MEDICARE PRESCRIPTION DRUG BENEFIT

2013 Part D Service Area Expansion Application for Prescription Drug Plan (PDP) Sponsors and Medicare Advantage - Prescription Drug Plans (MA-PD) Sponsors

2013 Contract Year

Expiration:

1.

General Information

1.1. Purpose of Solicitation

The Centers for Medicare & Medicaid Services is seeking applications from existing Part D Benefit organizations 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.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. Schedule

APPLICATION REVIEW PROCESS	
Date	**Milestone**
November 11, 2011	Recommended date by which Applicants should submit their Notice of Intent to Apply Form to CMS to ensure access to Health Plan Management System (HPMS) by the date applications are released
December 6, 2011	CMS User ID form due to CMS
January 10, 2012	Final Applications posted by CMS
February 7, 2012	Deadline for NOIA form submission to CMS
February 21 , 2012	Applications due
March 23, 2012	Release of Health Plan Management System (HPMS) formulary submissions module
April 6, 2012	Plan Creation module, Plan Benefit Package (PBP),

	and Bid Pricing Tool (BPT) available on HPMS
April 16, 2012	Formulary submission due to CMS Transition Policy Attestations and Policy due to CMS
May 2012	CMS sends Part D contract eligibility determination to Applicants, based on review of application. Applicant's bids must still be negotiated (see below)
May 11, 2012	PBP/BPT Upload Module available on HPMS
June 4, 2012	All bids due
Early August 2012	CMS publishes national average Part D premium
September 2012	CMS completes review and approval of bid data. CMS executes Part D contracts to those organizations who submit an acceptable bid
October 15, 2012	2013 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 2013 in the individual and/or employer markets. 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 2013.

2.2. Other Technical Support

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

CMS also conducts special training sessions, including a user group call dedicated to addressing issues unique to sponsors that are new to the Part D program.

CMS provides two user manuals to assist applicants with the technical requirements of submitting the Part D application through the Health Plan Management System (HPMS). The Basic Contract Management User's Manual provides information on completing and maintaining basic information required in Contract Management. These data must be completed prior to the final submission of any application. The Online Application User's Manual provides detailed instructions on completing the various online applications. Both manuals can be found in HPMS by clicking on Contract Management>Basic Contract Management>Documentation.

2.3. Health Plan Management System (HPMS) Data Entry

Part D sponsors are assigned a contract number (H/R/S/E 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 input contact and other related information into the 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 a contract, this information will also be used for frequent communications during implementation and throughout the contract year. It is important that the information in HPMS is accurate at all times.

2.4. Instructions and Format of Qualifications

Applications may be submitted until February 21, 2012. Applicants must use the 2013 solicitation. CMS will not accept or review in anyway those submissions using the prior

versions of the solicitation, including the use of CMS provided templates from prior years (e.g. 2012 and earlier).

2.4.1. Instructions

Applicants will complete the entire solicitation via HPMS.

In preparing your application in response to the prompts in Section 3 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 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 that its organization complies with the relevant requirements as of the date your application is submitted to CMS, unless a different date is stated by CMS.

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.

Organizations will receive a confirmation number from HPMS upon clicking final submit. Failure to obtain a confirmation number indicates that an applicant failed to properly submit itsr Part D application by the CMS-established deadline. Any entity that experiences technical difficulties during the submission process must contact the HPMS Help Desk and CMS will make case by case determinations where appropriate regarding the timeliness of the application submission.

CMS will check the application for completeness shortly after its receipt. Consistent with the 2010 Call Letter, CMS will make determinations concerning the validity of each organization’s submission. Some examples of invalid submissions include but are not limited to the following: Applicants that fail to upload executed agreements or contract templates, Applicants that upload contract crosswalks instead of contracts, or Applicants that fail to upload any pharmacy access reports. CMS will notify any Applicants that are determined to have provided invalid submissions.

For those Applicants with valid submissions, CMS will notify your organization of any deficiencies and afford a courtesy opportunity to amend the applications. CMS will only review the last submission provided during this courtesy cure period.

CMS will provide communication back to all Applicants throughout the application process via email. The email notifications will be generated through HPMS, so organizations must ensure that the Part D application contract information provided through the “Notice of Intent to Apply” process is current and correct, and that there are no firewalls in place that would prevent an email from the hpms@cms.hhs.gov web address from being delivered.

CMS has established that all aspects of the program that the Applicant attests to must be ready for operation by the application due date.

CMS clarified its Part D application review standards in a final rule (4085-F) published in the Federal Register on April 15, 2010, with an effective date of June 7, 2010.

Applicants must demonstrate that they meet all (not substantially all) Part D program requirements to qualify as a Part D sponsor in their proposed service area.

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

An individual with legal authority to bind the Applicant shall execute the certification found in Section 4. CMS reserves the right to request clarifications or corrections to a submitted application. Failure to provide requested clarifications within the time period specified by CMS for responding 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 clarifications 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. Eastern Standard Time on February 21, 2012. 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 2013 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 21, 2012; they are PDP, MA-PD, Cost Plan solicitations, and the Service Area Expansion Application. Organizations that intend to offer more than one of these types of Part D contracts must submit a separate application for each type. (PACE sponsors will also have separate solicitations). For example, a MA-PD and PDP product may not be represented in the same application. Entities intending to have both local MA-PD and Regional PPO contracts must submit separate MA-PD applications.

2.4.2. 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

hold multiple contracts for the same plan type (e.g. PDP, MA-PD, or Cost Plan) in the service area described in the application.

2.4.3. Organizations Seeking to Only Expand the Employer Service Area

For those Part D Sponsors that currently offer the prescription drug benefit in both the individual and employer market and are seeking to expand their service area for the employer market only must complete specified attestation sections of this application.

2.4.4. Withdrawal of an Service Area Expansion Application

In those instances where an organization seeks to withdraw its SAE application or reduce the service area of its pending SAE application prior to the execution of a Part D contract or addendum to its MA or Cost Plan contract, then the organization must send an official notice to CMS. The notice should be on organization letterhead and clearly identify the pending application number and service area (as appropriate). The notice should be delivered via email to drugbenefitimpl@cms.hhs.gov and the subject line of the email should read "Pending application withdrawal or reduction to pending service area." The withdrawal will be considered effective as of the deate of the email.

2.4.5. Technical Assistance

For technical assistance in the completion of this Application, contact:

Linda Anders by email at linda.anders@cms.hhs.gov, or by phone at 410-786-0459. As stated in section 2.4.1, Applicants must contact the HPMS Help Desk if they are experiencing technical difficulties uploading or completing any part of this solicitation within HPMS prior to the submission deadline. Applicants requesting technical assistance with uploading or completing any part of the online HPMS application after the published CMS application deadline will not be granted technical assistance, nor the opportunity to complete their application submission.

2.5. Submission Software Training

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

Applicants are required to upload their plan formularies to HPMS using a pre-defined file format and record layout. The formulary upload functionality will be available on March 23, 2012. The deadline for formulary submission to CMS is 11:59 PM EDT on April 16, 2012. 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 112012 and the CY 2013- bid deadline of June 4, 2012. 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 2012.

2.6. Summary Instruction and Format for Individual Market Bids

Each Part D Sponsor must submit to CMS a bid for each prescription drug plan it intends to offer. Applicants using this solicitation may apply to offer full risk Part D plans. Applicants must submit their formularies to HPMS on or before April 16, 2012 and the PBPs and BPTs on or before the bid submission date.

2.6.1. Format of Bids

- **Bid-Related Sections Due Prior to Bid Submission Date**

To facilitate the timely review of all the bid submissions, CMS requires Applicants to submit the portion of their bid related to formulary and covered drugs from March 23-April 16, 2012. CMS reviews areas of each proposed drug plan formulary by tier and drug availability and evaluates each element against evidence-based standards such as widely accepted treatment guidelines. Elements include, but may not be limited to the list of drugs, the categories and classes, tier structures (not cost sharing), and utilization management tools such as quantity limits, step therapy, and prior authorization. CMS makes the review criteria available to Applicants well in advance of the date Applicants must submit this information to CMS. Outliers are selected for further evaluation during the formulary review process prior to CMS approval of the bid. CMS makes reasonable efforts to inform Applicants of their outliers so that they may substantiate their offering. If such substantiation is not satisfactory to CMS, the Applicant is given the opportunity to modify the formulary. CMS intends to complete as much of this work as possible before the PBP and BPT submissions so that any modification may be reflected in those documents.

- **Bid Submissions**

The Applicant's bid represents the expected monthly cost to be incurred by the Applicant to provide 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 42 CFR §423.505(k)(4), the CEO, CFO, or a designee with the authority to sign on behalf of one of these officers, and who reports directly to such officer, must certify (based on best knowledge, information and belief) that the information in the bid submission, and assumptions related to projected reinsurance and low-income cost sharing subsidies, is accurate, complete, and truthful, and fully conforms to the requirements in 42 CFR §423.265. In addition, consistent with 42 CFR §423.265(c)(3), the pricing component of the bid must also be certified by a qualified actuary.

As part of its review of Part D bids, CMS conducts an analysis to ensure that multiple plan offerings by a sponsor represent meaningful variations based on plan characteristics that will provide beneficiaries with substantially different options. Pursuant to section 42 CFR §423.265(b), multiple bid submissions must reflect differences in benefit packages or plan costs that CMS determines represent substantial differences relative to a sponsor's other bid submissions. In order to be considered "substantially different," each bid must be significantly different from the sponsor's other bids with respect to beneficiary out-of-pocket costs or formulary structures. Applicants should review the CMS guidance on the submission of bids that are meaningfully different released on April 16, 2010.

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 that encourage use of generic drugs. Finally, CMS examines indicators concerning plan management, such as customer service.

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

2.6.3. Overview of Bid Negotiation

CMS evaluates the reasonableness of bids submitted by Part D sponsors by means of an actuarial valuation analysis. This requires evaluating assumptions regarding the expected distribution of costs, including average utilization and cost by drug coverage tier. CMS may test these assumptions for reasonableness through actuarial analysis and comparison to industry standards and other comparable bids. Bid negotiation may take the form of negotiating changes upward or downward in the utilization and cost per script assumptions underlying the bid's actuarial basis. We may 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 retail pharmacy access rules consistent with the standards delineated in 42 CFR §423.120. Furthermore, 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 that 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.

Applicants may use their contracted PBM's existing 2012 Part D network to demonstrate compliance with retail pharmacy access standards. If an Applicant is creating a new Part D network, the submission must be based on executed contracts for Year 2013. CMS conducts the review of Retail Pharmacy Access based on the service area that the Applicant has provided in HPMS by February 21, 2012. In an effort to reduce Applicant errors, CMS has automated the retail pharmacy access review. Applicants are required to input their pending service area into HPMS per the instructions at section 3.2 and as explained in section 3.4.1 Applicants must upload the retail pharmacy list in HPMS. Based on the pending service area documented in HPMS

for PDPs and pending and existing service area for local MA-PDs, the retail pharmacy list uploaded by the Applicant, and the Medicare Beneficiary Count file available on the CMS application guidance website, CMS will generate access percentages for all applicants. (In prior years, applicants provided their geo-reports as part of the pharmacy uploads.) In addition, CMS will use the information gathered from the pharmacy list upload to identify pharmacy addresses.

With limited exceptions, this information gathered from the pharmacy lists will be used by CMS to geo-code the specific street-level locations of the pharmacies to precisely determine retail pharmacy access. Exceptions to this process may include, but not be limited to, those instances where a street-level address cannot be precisely geo-coded. In those situations, CMS will utilize the ZIP code-level address information to geo-code the approximate pharmacy location.

In previous years CMS allowed Part D applicants to use one of several geo-coding methodologies: representative ZIP code geo-coding, or the more precise geo-coding methods including ZIP+4 Centroid Method, ZIP+@ Centroid Method, referred to as address-based geo-coding. As a result, some organizations may previously have coded all pharmacy addresses at the ZIP code/county level as opposed to the more precise street-level coding. CMS strongly encourages applicants conduct a closer and more precise inspection of their retail pharmacy locations and network access prior to submitting their pharmacy list.

The retail pharmacy lists may contain contracted pharmacies that are outside of the Applicant's service area (to account for Applicants who contract for a national pharmacy network); however, CMS will only evaluate the retail pharmacy access for the pending service area for the PDPs and the existing and pending service area for local MA-PDs. The retail pharmacy access calculations must meet the established standards at one of the following points in time:

- At the HPMS gate closing time of the 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
- At the HPMS gate closing 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
- At the HPMS gate closing 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.

While Applicants are required to demonstrate that they meet the Part D pharmacy access requirements at the time this application is submitted to CMS, CMS expects that pharmacy network contracting will be ongoing in order to maintain compliance with our retail pharmacy access requirements.

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 3.4.3). CMS uses this pharmacy listing to compare Applicants' home infusion pharmacy network against existing Part D sponsors in the same service area to ensure that Applicants have contracted with an adequate number of home infusion pharmacies. The adequate number of home infusion pharmacies is developed based on data provided by all Part D sponsors through the annual Part D Reporting Requirements. A reference file entitled "Adequate Access to Home Infusion Pharmacies" is provided on the CMS website.

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 3.4.4). CMS uses this pharmacy listing, as well as information reported as part of Applicants' reporting requirements and complaints data, to evaluate initial and ongoing compliance with the convenient access standard.

2.7.4. Indian Tribe and Tribal Organization, and Urban Indian Organization (I/T/U)

Applicants must demonstrate that they have offered standard contracts to all I/T/U pharmacies residing within the Applicants' service areas. In order to demonstrate convenient access to I/T/U pharmacies, Applicants must provide a list of all I/T/U pharmacies to which they have offered contracts (see section 3.4.5). CMS provides the current national list of all I/T/U pharmacies to assist Applicants in identifying the states in which I/T/U pharmacies reside at the www.cms.gov/PrescriptionDrugCovContra/ website.

2.7.5. Waivers Related to Pharmacy Access

Waivers for MA-PD Plans CMS guidance regarding waivers of the 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.

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 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 sponsors that operate their own pharmacies. MA-PD 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 50.8.2 of Chapter 5 of the Prescription Drug Benefit Manual, the requirement that MA-PD sponsors must offer a network pharmacy contract to any willing pharmacy that agrees to accept MA-PD sponsor's standard terms and conditions is waived for MA-PD sponsors that own and operate the pharmacies in their network. MA-PD 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 (excluding Puerto Rico)

To ensure access to coverage in the territories, §1860D-42(a) of the Social Security Act 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 at 42 CFR §423.859(c) allow CMS to waive or modify the requirement for access to coverage in the territories either at an Applicant's request or at CMS' own determination. Under that authority, CMS will consider waiving the convenient access requirements for a plan's Part D contracted retail pharmacy network, found in 42 CFR §423.120(a)(1) for the Territories, if an Applicant requests such a waiver, and demonstrates that it has made a good faith effort to meet the requirements described in Section 3.5.1C of this solicitation.

2.8. Standard Contract with Part D Sponsors

Successful Applicants will be deemed qualified to enter into a Part D addendum to their Medicare Advantage or Prescription Drug Plan contract after CMS has reviewed the Applicant's entire submission. Under this addendum the Part D 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. Approved Part D applications are valid for the forthcoming contract year. Should an Applicant decide to not execute a contract after receiving application approval, then the organization will need to submit a new application if it chooses to enter the Part D market in a future contract year.

2.9. Protection of Confidential Information

Applicants may seek to protect their information from disclosure under the Freedom of Information Act (FOIA) by claiming that FOIA Exemption 4 applies. The Applicant is required to label the information in question "confidential" or "proprietary", and explain the applicability of the FOIA exemption it is claiming. 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 for MA-PD and Cost Plan SAE Applicants

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. Accordingly, CMS has identified the waivers it is granting to all MA-PD sponsors in the chart shown in ***Summary of Medicare Part D Regulatory Requirements Fulfilled under Part C for Medicare Advantage Prescription Drug (MA-PD) Applicants*** (Appendix II). As a result of these CMS-granted waivers, the MA-PD sponsor application is less comprehensive than the PDP sponsor application. These waivers will be reflected in each MA-PD sponsor's Part D addendum.

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 provide, as an 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 both the "Yes" box and the "Waiver Requested" box 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 21, 2012 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, 2012. 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 Medicare

Attention: Application Withdrawal

7500 Security Boulevard

Mail Stop C1-26-12

Baltimore, Maryland 21244-1850

2.11. Waivers Related to Attestations for EGWP, PDP Direct, and MA-PD Direct Contract Applicants

As a part of the application process, those organizations seeking to offer 800 series plans may submit individual waiver/modification requests to CMS. Applicants should submit an attachment via an upload in the HPMS Part D Attestations section that addresses the following:

- Specific provisions of existing statutory, regulatory, and/or CMS policy requirement(s) the entity is requesting to be waived or modified (please identify the specific requirement (e.g., 42 CFR §423.32, Section 30.4 of the Part D Enrollment Manual) and whether you are requesting a waiver or a modification of these requirements);
- How the particular requirement(s) hinder the design of, the offering of, or the enrollment in, the employer-sponsored group plan;
- Detailed description of the waiver/modification requested including how the waiver/modification will remedy the impediment (i.e., hindrance) to the design of, the offering of, or the enrollment in, the employer-sponsored group prescription drug plan;
- Other details specific to the particular waiver/modification that would assist CMS in the evaluation of the request; and
- Contact information (contract number, name, position, phone, fax and email address) of the person who is available to answer inquiries about the waiver/modification request.

Note: Applicants should review the waivers currently approved by CMS in Chapter 12 of the Medicare Prescription Drug Benefit Manual to assess whether the sponsoring organization is similarly situated to qualify for an existing waiver prior to submitting a request to CMS.

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. Applicant Experience 42 CFR Part 423 Subpart K

A. In HPMS, complete the table below:

Applicant must attest 'yes' or 'NA', to each of the following qualification to be approved for a Part D contract. Attest 'yes', 'no', or 'NA' to each of the following qualifications by clicking on the appropriate response in HPMS:	**Yes**	**No**	**NA**
1. If Applicant, Applicant's parent organization, or any subsidiaries of Applicant's parent organization has an existing contract(s) with CMS to operate a Prescription Drug Plan(s), at least one of those contracts has been in effect since January 1, 2011 or earlier.			

3.2. Service Area 42 CFR §423.112; Prescription Drug Benefit Manual, Chapter 5

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.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 that are provided under the Pharmacy Access section of the application.

3.3. Licensure and Solvency 42 CFR §423.401; 42 CFR §423.410; 2008 Call Letter

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

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

B. In HPMS, complete the table below:

Attest 'yes' or 'no' to the following licensure requirements.	**Yes**	**No**	**Does Not Apply**

1. Applicant is licensed under State law as a risk-bearing entity eligible to offer health insurance or health benefits coverage in each State in which the Applicant proposes to offer Part D drug benefits. • 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 licensed as a risk-bearing entity in at least one State? • 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 Financial Solvency Documentation.			
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 Application to Request Federal Waiver of State Licensure Requirement for Prescription Drug Plan (PDP) for each State 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. • 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.			

3.4. 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.

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 clicking on the appropriate response in HPMS:	**Yes**	**No**	**Requesting Waiver? *Yes or No***
1. Applicant uses a contracted network of pharmacies and therefore meets the retail pharmacy convenient access standards; LTC and I/T/U pharmacy convenient access standards; and home infusion pharmacy adequate access standards. Note: If answer Yes, Applicant must complete all of Section 3.4.			
2. If Applicant attests 'NO' to 3.3A1, Applicant provides coverage for drugs purchased from all pharmacies, regardless of whether they are network pharmacies.			
3. If Applicant attests 'NO' to 3.3A1, Applicant does not charge additional cost-sharing to beneficiaries for obtaining their drugs at a non-network pharmacy.			
4. If Applicant attests 'NO' to 3.3A1, Applicant provides access at non-network pharmacies 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.			
5. If Applicant attests 'NO' to 3.3A1, Applicant does not routinely rely on billing practices that require enrollee to pay the usual and customary price upfront and then submit a paper claim to the applicant for reimbursement.			
6. If Applicant attests 'NO' to 3.3A1, Applicant has 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.			
7. If Applicant attests 'NO' to 3.3A1, Applicant arranges 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).			

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.

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

3.5.1. Retail Pharmacy 42 CFR §423.120(a); 42 CFR §423.859(c); Prescription Drug Benefit Manual, Chapter 5

A. In HPMS, complete the table below. Note: Employer Union/Only Group Waiver Plan Applicants complete questions 1 and 2 only.

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 clicking on the appropriate response in HPMS.	**Yes**	**No**	**Requesting Waiver? *Yes or No***
1. Applicant meets the CMS Standards for Convenient Access [42 CFR §423.120 (a) (1) and (2) no later than the application submission date.			
2. Applicant agrees that when Applicant is offering extended supplies via mail order, it also has contracts 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.			

B. Upload in HPMS the Retail Pharmacy List (not applicable to Employer Union/Only Group Waiver Plan Applicants):

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

C. Submission of Supporting Discussion in Areas Failing to Meet Access Standards (not applicable to Employer Union/Only Group Waiver Plan Applicants)

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

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

1. Indicate the geographic areas in which the applicant cannot demonstrate that it meets the retail pharmacy convenient access standards.
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.

D. In HPMS, indicate whether you are seeking a waiver of the convenient access standards for the territories in which your organization intends to offer the Part D benefit. If your organization is not intending to offer the Part D benefit in the territories check N/A within HPMS. (not applicable to Employer Union/Only Group Waiver Plan Applicants)

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 39 – US Virgin Islands			

E. Complete the following if you marked YES to requesting a waiver of convenient access standards for any of the territories in 3.4.1E. In HPMS, in .pdf format, provide the following information: (not applicable to Employer Union/Only Group Waiver Plan Applicants)

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 42 CFR §423.120(a)(1).

F. In HPMS complete the table below: (not applicable to Employer Union/Only Group Waiver Plan Applicants)

Waiver of Retail Convenient Access Standards for MA-PDs	
Provide the number of prescriptions provided in 2011 by retail pharmacies owned and operated by Applicant	
Provide the number of prescriptions provided in 2011 at all retail pharmacies contracted by Applicant.	

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

G. In HPMS complete the table below: (not applicable to Employer Union/Only Group Waiver Plan Applicants)

Waiver of Any Willing Pharmacy Requirements for MA-PDs	
Provide the number of prescriptions provided in 2011 by all pharmacies owned and operated by Applicant	
Provide the number of prescriptions provided in 2011 at all pharmacies contracted by Applicant.	

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

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

A. In HPMS, complete the table below:

Applicants may offer a mail order option in addition to their contracted Part D pharmacy network but mail order pharmacies do not count in meeting network adequacy standards. Indicate in HPMS 'yes' or 'no' whether such mail order pharmacy is offered.	**Yes**	**No**	**Requesting Waiver? *Yes or No***
1. Applicant offers mail order pharmacy as part of its Part D plan(s).			

2. If Applicant attests 'Yes' to 3.4.3A1, does Applicant's mail order contract include an extended (e.g., 90) day supply?			
3. If Applicant attests 'YES' to 3.4.3A2, then Applicant includes in its contracts with at least some retail pharmacies a provision that allows a retail pharmacy to offer an extended supply of drugs to any Plan beneficiary at the same price, reimbursement rate and cost sharing as the Plan's mail order pharmacy or pharmacies—the network mail order pharmacy rate; or an Applicant may use an alternative retail/mail order pharmacy rate with a higher contracted reimbursement rate provided that any differential in charge between the Network Mail Order Pharmacy rate and the higher contract reimbursement rate would be reflected in higher cost sharing paid by the beneficiary. 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 one-month supply increments at retail pharmacy rates.			

B. Mail Order Pharmacy List

(not applicable to Employer Union/Only Group Waiver Plan Applicants)

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

3.5.3. 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 clicking on the appropriate response in HPMS:	**Yes**	**No**	**Requesting Waiver? *Yes or No***
1. Applicant provides adequate access to home infusion pharmacies.			
2. Applicant's network contracts address Part D drugs			

delivered and administered in the home setting.			
3. Applicant's contracted home infusion pharmacies 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's 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's 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.			
6. Applicant's contracted network pharmacies that deliver home infusion drugs provide home infusion drugs within 24 hours of discharge from an acute setting, unless the next required dose, as prescribed, is required to be administered later than 24 hours after discharge.			

B. Home Infusion Pharmacy List

(not applicable to Employer Union/Only Group Waiver Plan Applicants) To submit home infusion pharmacy listings to CMS, Applicants must download the Microsoft Excel worksheet template from HPMS that is located on the Pharmacy Upload page, complete the worksheet and upload the finished document back into HPMS.

3.5.4. 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 clicking on the appropriate response in HPMS:	**Yes**	**No**	**Requesting Waiver? *Yes or No***
1. Applicant offers 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 50.5.2 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 recognizes 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 ensures 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 provides convenient access to network LTC pharmacies for all of their enrollees who are inpatients in a hospital that is a "medical institution" under section 1902(q)(1)(B) of the Act – and therefore would meet the Part D definition of a LTC facility – and whose Part A benefits have been exhausted.			
6. Applicant contracts with a sufficient number of LTC pharmacies to provide all of the plan's institutionalized enrollees' convenient access to the plan's LTC pharmacies.			
7. Applicant does not rely upon beneficiary SEPs or on out-of-network access in lieu of contracting with a sufficient number of pharmacies to ensure that an enrollee can remain in his/her current plan for as long as he/she reside in a LTC facility in Applicant's service area.			
8. Applicant ensures that LTC pharmacy contracting is ongoing as Applicant continues to identify LTC facilities and LTC pharmacies, and as Applicant examines auto-enrollment assignments and incoming enrollments.			

9. Applicant agrees that the appropriate action to take when a beneficiary is enrolled in its plan and Applicant does not have a contract with an LTC pharmacy that can serve the LTC facility in which that enrollee resides is to sign a contract with the facility's contracted pharmacy, or – if that pharmacy will not sign a contract – with another pharmacy that can serve that facility. Applicant recognizes that, in some cases, a retroactive contract may be necessary to ensure convenient access to LTC pharmacies.			
10. Applicant readily negotiates with States with regard to contracting with State-run and operated LTC pharmacies in facilities such as ICFs/MR, IMDs, and LTC hospitals, and that timely and – in some cases, retroactive – contracting may be necessary to ensure convenient access to LTC facilities for enrollees residing in such LTC facilities.			
11. Applicant utilizes CMS data on beneficiary residence in LTC facilities to facilitate its LTC contracting efforts.			
12. Applicant, in contracting with LTC pharmacies, 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 other network LTC pharmacies whose contracts with the Applicant may not include the same provisions.			

B. LTC Pharmacy List

(not applicable to Employer Union/Only Group Waiver Plan Applicants) To submit LTC pharmacy listings to CMS, Applicants must download the Microsoft Excel worksheet template from HPMS that is located on the Pharmacy Upload page, complete the worksheet and upload the finished document back into HPMS.

3.5.5. 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 clicking on the appropriate response in HPMS to be	**Yes**	**No**	**N/A**	**Requesting Waiver? *Yes or No***

approved for a Part D contract:				
1. Using the list of I/T/U pharmacies provided at the www.cms.gov/PrescriptionDrugCovContra/ indicate whether your service area includes at least one state in which an I/T/U pharmacy resides.				
Not all Part D regions have I/T/U pharmacies. If the Applicant's service area covers <u>any</u> 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 <u>all</u> of the Applicant's service area <u>does not</u> 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 clicking on the appropriate response in HPMS.	**Yes**	**No**	**N/A**	**Requesting Waiver?** ***Yes or No***
2. Applicant offers standard terms and conditions that conform to the model contract addendum provided by CMS to all I/T/U pharmacies in its service area by sending a conforming contract offer to all such pharmacies. The model contract addendum is posted on the www.cms.gov/PrescriptionDrugCovContra/ website. The model contract addendum account for differences in the operations of I/T/U pharmacies and retail pharmacies.				
3. Applicant agrees to submit documentation upon CMS' request to demonstrate offering all I/T/U pharmacies in its service area a conforming contract. Such documentation may be proof of fax or U.S. postage or other carrier's receipt of delivery.				

B. I/T/U Pharmacy List

(not applicable to Employer Union/Only Group Waiver Plan Applicants) In order to demonstrate that a Part D Applicant meets these requirements Applicants must submit, a complete list of all I/T/U pharmacies to which it has offered contracts, CMS provides

the current list of all I/T/U pharmacies, including the official name, address, and provider number (when applicable). The Applicant's list must be submitted using the Microsoft Excel template provided by CMS on the HPMS Pharmacy Upload page, and must include all I/T/U pharmacies residing in any part of its service area.

To submit I/T/U pharmacy listings to CMS, Applicants must download the Microsoft Excel worksheet template from HPMS that is located 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, _____, attest to the following:

Name, Title

1. I have read the contents of the completed application and the information contained herein is true, correct, and complete. If I become aware that any information in this application is not true, correct, or complete, I agree to notify the Centers for Medicare & Medicaid Services (CMS) immediately and in writing.
2. I authorize CMS to verify the information contained herein. I agree to notify CMS in writing of any changes that may jeopardize my ability to meet the qualifications stated in this application prior to such change or within 30 days of the effective date of such change. I understand that such a change may result in termination of the approval.
3. I agree that if my organization meets the minimum qualifications and is Medicare-approved, and my organization enters into a Part D contract with CMS, I will abide by the requirements contained in Section 3.0 of this Application and provide the services outlined in my application.
4. I agree that CMS may inspect any and all information necessary including inspecting of the premises of the Applicant's organization or plan to ensure compliance with stated Federal requirements including specific provisions for which I have attested. I further agree to immediately notify CMS if despite these attestations I become aware of circumstances which preclude full compliance by January 1 of the upcoming contract year 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 Call Letter, relevant to this application that is posted on the CMS website and that it is continually updated. Organizations submitting an application in response to this solicitation acknowledge that they will comply with such guidance should they be approved for a SAE to their existing contract.

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

5. Appendices

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

Only if applying to request a federal waiver of state licensure requirement for Prescription Drug Plan then download, complete and upload into HPMS the following form:

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

I. Complete the table below.

Contract# _____

Identify the corporation seeking waiver of state licensure requirement for PDP plan	
Full Legal Corporate Name:	D.B.A:
Full Address of Corporation: *(Street, City, State, Zip – No Post Office Boxes):*	
Corporation Telephone Number:	Corporation Fax Number:
Provide the corporation's contact information for the person who will act as the main contact	
Name of Individual:	Title:
Address of Individual: *(Street, City, State, Zip – No Post Office Boxes):*	
Direct Telephone Number:	Fax Number:
Email Address:	

II. Request

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

III. Certification

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

Corporate Name: _____

Date: _____

By: _____

Print Name: _____

Title: _____

Witness/Attest: _____

IV. Instructions for completing the cover sheet of licensure waiver application

Section A Contract #_____

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

Section B

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

Section C

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

If you have any questions regarding this form please contact:

Joseph Millstone

410-786-2976

Instructions Follow

(THIS SECTION FOR OFFICIAL USE ONLY)

Supporting Documentation for Request of Federal Waiver of State Licensure Requirement for Prescription Drug Plan (PDP) Sponsors

Complete Sections II and IV

I. Background and Purpose

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

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

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

Waiver requests should be submitted to CMS using the criteria described 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 is required to submit a Medicare contract application that demonstrates that the Applicant meets the Federal definition of a PDP sponsor and that the prescription drug plan being offered meets 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 in your response to section IV. (Information to be included in this request/ the grounds upon which you are requesting a waiver (cover 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).

    a) 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 have been received by a State(s) no later than November 1st of the year prior to submission of the licensure waiver applications to CMS. This will insure that the State had time to confirm "the receipt and completeness of the application" which is necessary to establish that the 90-day period has been met. A state's denial of an application that was not complete does not create grounds for waiver approval.

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:

a) The State failed to complete 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

b) 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.

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.

A. Single-State Waiver:

1. Specify the grounds from section II.A above, upon which you are requesting a waiver. 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.

2. Provide documentation to substantiate the narrative required in (1). Depending on the grounds for waiver eligibility, this documentation should include but is not necessarily limited to the list below:

    a) Evidence of state's failure to act on a licensure application on a timely basis, including a 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.

    b) Evidence of denial of the application based on discriminatory treatment, including:

        (i) Documentation in 2.a above, and,

        (ii) 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 its rationale for the denial, etc.

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

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

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

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

   a) Documentation in 2.a above, and,

   b) 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.

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

   a) Documentation in 2.a above, and,

   b) 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 how those standards differ from those required by Federal law.

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

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

B. Regional Plan Waivers

1. Evidence of licensure in one state within the region and

2. 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.

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

4. 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 pdf format into HPMS on the Part D Financial Solvency Upload Page.

I. DOCUMENTATION

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

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 the time-period to breakeven. Except for the use of guarantees as provided in section (i) below, letters of credit as provided in section (ii) below, and other means as provided in section (iii) 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

1. 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.

2. 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:

        (i) The current ratio declines significantly; or

(ii) 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

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

   a) Generally Accepted Accounting Principles (GAAP) are those accounting principles or practices prescribed or permitted by the Financial Accounting Standards Board.

   b) Statutory Accounting Principles are those accounting principles or practices prescribed or permitted by the domiciliary State insurance department in the State in which the PDP Sponsor operates.

2. 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.

3. Waivered PDP Sponsors should adjust their balance sheets as follows:

   a) Calculation-Assets

   The following asset classes will not be admitted as assets:

   (i) Good will;

   (ii) Acquisition costs;

   (iii) Other similar intangible assets.

   b) Calculation- Liabilities

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

(ii) 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

1. 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:

   a) Jurat Page;

   b) Assets;

   c) Liabilities, Capital and Surplus;

   d) Statement of Revenue and Expenses;

   e) Capital and Surplus Account;

   f) Cash Flow;

   g) 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.

2. Reporting shall be on the following schedule:

   a) 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.

   b) 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.

   c) Financial reporting may be the 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.

   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.

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' approval at least 90 days before the proposed effective date of the modification, substitution, or termination;

2. Demonstrates to CMS' satisfaction that the modification, substitution, or termination will not result in insolvency of the PDP Sponsor; and

3. Demonstrates how the PDP Sponsor will meet the requirements of this section.

G. Nullification.

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

1. Meet the applicable requirements of this section within 15 business days; and

2. If required by CMS, meet a portion of the applicable requirements in less than the time period granted in paragraph (G.1.) of this section.