specified in HPMS.

PDP Applicants

PDPs and RPPOs are required to demonstrate the accessibility standards at the state level. Applicants must also present access statistics at the county level. Please note that it is not a requirement for PDP (or RPPO) Applicants to provide summary statistics related to the accessibility standards at the region level.

- Define the service area by navigating to Service Area and Add and select your service area.
- Verify that the service area in your report EXACTLY matches the service area you have entered in HPMS. New Applicants must include all regional (and their component States) in their report. Service Area Expansion (SAE) applicants MUST include only new regions (and their component States) in their report.
- Verify that the reports provided to CMS include subtotals for each individual state and grand total summary statistics encompassing all states in the service area. For SAE applicants the reports provided to CMS should include subtotals for each individual state and grand total summary statistics encompassing all states in the expansion area.

5. Generating the Accessibility Analyses Reports

A report template is included in the Quest Analytics project file that you downloaded. This includes all the report pages and access standards along with the applicable sorting options.

6. Providing copies of the Analysis to CMS for review

Applicants must upload their report in Adobe Acrobat readable (*.pdf) format into HPMS.

II. Instructions for Part D Applicants using GeoNetworks®

1. Defining the Medicare Beneficiary File in GeoNetworks®:

The Medicare Beneficiary File “**Medicare Beneficiaries by State, Region, ZIP 09242007v1.xls**” is provided by CMS.

The Medicare Beneficiary File referenced above contains ZIP Codes and beneficiary counts for SAE Applicants as of September, 2008. Use of this file is required for the accessibility analysis submission. SAE Applicants should download this census file and create a sub-file(s) specific to their service area and/or region(s) and/or state as needed to support the level of analyses required (specified below). SAE Applicants may not use beneficiary counts from other sources in their accessibility analyses.

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

SAE 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, SAE Applicant may assign geocodes by navigating to Data > Assign Geocodes > Select and open file > Click OK. SAE 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).

SAE 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.

SAE 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:** SAE Applicant should verify that the urban, suburban, and rural definitions are defined appropriately for each page of the report. These (filtered) sub-populations are used to verify access compliance. CMS will compare the total of urban, suburban, and rural beneficiaries for specific counties to totals derived from the Medicare Beneficiary File. Additionally, SAE 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®

SAE 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 3.5.1C of this solicitation that includes address information to define their provider file. If an SAE 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 3.5.1B of this solicitation to represent one complete Part D network).

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

Next, SAE 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:** SAE 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 3.5.1C 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 and local MA-PDPs contract with PBMs to provide national networks. Our review testing will reject instances where the total number of pharmacies in the GeoNetworks® analysis is greater than the number of retail

pharmacies provided in the retail Pharmacy listing provided in Section 3.5.1C of this solicitation.

3. Defining Access Criteria Consistent with Part D requirements

SAE 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)

The following two sections provide instructions specific to the type of Part D Sponsor. Section 4.a. should be referenced by Local MA-PD and Cost Plan SAE Applicants. Section 4.b. should be referenced by MA-PD Regional (RPPO) SAE Applicants and PDPs.

a. Local MA-PD SAE Applicants

Service Areas may be defined in GeoNetworks® by navigating to Define > Service Areas > Add > Use buttons on right to select your service area.

Within each contract number, local MA-PD SAE Applicants must define their service areas. As specified in 42 CFR 423.120 (a), access standards must be met at the **plan** level. However, as discussed in Part A (1) (b) of this appendix, MA-PD SAE Applicants for Part D should submit their pharmacy access analyses at the contract level, including the entire service area for the contract. GeoNetworks® reports provided at the contract level must include detail on the number of beneficiaries and the number of contracted pharmacies at the county level. MA-PD SAE Applicants for Part D are not required to submit separate geographic accessibility analyses for each unique PBP service area or each unique combination of PBPs offered in the same service area.

Table I		
Example MA-PD Contractor PBP Offerings		
Contract	Contract Service Area	Pharmacy Network
H0000 - MA-PD of the Greater Baltimore Area	Anne Arundel County Baltimore County Carroll County Frederick County	Part D Pharmacy Network 1

In this example, MA-PD SAE Applicant should define one service area (labeled H0000 in the description field) that includes the counties in the MA-PD service area.

✓ **Quality Check:** SAE Applicants must verify that the contract and its service area are represented appropriately. CMS will verify the service area of plans using data submitted to the Health Plan Management System (HPMS). Inconsistencies between the Contract's Part D service area specified in HPMS and the Contract Service Area specified in the GeoNetworks Analysis will cause delays in review and, potentially, denial of the SAE Applicant's Part D application.

b. PDP and Regional PPO SAE Applicants

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

Please note that it is not a requirement for PDP and RPPO SAE Applicants to provide summary statistics related to the accessibility standard at the region level (even in the case where the region covers multiple states). As outlined in Section B, under 42 CFR 423.120 (a). PDPs and RPPOs are required to adhere to the accessibility standards at the state level, although SAE Applicants 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:** SAE Applicants must verify that the reports provided to CMS include totals and summary statistics for each individual state within the PDP and RPPO regions.

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

Table II		
Example PDP Contractor PBP Offerings		
Contract	Contract Service Area	Pharmacy Network
S0000	PDP Region 5: Maryland, Delaware and the District of Columbia	Part D Pharmacy Network 1

In this example, the SAE Applicant should define one service area (labeled PDP Region 05: S0000) in the description field that includes the 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 MA-PD and PDP/RPPO plans separately. Sub-part (a.) provides instructions for completion of the MA-PD reports. Sub-part (b.) provides instructions for the completion of reports for PDPs and RPPOs.

a. MA-PDs

SAE 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 areas defined. There should be six reports for each unique combination of a plan service area(s) and pharmacy network(s).

As stated earlier in this appendix, for a given contract number Local MA-PD must provide separate retail pharmacy accessibility analyses for beneficiaries classified as Urban, Suburban, and Rural for each unique combination of contractor service area and pharmacy network (i.e., preferred only; preferred and non-preferred). The title of 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. As specified in the instructions below, statistics for **each county** within the service area individually, and statistics for **the entire contract service area** in total must be provided.

Using the example outlined in part 4.a the steps to define the accessibility detail report for urban beneficiaries in the service area of H0000 are as follows:

- Navigate to Page > Add > Accessibility Detail > Double click on the page that appears
- Under the Specifications tab for the new Accessibility Detail Page set Employee Group to be your urban beneficiaries, set Provider Group to be "Part D Pharmacy Network 1", set Access Standard to be "Urban: 1 provider within 2 miles", set Access filter to "all", and set Service Area to "H0000".
- 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 "H0000"

The steps to define the service area report for all beneficiaries with access in the service area of H0000 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 Pharmacy Network 1", set Service Area to H0000.
- Under the Options tab for the new Service Area Detail Page, select to summarize by county, set service area filter to inside, ensure that the following options are checked: state, number of employees, number of providers, and totals.
- Under the Titles tab, uncheck the default Title 1 and specify a title that describes the unique service area. In this instance the title would be "H0000"
- Ensure that no specifications are indicated under the Include tab.
- Under the Sort tab ensure that sort order is State (ascending), then County (ascending).

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

Including the title and table of contents, a six page report will be generated using the CMS example for H0000, 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) provision of analyses with “all” beneficiary specification. An overview of this report is specified in Table III. An example of the MA-PD GeoAccess report with the file name; “Example MA-PD GeoNetworks Analysis.tif” accompanies this document.

Table III**Example H0000 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 Beneficiaries	Part D Pharmacy Network 1	Urban: 1 provider within 2 miles	H0000	All
4	Accessibility Detail	County	Suburban Beneficiaries	Part D Pharmacy Network 1	Suburban: 1 provider within 5 miles	H0000	All
5	Accessibility Detail	County	Rural Beneficiaries	Part D Pharmacy Network 1	Rural: 1 provider within 15 miles	H0000	All
6	Service Area	County	All Beneficiaries	Part D Pharmacy Network 1		H0000	
7	GeoNetworks Report (auto generated summary information to be included in submission)						

b. PDP and RPPO Reports

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

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

As stated earlier in this appendix, a Regional PPO's service area is defined by the MA region(s) that it will serve. 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). SAE Applicants should provide reports for each unique combination of contract and network. Reports should be provided that include each state in the applicants RPPO service area ***The title in the accessibility detail report should specify the network represented in the pharmacy list. The network reference should match the "List Identifier" entry in your submission of the "Retail Pharmacy List.xls" file.*** For each accessibility analysis, a report is created that provides the percentage of beneficiaries with access and the percentage of beneficiaries without access. As specified in the instructions below, statistics for **each individual county** within the service area and statistics for **each State** (in total) must be provided.

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

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

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

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

- Navigate to Page > Add > Service Area Detail > Double click on the page that appears.
- Under the Specifications tab for the new Service Area Detail Page set Employee Group to be all beneficiaries, set Provider Group to be "Part D Pharmacy Network 1", set Service Area to S0000.
- Under the Options tab for the new Service Area Detail Page, select to summarize by state, set service area filter to inside, ensure that the following options are checked: number of employees, number of providers, and totals.
- Under the Titles tab, uncheck the default Title 1 and specify a title that describes the service area. In this instance the title would be "PDP Region 05: Mid-Atlantic (DE, DC, MD)".
- Ensure that no specifications are indicated under the Include tab.

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

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

Table IV**Example S0000 Report Pages Specification**

Rpt #	Page	Summarized by	Employee Group	Provider Group	Access Standard	Service Area / Title 1	Access Filter
1	Title						
2	Table of Contents						
3	Accessibility Detail	County	Urban PDP Region 05 Beneficiaries	Part D Pharmacy Network 1	Urban: 1 provider within 2 miles	S0000	All
4	Accessibility Detail	County	Suburban PDP Region 05 Beneficiaries	Part D Pharmacy Network 1	Suburban: 1 provider within 5 miles	S0000	All
5	Accessibility Detail	County	Rural PDP Region 05 Beneficiaries	Part D Pharmacy Network 1	Rural: 1 provider within 15 miles	S0000	All
6	Service Area	State	All Beneficiaries	Part D Pharmacy Network 1		S0000	
7	GeoNetworks Report (auto generated summary information report to be included in submission)						

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

Example of the MA-PD and PDP GeoAccess reports with the file names, “Example MA-PD GeoNetworks Analysis.tif” and “Example PDP GeoNetworks Analysis.tif” accompanies this document.

*✓ **Quality Check:** SAE 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 upload their GeoNetworks® report in Adobe Acrobat readable (*.pdf) format into HPMS.