

## **MEDICARE PRESCRIPTION DRUG BENEFIT**

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

#### **2013 Contract Year**

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Expiration:

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# **1 GENERAL INFORMATION**

## **1.1 Purpose of Solicitation**

The Centers for Medicare & Medicaid Services is seeking applications from qualified entities to enter into contracts to offer Medicare Prescription Drug Plans (PDPs) as described in the Medicare Prescription Drug Benefit Final Rule published in the Federal Register on January 28, 2005 (70 Fed. Reg.4194). Please submit your applications according to the process described in Section 2.0.

If your organization, or your parent or affiliated organization is already under a PDP contract with CMS to offer the Part D benefit, and you are expanding your service area offered under the existing contract please refer to the [www.cms.hhs.gov/](http://www.cms.hhs.gov/) website for the Part D Service Area Expansion application for instructions to complete an application for a Service Area Expansion (SAE). If your organization, or your parent or affiliated organization already has a Medicare Advantage – Prescription Drug (MA-PD) or Cost Plan contract with CMS to offer the Part D benefit, and you are seeking a PDP contract, you are required to complete this PDP application package.

## **1.2 Background**

The Medicare Prescription Drug Benefit program was established by section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), as amended, and is codified in sections 1860D-1 through 1860 D-43 of the Social Security Act (the Act).

## **1.3 Objectives and Structure**

Effective January 1, 2006, MMA established an optional prescription drug benefit, known as the Part D program for individuals who are entitled to Medicare Part A and/or enrolled in Part B.

In general, coverage for the prescription drug benefit is provided predominantly through prescription drug plans (PDPs) that offer drug-only coverage, or through Medicare Advantage (MA) plans that offer integrated prescription drug and health care coverage (MA-PD plans). PDPs must offer a basic drug benefit and may also offer an enhanced or alternative basic drug benefit. MA-PD sponsors must offer either a basic benefit, or broader coverage for no additional cost. If the MA-PD sponsor meets the basic requirement, then it may also offer supplemental benefits through enhanced alternative coverage for an additional premium. Medicare Cost Plans may, at their election, offer a Part D drug plan as an optional supplemental benefit, subject to the same rules that apply to an MA-PD plan. Program of All-Inclusive Care for the Elderly (PACE) organizations may elect to offer a Part D plan in a similar manner as MA-PD local sponsors in order to account for the shift in payor source from the Medicaid capitation rate to a private Part D Sponsors.

Applicants who offer either a PDP or MA-PD plan may offer national plans (with coverage in every region) or regional plans. MA-PD plan applicants may also offer local plans. CMS has identified 26 MA Regions and 34 PDP Regions; in addition, each

territory is its own PDP region. Additional information about the regions can be found on the [www.cms.hhs.gov/](http://www.cms.hhs.gov/) website.

This solicitation is only for entities seeking to operate a PDP (either in the individual market, employer market or a combination of both markets). Separate Part D solicitations are also posted on the CMS website for entities offering MA Plans with a Part D Drug benefit at the local or regional levels, entities offering Cost Plans with a Part D benefit, and for entities offering PACE Plans with a Part D benefit. Reference throughout this solicitation will be made to a Part D Sponsor, which is meant to encompass stand-alone PDPs, MA Plans with a Part D benefit, PACE Plans, and Cost Plans with a Part D benefit.

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

## 1.4 Schedule

<b>APPLICATION REVIEW PROCESS</b>	
<b>Date</b>	<b>Milestone</b>
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.

## 1.5 Summary of Part D Sponsor Role and Responsibilities

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

- Submit a formulary (considered an element of the bid) each year for CMS approval.
- Submit a Part D Sponsor plan bid each year for CMS approval.
- Enroll all eligible Medicare beneficiaries who apply and reside within the Part D Sponsor's approved service area. A sponsor must serve at least one entire region.
- Administer the Part D benefit (consistent with the Part D Sponsor's approved bid), including providing coverage for drugs included in a CMS-approved formulary, administering appropriate deductibles and co-payments, managing the benefit using appropriate pharmacy benefit managerial tools, making discounts for applicable name brand drugs available to eligible enrollees (i.e., non-LIS beneficiaries in the coverage gap) at the point of sale, and operating effective oversight of that benefit.
- Provide access to negotiated prices on covered Part D drugs, with different strengths and doses available for those drugs, including a broad selection of generic drugs.
- Ensure that records are maintained in accordance with CMS rules and regulations and that both records and facilities are available for CMS inspection and audit.

- Disclose the information necessary for CMS to oversee the program and ensure appropriate payments.
- Offer a contracted retail pharmacy network, providing convenient access to retail pharmacies.
- Process claims at the point of sale.
- Operate quality assurance, drug utilization review, and medication therapy management programs.
- Administer coverage determinations (including exceptions), grievances, and an appeals process consistent with CMS requirements.
- Provide customer service to beneficiaries, including enrollment assistance, toll-free telephone customer service help, and education about the Part D benefit.
- Protect the privacy of beneficiaries and beneficiary-specific health information.
- Develop marketing materials and conduct outreach activities consistent with CMS standards.
- Develop and/or maintain systems to support enrollment, provide claims-based data to CMS, accept CMS payment (including subsidies for low-income beneficiaries), track true out-of-pocket costs and gross covered prescription drug costs, coordinate benefits with secondary insurers (or primary insurers when Medicare is secondary) and support e-prescribing.
- Provide necessary data to CMS to support payment (including Prescription Drug Event (PDE) records and data on direct and indirect remuneration), oversight, and quality improvement activities and otherwise cooperate with CMS oversight responsibilities.
- Provide accurate drug pricing and pharmacy network data that will be published on the Medicare Plan Finder tool. Sponsors must submit data based on the format and schedule provided by CMS.

## **1.6 Summary of CMS Role and Responsibilities**

### **1.6.1 Application Approval, Part D Bid Review, and Contracting Processes**

There are three distinct phases to the overall review to determine whether CMS will enter into a contract with an Applicant. The first phase is the application review process. CMS will review all applications submitted on or by February 21, 2012 to determine whether the Applicant meets the qualifications we have established to enter into a Part D contract.

The second phase has two steps – the formulary upload which begins March 23, 2012 and the bid upload which begins May 11, 2012. The formulary review entails determining that the proposed formulary (if one is used) has at least two drugs in every therapeutic category and class (unless special circumstances exist that would allow only one drug); does not substantially discourage enrollment by certain types of Part D eligible individuals; includes adequate coverage of the types of drugs most commonly

needed by Part D enrollees; includes all drugs in certain classes and categories as established by the Secretary, and includes an appropriate transition policy. CMS will contact Applicants if any issues are identified during the review for discussion and resolution. The intent is to provide an opportunity for Applicants to make any necessary corrections prior to the Part D bid submission date which is on the first Monday in June each year. The second step involves the bid review and negotiations with applicants to ensure valuations of the proposed benefits are reasonable and actuarially equivalent.

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

### **1.6.2 Part D Program Oversight**

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

We monitor compliance through the analysis of data we collect from Part D sponsors, CMS contractors, and our own systems. The types of data we collect from sponsors include: certain benefit data, PDE records, direct and indirect remuneration data, cost data, benefit management data, marketing review information, customer satisfaction and complaints data, and information used to determine low-income subsidy (LIS) match rates. We also conduct beneficiary satisfaction surveys and operate a complaints tracking system to monitor and manage complaints brought to our attention that are not satisfactorily resolved through PDP sponsors' grievance processes as well as conduct periodic site visits to verify PDP sponsor compliance with Part D program requirements. We use information from all the specified sources to analyze the appropriateness and value of the benefit delivered, and to evaluate the opportunity for additional value and quality improvement. We publish the results of our monitoring activities on CMS' websites, including performance ratings on the Medicare Plan Finder, and we also post information regarding the issuance of Corrective Action Plans on our website.

If any trends we identify indicate less than satisfactory performance (as described in 42 CFR §423.505(n) ), contract violations, significant departures from the marketed Part D offering, or fraud or other violations of State or Federal laws, appropriate action is taken

consistent with 42 CFR §423.509 and Part 423, Subpart O. We also make referrals if appropriate to the Office of the Inspector General or to Federal and State authorities where violations of laws under the jurisdictions of these agencies are in question.

### **1.6.3 Education and Outreach**

CMS is committed to educating Medicare beneficiaries about the Part D program. CMS plans to continue to educate beneficiary and consumer groups, health care providers, States, and other interested groups about the Part D program. Among the topics discussed with these groups is the identification and reporting of possible fraud and/or abuse. CMS also engages in other activities that publicize or otherwise educate beneficiaries about the program. For example, the Medicare Plan Finder assists beneficiaries in finding a plan to meet their specific needs; refer to the [www.medicare.gov/find-a-plan](http://www.medicare.gov/find-a-plan) website. CMS displays data that allow comparisons of plans' costs, quality and operational performances. As described above, these data may also be used for monitoring purposes.

### **1.6.4 Marketing Guidelines and Review**

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

### **1.6.5 Eligibility for the Low Income Subsidy Program**

Low-income Medicare beneficiaries receive full or partial subsidies of premiums and reductions in cost sharing under the Part D benefit. Certain groups of Medicare beneficiaries are automatically eligible for the low-income subsidy program. These beneficiaries include Medicare beneficiaries who are full-benefit dual eligible individuals (eligible for full benefits under Medicaid), Medicare beneficiaries who are recipients of Supplemental Security Income benefits; and participants in Medicare Savings Programs as Qualified Medicare Beneficiaries (QMBs), Specified Low-Income Medicare Beneficiaries (SLMBs), and Qualifying Individuals (QIs). Beneficiaries who are low-income and who do not fall into one of the automatic subsidy eligibility groups apply for a low-income subsidy and have their eligibility determined by either the state in which they reside or the Social Security Administration (SSA). CMS has developed a database to track individuals who are automatically deemed subsidy-eligible or who are determined subsidy-eligible by states or SSA, and communicates the names and eligibility category of those individuals to Part D sponsors as part of the enrollment files from the enrollment processing system described below. Occasionally, due to time lags, CMS's database does not reflect a low-income subsidy eligible individual true maximum cost sharing amount under the program or an individual's correct low-income subsidy status. Part D Sponsors are required to adhere to CMS's Best Available Evidence policy under 42 CFR §423.800(d), under which an individual can provide acceptable evidence supporting a revised cost-sharing amount that the sponsor must accept for the purpose of administering the benefit. For additional information regarding the low income subsidy program, refer to the [www.cms.gov/](http://www.cms.gov/) website.

### **1.6.6 General Enrollment Processing**

CMS has a system to receive and process enrollment, disenrollment and membership information provided by Part D sponsors. CMS tracks enrollments and ensures that the beneficiary does not enroll in more than one Part D plan. Also, CMS tracks low-income subsidy status and auto-enrollments of full-benefit dual eligible individuals into Part D plans and facilitated enrollments for other low-income Medicare beneficiaries. Finally, CMS tracks disenrollments from Part D plans and will deny new enrollments during any given year unless the enrollment occurs during an allowable enrollment period. For additional information regarding enrollment processing, refer to the [www.cms.gov/](http://www.cms.gov/) website.

### **1.6.7 Payment to Part D Sponsors**

CMS provides payment to Part D sponsors in the form of advance monthly payments (consisting of the Part D Sponsor plan's standardized bid, risk adjusted for health status, minus the beneficiary monthly premium), estimated reinsurance subsidies, estimated low-income subsidies (low-income cost sharing and premiums), and estimated gap discount payments. After the end of the payment year, CMS reconciles the actual amounts of low-income cost sharing subsidies, reinsurance amounts, and gap discount amounts reported on PDE records against the amount paid as a part of the prospective monthly payments. Risk sharing amounts (if applicable) are determined after all other reconciliations have been completed. For a more complete description refer to CMS' prescription drug event reporting instructions that are posted at [www.csscooperations.com](http://www.csscooperations.com) and on the [www.cms.gov](http://www.cms.gov) website.

## 2 INSTRUCTIONS

### 2.1 Overview

There are six types of entities with which CMS contracts to offer the Medicare prescription drug benefit: PDP sponsors, Medicare Advantage organizations that offer MA-PDs (including local HMO plans, local, PPOs, regional PPOs, and Private Fee-for-Service plans); organizations with Cost Plans under section 1876 of the Social Security Act, Employer Groups, and PACE organizations. This application is to be completed only by entities seeking to offer new PDPs during 2013 in either the individual and/or employer markets.

### 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/](http://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 organizations that submit a Notice of Intent to Apply form are assigned a pending contract number (S number) to use throughout the application and subsequent operational processes. Once the contract number is assigned, and Part D Applicants apply for, and receive, their CMS User ID(s) and password(s) for HPMS access, they are required to input contact and other related information into the HPMS (see section 3.1.5). 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 status 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 its 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](mailto: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.

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 Seeking to Offer New Employer/Union-Only Group Waiver Plans (EGWPs)**

All new PDP Sponsor Applicants seeking to offer new “800 series” EGWPs – with or without corresponding individual plans, including applicants that have not previously applied to offer plans to individual beneficiaries or “800 series” EGWPs must complete the appropriate EGWP attestation provided in Appendix I. The Appendix provides the Applicant with the ability to choose between only offering “800 series” plans and participating in both the individual and group markets. The attestation provided in Appendix I specifies those individual market requirements that are not applicable in the employer market.

### **2.4.2.1 PDP EGWP Service Area**

New PDP Sponsor Applicants and existing PDP Sponsors will be able to enter their EGWP service areas directly into HPMS during the application process (refer to HPMS User Guide). PDP Sponsor Applicants may provide coverage to employer group members wherever they reside (i.e., nationwide). However, in order to provide coverage to retirees wherever they reside, PDP Applicants must set their service area to include all areas where retirees reside during the plan year (i.e., set national service areas).

### **2.4.2.2 New PDP Sponsors Offering Individual and “800 Series” Plans – Pharmacy Access**

PDP Sponsors offering both individual and “800 series” plans are not required to submit separate pharmacy access lists (retail, mail order, home infusion, long-term care, I/T/U) for their “800 series” service areas in addition to those required to be submitted for their individual plan service areas. PDP sponsors will not initially be required to have retail and other pharmacy networks in place for those designated EGWP service areas outside of their individual plan service areas. However, in accordance with employer group waiver pharmacy access policy, pharmacy access sufficient to meet the needs of enrollees must be in place once the PDP Sponsor enrolls members of an employer or union group residing in particular geographic locations outside of its individual plan service area.

### **2.4.2.3 New PDP Sponsors Only Offering “800 Series” Plans – Pharmacy Access**

PDP sponsors that intend to only offer “800 series” plans (i.e., no plans will be offered to individual Medicare beneficiaries under this contract number) will be required to submit retail and other pharmacy access information (mail order, home infusion, long-term care, I/T/U) for the entire defined EGWP service area during the application process and demonstrate sufficient access in these areas in accordance with employer group waiver pharmacy access policy.

### **2.4.3 Applicant Seeking to Offer New Employer/Union Direct Contract PDPs**

New Direct Contract PDP Applicants will be able to enter their service area directly into HPMS during the application process.

In general, Part D sponsors can only cover beneficiaries in the service areas in which they are licensed and approved by CMS to offer benefits. CMS has waived these requirements for Direct Contract PDP Sponsors. Direct Contract PDP Sponsors can extend coverage to all of their retirees, regardless of whether they reside in one or more PDP regions in the nation. In order to provide coverage to retirees wherever they reside, Direct Contract PDP Applicants must set their service areas to include all areas where retirees may reside during the plan year.

Direct Contract PDP applicants are required to submit retail and other pharmacy access information for the entire defined service area during the application process and demonstrate sufficient access in these areas in accordance with employer group waiver pharmacy access policy.

Those employers or unions seeking to directly contract with CMS to become PDP Sponsors for their Medicare-eligible retirees must complete the following materials:

- The 2013 Solicitation for Applications for New Prescription Drug Plan Sponsors
- Appendix III-- 2013 Part D Financial Solvency & Capital Adequacy Documentation for Direct Contract PDP Sponsor Applicants
- Appendix II—2013 Direct Contract PDP Attestation

### **2.4.4 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.

### **2.4.5 Joint Enterprise as Applicant and Contracting Entity**

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

The joint enterprise need submit only one application on behalf of the enterprise's member organizations and such application shall represent the joint enterprise's commitment to offering a uniform benefit in each PDP region in which it will offer Part D benefits. However, the information requested in Section 3.1 of this solicitation must be provided for each member of the joint enterprise with separate accompanying Appendices as necessary. For example, each joint enterprise member must provide

identifying information about its organization, copies of its executed contracts with entities performing critical tasks related to the delivery of the Part D benefit, and information related to its business integrity. The responses provided in the remainder of the application may be made once by the joint enterprise applicant and will be considered binding on each member of the joint enterprise. Also, a separate certification statement, shown in Section 4.0, must be provided for each joint enterprise member organization. Each certification statement must be signed by an individual specifically granted the authority to bind the member organization.

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

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

#### **2.4.6 Automatic Enrollment of Full-benefit Dual Eligible Individuals**

As provided for in 42 CFR §423.34(d), individuals who are dually eligible for Medicare and full Medicaid benefits, and who fail to enroll in a Part D plan, will be enrolled automatically in a plan with a beneficiary premium that does not exceed the low-income premium subsidy amount or has waived the *de minimis* amount above the low-income benchmark premium amount. If there is more than one PDP with a premium that meets this description, CMS will enroll the beneficiaries in those PDPs, on a random basis.

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

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

#### **2.4.7 Withdrawal of a Part D Application**

In those instances where an organization seeks to withdraw its application or reduce the service area of a pending application prior to the execution of a Part D 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](mailto: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 date of the email.

## **2.4.8 Technical Assistance**

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

Linda Anders by email at [linda.anders@cms.hhs.gov](mailto: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 11, 2012 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 System Access and Data Transmissions with CMS**

### **2.6.1 HPMS**

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

## **2.6.2 Enrollment and Payment**

All Part D sponsors must submit information about their membership to CMS electronically and have the capability to download files or receive electronic information directly. Prior to the approval of your contract, Part D sponsors must contact the MAPD Help Desk at 1-800-927-8069 for specific guidance on establishing connectivity and the electronic submission of files. Instructions are also on the MAPD Help Desk web page, [www.cms.gov/mapdhelpdesk](http://www.cms.gov/mapdhelpdesk), in the Plan Reference Guide for CMS Part C/D systems link. The MAPD Help Desk is the primary contact for all issues related to the physical submission of transaction files to CMS.

Daily CMS provides responses to Sponsor submitted information and reports to each Part D sponsor for each of their plans with member and plan-level information. Part D sponsors must compare the membership and payment information in those reports on an ongoing basis with their records and report any discrepancies to CMS according to the instructions and within the timeframes provided by CMS for that purpose. Each Part D Sponsor must complete and submit the monthly CEO certification of enrollment data for payment on or before the due date each month. The due date is provided in the Plan Monthly MARx Calendar, which is updated annually. Definitive information about the format and submission of files, as well as the MARx calendar, can be found in the Plan Communications User's Guide (available at [http://www.cms.gov/MAPDHelpDesk/02\\_Plan\\_Communications\\_User\\_Guide.asp#TopOfPage](http://www.cms.gov/MAPDHelpDesk/02_Plan_Communications_User_Guide.asp#TopOfPage)). The MAPD Help Desk also provides additional system and technical information at [www.cms.gov/mapdhelpdesk/](http://www.cms.gov/mapdhelpdesk/).

## **2.6.3 Payment – Part D Sponsors**

Payments will be wired to sponsor accounts on the first day of each month (or the last business day of the prior month if the first day of the month is not a business day). CMS must receive current banking information at a minimum of 6 weeks prior to the first payment to your organization. The specific banking information form and instructions may be obtained from the CMS Central Office contacts listed in Appendix B of the Plan Communication User's Guide found at [www.cms.gov/MAPDHelpDesk](http://www.cms.gov/MAPDHelpDesk).

The monthly payment includes premiums that SSA or other agencies are deducting from beneficiary Social Security payments or other payments as well as those premiums CMS is paying on behalf of low-income individuals. Estimated monthly reinsurance subsidies, low-income subsidies, and estimated gap discount amounts are also included.

## **2.7 Summary Instruction and Format for Individual Market Bids**

Each Part D Applicant must submit to CMS a bid for each prescription drug plan it intends to offer. Applicants using this solicitation may apply to offer full or limited risk plans. CMS reviews bids for limited risk plans only in those regions where there are not at least two prescription drug plans, one of them being a PDP plan. Note, that only PDP sponsor Applicants and not MA organizations may submit a bid to be limited risk. Furthermore, in the event a PDP region does not have two prescription drug plans, CMS will approve at a maximum two partial risk plans. (Please note that Applicants that

indicate in their applications that they intend to offer limited risk plans are not precluded from later submitting full risk bids, but a PDP sponsor Applicant that does submit a limited risk bid must apply the same limitation of risk to all PDPs offered by the sponsor in the PDP region). Where there are not at least two plans offering qualified prescription drug coverage, one of them being a PDP plan, CMS will contract with entities to offer fallback plans. Applicants must submit their formularies to HPMS on or before April 16, 2012 and the PBPs and BPTs on or before the bid submission date.

## **2.7.1 Format of Bids**

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

To facilitate the timely review of all the bid submissions, CMS requires Applicants to submit the portion of their bid related to formulary and covered drugs from March 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.

### **2.7.2 CMS Review of Bids**

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

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

### **2.7.3 Overview of Bid Negotiation**

CMS evaluates the reasonableness of bids submitted by Part D sponsors by means of an actuarial valuation analysis. This requires evaluating assumptions regarding the expected distribution of costs, including average utilization and cost by drug coverage tier. CMS 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.

## **2.8 Pharmacy Access**

An integral component of this Solicitation concerns the pharmacy access standards established under section 1860D-4(b)(1)(C) of the Social Security Act. The standards require in part that each Part D sponsor must secure the participation in their pharmacy networks of a sufficient number of pharmacies to dispense drugs directly to patients (other than by mail order) to ensure convenient access to covered Part D drugs by Part

D plan enrollees. To implement this requirement, specific 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.

### **2.8.1 Retail Pharmacy Access**

Applicants must ensure that their retail pharmacy network meets the criteria established under 42 CFR §423.120. Applicants must ensure the pharmacy network has a sufficient number of pharmacies that dispense drugs directly to patients (other than by mail order) to ensure convenient access to Part D drugs. CMS rules require 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 3.3, and as explained in section 3.4.1B Applicants must upload the retail pharmacy list in HPMS. Based on the pending service area documented in HPMS, 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 pending service area (to account for applicants who contract for a national pharmacy network); however, CMS will only evaluate retail pharmacy access for the pending service area.

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.

### **2.8.2 Home Infusion Pharmacy Access**

Applicants must demonstrate that their contracted pharmacy network provides adequate access to home infusion pharmacies. In order to demonstrate adequate access to home infusion pharmacies, Applicants must provide a list of all contracted home infusion pharmacies (see section 3.4.4). CMS uses this pharmacy listing to 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.

### **2.8.3 Long-Term Care Pharmacy Access**

Applicants must demonstrate that their contracted pharmacy network provides convenient access to long-term care pharmacies. In order to demonstrate convenient access to long-term care pharmacies, Applicants must provide a list of all contracted long-term care pharmacies (see section 3.4.5). CMS uses this pharmacy listing, 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.

### **2.8.4 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 3.4.6). 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/](http://www.cms.gov/PrescriptionDrugCovContra/) website.

### **2.8.5 Waivers Related to Pharmacy Access**

*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 3.4.1E of this solicitation.

## **2.9 Waivers Related to Attestations for PDP EGWP and PDP 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.

## **2.10 Standard Contract with PDP Sponsors**

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

## **2.11 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.

### 3 APPLICATION

Note: Nothing in this application is intended to supersede the regulations at 42 CFR Part 423. Failure to reference a regulatory requirement in this application does not affect the applicability of such requirement, and PDP sponsors and/or Applicants are required to comply with all applicable requirements of the regulations in Part 423 of 42 CFR. In particular, the attestations in this application are intended to highlight examples of key requirements across a variety of functional and operational areas, but are in no way intended to reflect a complete or thorough description of all Part D requirements.

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

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, Contracts, Licensure and Financial Stability

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

##### 3.1.1 Management and Operations 42 CFR Part 423 Subpart K; CMS issued guidance 08/15/06 and 08/26/08

A. In HPMS, complete the table below:

Applicant must attest ‘yes’ or, if permitted, “NA”, 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	NA
1. Applicant is a non-governmental legal entity that intends to enter into a Medicare Prescription Drug Plan contract with CMS.			
2. Applicant does not have any other related entities offering a Prescription Drug Plan.			

3. 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.			
4. Applicant abides by all applicable Federal laws, regulations and CMS instructions.			
5. Applicant has administrative and management arrangements that feature a policy-making body (e.g., board of directors) exercising oversight and control over the PDP sponsor's policies and personnel (e.g., human resources) to ensure that management actions are in the best interest of the organization and its enrollees.			
6. Applicant has administrative and management arrangements that feature personnel and systems sufficient for the Part D sponsor to organize, implement, control and evaluate financial and marketing activities, the furnishing of prescription drug services, the quality assurance, medication therapy management, and drug and drug utilization management programs, and the administrative aspects of the organization.			
7. Applicant has administrative and management arrangements that feature an executive manager whose appointment and removal are under the control of the policy-making body.			
8. Applicant has administrative and management arrangements that feature a fidelity bond or bonds, procured by the Applicant, in an amount fixed by its policymaking body, but not less than \$100,000 per individual, covering each officer and employee entrusted with the handling of its funds.			
9. Applicant has administrative and management arrangements that feature insurance policies secured and maintained by the Applicant, and approved by CMS to insure the Applicant against losses arising from professional liability claims, fire, theft, fraud, embezzlement, and other casualty risks.			
10. Applicant maintains contracts or other legal arrangements between or among the entities combined to meet the functions identified in subsection 3.1.1C.			

<p>11. Applicant does not have any covered persons who also served as covered persons for an entity that nonrenewed a contract pursuant to 42 CFR §423.507(a), or that terminated its contract with CMS by mutual consent, pursuant to 42 CFR §423.508, or unilaterally, pursuant to 42 CFR §423.510, since June 6, 2011. “Covered persons”, as defined at 42 CFR §§ 423.507(a)(4), 423.508(f), 423.510(e)(2), include:</p> <ul style="list-style-type: none"> <li>• All owners of nonrenewed or terminated organizations who are natural persons, other than shareholders who have an ownership interest of less than 5 percent;</li> <li>• An owner of a whole or part interest in a mortgage, deed of trust, note, or other obligation secured (in whole or in part) by the organization, or by any property or assets thereof, which whole or part interest is equal to or exceeds 5 percent of the total property and assets of the organization; and</li> <li>• A member of the board of directors or board of trustees of the entity, if the organization is organized as a corporation.</li> </ul>			
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**B. Upload in HPMS, organizational background and structure information.**  
**Submit this information by downloading the appropriate template found in HPMS that mimics the Appendix entitled, *Organization Background and Structure*. Also upload into HPMS proof of your organization’s incorporation, such as articles of incorporation or a certificate of good standing from your state of incorporation.**

**C. First tier, Downstream and Related entities Function Chart**

In HPMS, on the Contract & Management/Part D Information/Part D Data Page, provide names of the first tier, downstream and related entities you will use to carry out	Function	<u>First tier, Downstream and Related entities</u>	<u>Off-Shore yes/no</u>
	A pharmacy benefit program that performs adjudication and processing of pharmacy claims at the point of sale.		

<p>each of the functions listed in this chart and whether the first tier, downstream and related entities are off-shore:</p> <p>(Indicate with “name of Applicant’s Organization” where applicant will perform those functions)</p>	<p>A pharmacy benefit program that performs negotiation with prescription drug manufacturers and others for rebates, discounts, or other price concessions on prescription drugs.</p>		
	<p>A pharmacy benefit program that performs administration and tracking of enrollees’ drug benefits in real time, including TrOOP balance processing.</p>		
	<p>A pharmacy benefit program that performs coordination with other drug benefit programs, including, for example, Medicaid, state pharmaceutical assistance programs, or other insurance.</p>		
	<p>A pharmacy benefit program that develops and maintains a pharmacy network.</p>		
	<p>A pharmacy benefit program that operates an enrollee grievance and appeals process</p>		
	<p>A pharmacy benefit program that performs customer service functionality, that includes serving seniors and persons with a disability.</p>		



	A pharmacy benefit program that performs pharmacy technical assistance service functionality.		
	A pharmacy benefit program that maintains a pharmaceutical and therapeutic committee.		
	A pharmacy benefit program that performs enrollment processing.		

**D. In HPMS, upload copies of executed contracts, fully executed letters of agreement, administrative services agreements, or intercompany agreements (in .pdf format) with each first tier, downstream or related entity identified in Sections 3.1.1 C and with any first tier, downstream, or related entity that contracts with any of the identified entities on the applicant's behalf. All contracts must:**

1. Clearly identify the parties to the contract (or letter of agreement). If the applicant is not a direct party to the contract (e.g., if one of the contracting entities is entering into the contract on the applicant's behalf), the applicant must be identified as an entity that will benefit from the services described in the contract.
2. Describe the functions to be performed by the first tier, downstream or related entity, and the reporting requirements the first tier, downstream, or related entity has to the Applicant. 42 CFR §423.505(i)(4)(i)
3. Contain language clearly indicating that the first tier, downstream, or related entity has agreed to participate in your Medicare Prescription Drug Benefit program (except for a network pharmacy if the existing contract would allow participation in this program).
4. Contain flow-down clauses requiring that their activities be consistent and comply with the Applicant's contractual obligations as a Part D sponsor. 42 CFR §423.505(i)(3)(iii)
5. Describe the payment the first tier, downstream, or related entity will receive for performance under the contract, if applicable.
6. Clearly indicate that the contract is for a term of at least the initial one-year contract period (i.e., January 1 through December 31) for which this application is being submitted. Where the contract is for services or products to be used in preparation for the next contract year's Part D operations (e.g., marketing, enrollment), the initial term of such contract must include this period of performance (e.g., contracts for enrollment-related services must have a term beginning no later than October 15 extending through the full contract year ending on December 31 of the next year).

7. Be signed by a representative of each party with legal authority to bind the entity.
8. Contain language obligating the first tier, downstream, or related entity to abide by all applicable Federal laws and regulations and CMS instructions. 42 CFR §423.505(i)(4)(iv)
9. Contain language obligating the first tier, downstream, or related entity to abide by State and Federal privacy and security requirements, including the confidentiality and security provisions stated in the regulations for this program at 42 CFR §423.136.
10. Contain language ensuring that the first tier, downstream, or related entity will make its books and other records available in accordance with 42 CFR §423.505(e)(2) and 42 CFR §423.505(i)(2). Generally stated these regulations give HHS, the Comptroller General, or their designees the right to audit, evaluate and inspect any books, contracts, records, including medical records and documentation involving transactions related to CMS' contract with the Part D sponsor and that these rights continue for a period of 10 years from the final date of the contract period or the date of audit completion, whichever is later. 42 CFR §423.505(e)(2) and (i)(2)
11. Contain language that the first tier, downstream, or related entity will ensure that beneficiaries are not held liable for fees that are the responsibility of the Part D sponsor. 42 CFR §423.505(i)(3)(i)
12. Contain language that if the Applicant, upon becoming a Part D sponsor, delegates an activity or responsibility to the first tier, downstream, or related entity, that such activity or responsibility may be revoked if CMS or the Part D sponsor determines the first tier, downstream, or related entity has not performed satisfactorily. Note: The contract/administrative services agreement may include remedies in lieu of revocation to address this requirement. 42 CFR § 423.505(i)(4)(ii)
13. Contain language specifying that the Applicant, upon becoming a Part D sponsor, will monitor the performance of the first tier, downstream, or related entity on an ongoing basis. 42 CFR §423.505(i)(4)(iii)
14. If the first tier, downstream, or related entity will establish the pharmacy network or select pharmacies to be included in the network contain language that the Part D sponsor retains the right to approve, suspend, or terminate any arrangement with a pharmacy. 42 CFR §423.505(i)(5)
15. If the first tier, downstream, or related entity will establish the pharmacy network or select pharmacies to be included in the network contain language that payment to such pharmacies (excluding long-term care and mail order) shall be issued, mailed, or otherwise transmitted with respect to all clean claims submitted by or on behalf of pharmacies within 14 days for electronic claims and within 30 days for claims submitted otherwise. 42 CFR §§423.505(i)(3)(vi) and 423.520
16. If the first tier, downstream, or related entity will establish the pharmacy network or select pharmacies to be included in the network contain language that if a prescription drug pricing standard is used for reimbursement, identify the source used by the Part D sponsor for the standard of reimbursement. 42 CFR §§423.505(b)(21) and 423.505(i)(3)(viii)(B)

17. If the first tier, downstream, or related entity will establish the pharmacy network or select pharmacies to be included in the network and a prescription drug pricing standard is used for reimbursement, contain a provision that updates to such a prescription drug pricing standard occur not less frequently than once every 7 days beginning with an initial update on January 1 of each year, to accurately reflect the market price of acquiring the drug. 42 CFR §423.505(b)(21) and (i)(3)(viii)(A)
18. If the first tier, downstream, or related entity will establish the pharmacy network or select pharmacies to be included in the network contain language requiring the network pharmacies to submit claims to the Part D sponsor or first tier, downstream or related entity whenever the membership ID card is presented or on file at the pharmacy unless the enrollee expressly requests that a particular claim not be submitted. 42 CFR § 423.120(c)(3)
19. If the first tier, downstream, or related entity will adjudicate and process claims at the point of sale and/or negotiate with prescription drug manufacturers and others for rebates, discounts, or other price concessions on prescription drugs contain language that the first tier, downstream, or related entity will comply with the reporting requirements established in Section 6005 of the Affordable Care Act.

Each complete contract must meet all of the above requirements when read on its own.

**E. Upload in HPMS electronic lists of the contract/administrative service agreement/intercompany agreement citations demonstrating that the requirements of Section 3.1.D are included in each contract and administrative service agreement. Submit these data by downloading the appropriate spreadsheet found in HPMS that mimics the Appendix entitled, *Crosswalk of Citations of Section 3.1.1D to location in contracts/administrative service agreements/intercompany agreements submitted as attachments to Section 3.1.1*. If the Applicant fails to upload crosswalks for executed agreements and contract templates, CMS cannot guarantee that the Applicant will receive notice of any deficiencies in the contracting documents as part of this courtesy review.**

**F. In HPMS, complete the table below:**

Attest 'yes' or 'no' to the following qualification by clicking on the appropriate response in HPMS:	Yes	No
1. Applicant is applying to operate as a Part D sponsor through a joint enterprise agreement.		

**G. Special Requirement for Joint Enterprise Applicants: If Applicant answered 3.1.1F1 (table above) as YES, then Joint Enterprise Applicants must upload (in .pdf format) a copy of the agreement executed by the State-licensed entities describing their rights and responsibilities to each other and to CMS in the operation of a Medicare Part D benefit plan. Such an agreement must address at least the following issues:**

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

### **3.1.2 Licensure and Solvency 42 CFR Part 423, Subpart I; 2008 Call Letter; CMS issued guidance 03/17/09**

**A.** In HPMS, on the Contract Management/General Information/NAIC Data Page, provide the National Association of Insurance Commissioners (NAIC) number if currently licensed. \_\_\_\_\_

**B.** In HPMS, complete the table below:

<b>Attest 'Yes,' 'No,' or "Does Not Apply" to the following licensure requirements.</b>	<b>Yes</b>	<b>No</b>	<b>Does Not Apply</b>
<p>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.</p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• If the answer to this attestation is "NO" see Attestation #2.</li> </ul>			
<p>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?</p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• If the answer to this attestation is "NO," the Applicant must submit via HPMS the Appendix entitled Financial Solvency Documentation.</li> </ul>			
<p>3. Applicant maintains a fiscally sound operation by at least maintaining a positive net worth, as required by 42 CFR §423.505(b)(23).</p>			
<p>4. If the Applicant does not meet Requirement #1, then, as part of this application, the Applicant has completed</p>			

and provided 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.			
5. If Applicant is seeking a waiver of the licensure requirement, the Applicant meets the CMS-published financial solvency and capital adequacy requirements.			
6. Applicant is currently under supervision, corrective action plan or special monitoring by the State licensing authority in any State. <ul style="list-style-type: none"> <li>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.</li> </ul>			

### 3.1.3 Program Integrity 2 CFR § 376 and Compliance Program 42 CFR § 423.504(b)(4)(vi); Prescription Drug Benefit Manual, Chapter 9

**A. In HPMS, complete the table below:**

<b>Applicant must attest ‘yes’ or ‘no’ to each of the following qualifications to be approved for a Part D contract. Attest ‘yes’ or ‘no’ to each of the following qualifications by clicking on the appropriate response in HPMS:</b>	<b>Yes</b>	<b>No</b>
1. Applicant, applicant staff, and its affiliated companies, subsidiaries or first tier, downstream and related entities, and staff of the first tier, downstream and related entities agree that they are bound by 2 CFR Part 376 and attest that they are not excluded by the Department of Health and Human Services Office of the Inspector General or by the General Services Administration exclusion lists. Please note that this includes any member of its board of directors, and any key management or executive staff or any major stockholder. Additionally, given Medicare payment may not be made for items or services furnished by an excluded provider or entity, applicant should follow the guidance provided in the January 13, 2010 HPMS memo entitled Claims for Drugs Prescribed or Dispensed by Excluded Providers.		

**B. Provide as an upload via HPMS, in a .pdf format, a copy of your organization’s Medicare Part D Compliance Program that you intend to use for this contract.**

The Part D compliance program must be in accordance with 42 CFR 423.504(b)(4)(vi). The compliance program must explicitly include the name of the applicant. (The name of a parent organization is insufficient.) The Part D compliance program must include all 7 elements in the regulation and in Chapter 9 and are specific to the issues and challenges presented by the Part D program. The compliance plan must explicitly state that it encompasses Medicare Part D. A general compliance program applicable to healthcare operations is not acceptable.

Please be advised that the Applicant is ultimately responsible for the implementation and monitoring of the day-to-day operations of its Part D compliance program. 42 CFR § 423.504(b)(vi)(B)(1) and section 40.1 of Chapter 9 of the Prescription Drug Benefit Manual indicates that the compliance officer and compliance committee functions may not be delegated or subcontracted. This means that the Medicare Compliance Officer identified in HPMS contacts (see section entitled HPMS Part D Contacts) must be an employee of the Applicant, the Applicant's parent organization, or a corporate affiliate of the Applicant. A compliance program adopted and operated by an Applicant's first tier, downstream, and related entities is not sufficient to demonstrate that the Applicant meets the compliance program requirement.

**C. In HPMS, complete and upload the table in Appendix XV for the Compliance Plan.**

**3.1.4 HPMS Part D Contacts CMS Guidance issued 08/16/06, 08/22/07, 11/30/07, 08/06/07, 03/17/09, 07/09/09, 08/04/09, and 01/25/10**

**A. In HPMS, in the Contract Management/Contact Information/Contact Data page provide the name/title; mailing address; phone number; fax number; and email address for the following required Applicant contacts:**

**Note:** The same individual should not be identified for each of these contacts. If a general phone number is given then CMS requires specific extensions for the individual identified. Under no circumstances should these numbers merely lead to a company's general automated phone response system. Further, Applicants must provide specific email addresses for the individuals named.

**Note:** Contact definitions are provided in HPMS in the Contract Management/Contact Information/Contact Data/Documentation link entitled Contact Definitions.

Contact	Name/Title	Mailing Address (PO Boxes may not be used)	Phone/Fax Numbers	Email Address
Corporate Mailing				
CEO – Sr. Official for Contracting				
Chief Financial Officer				

Medicare Compliance Officer				
Enrollment Contact				
Medicare Coordinator				
System Contact				
Customer Service Operations Contact				
General Contact				
User Access Contact				
Backup User Access Contact				
Marketing Contact				
Medical Director				
Bid Primary Contact				
Payment Contact				
Part D Claims Submission Contact				
Formulary Contact				
Pharmacy Network Management Contact				
Medication Therapy Management Contact				
Part D Benefits Contact				
Part D Quality Assurance Contact				
Part D Application Contact				
Pharmacy Director				

HIPAA Security Officer				
HIPAA Privacy Officer				
Part D Price File Contact (Primary)				
Part D Price File Contact (Back-up)				
Part D Appeals				
Government Relations Contact				
Emergency Part D Contact				
Pharmacy Technical Help Desk Contact				
Processor Contact				
CMS Casework Communication Contact				
Part D Exceptions Contact				
Coordination of Benefits Contact				
CEO – CMS Administrator Contact				
Plan to Plan Reconciliation Contact				
Bid Audit Contact				
Plan Directory Contact for Public Website				
CAP Report Contact for Public Website				
Financial Reporting				



Contact				
Best Available Evidence Contact				
Automated TrOOP Balance Transfer Contact				
Agent/Broker Compensation Data Contact				
Complaint Tracking Module (CTM) Contact				
Part D Reporting Requirement Contact				
Fraud Investigations Contact				
Reconciliation Contact				
DIR Contact				

**B. In HPMS, complete the table below:**

<b>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:</b>	<b>Yes</b>	<b>No</b>
1. Applicant agrees that CMS may release contact information to States, SPAPs, providers, Part D sponsors, and others who need the contact information for legitimate purposes.		

## **3.2 Benefit Design**

### **3.2.1 Formulary/Pharmacy and Therapeutics (P&T) Committee Affordable Care Act, §3307, 42 CFR §423.120(b), 42 CFR §423.272(b)(2); Prescription Drug Benefit Manual, Chapter 6; CMS issued guidance 03/25/10**

**A. In HPMS, complete the table below:**

<b>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:</b>	<b>Yes</b>	<b>No</b>
1. Applicant will submit a formulary to CMS for the Part D benefit by the date listed in section 1.4.		
2. Applicant will link all associated contracts to an initial formulary submission on or before the formulary submission deadline; otherwise, Applicant will be considered to have missed the formulary submission deadline.		
3. Applicant complies with formulary guidance that is contained in Chapter 6 of the Prescription Drug Benefit Manual, the HPMS Formulary Submission Module and Reports Technical Manual, and all other formulary instructions.		
4. Applicant agrees, when using a formulary, to meet all formulary submission deadlines established by CMS. Applicant further agrees that CMS may discontinue its review of the Applicant’s formulary submission upon the Applicant’s failure to meet any of the formulary submission deadlines. Applicant acknowledges that failure to receive CMS approval of its formulary may prevent CMS from approving the Applicant’s bid(s) and contracting with the Applicant for the following benefit year.		
5. Applicant agrees that its formulary includes substantially all drugs in the protected classes that are specified as of the CMS-established formulary submission deadline. Applicant further agrees that any new drugs or newly approved uses for drugs within the protected classes that come onto the market after a CMS-established formulary submission deadline will be subject to an expedited P&T committee review. The expedited review process requires P&T committees to make a decision within 90 days, rather than the normal 180-day requirement.		
6. Applicant provides for an appropriate transition for new enrollees into Part D plans following the annual coordinated election period, newly eligible Medicare enrollees from other coverage, individuals who switch from one plan to another after the start of the contract year, and current enrollees remaining in the plan affected by formulary changes prescribed Part D drugs that are not on its formulary. This transition process satisfies the requirements specified in Chapter 6 of the Prescription Drug Benefit Manual.		

7. Applicant attests that its organization's approach to transitioning beneficiaries on drug regimens that are not on the plan's Part D approved formulary meets CMS criteria. The transition policy attestation will be completed in HPMS by close of business on the CMS-established formulary submission deadline in section 1.4.		
8. Applicant agrees to submit its organization's transition policy and a description of how the transition policy will be implemented within the applicant's claims adjudication system, including pharmacy notification via email to PartDtransition@cms.hhs.gov by close of business on the CMS-established formulary submission deadline in section 1.4.		
9. Applicant extends, where appropriate, transition periods beyond 30 days for enrollees using non-formulary drugs that have not been transitioned to a formulary drug or gone through the plan exception process within 30 days.		
10. Applicant ensures that staff is trained and information systems are in place to accommodate administration of the transition policy. This includes adoption of necessary information system overrides.		
11. Applicant provides an emergency supply of non-formulary Part D drugs (31-day supplies, unless the prescription is written for fewer days) for long-term care residents to allow the plan and/or the enrollee time for the completion of an exception request to maintain coverage of an existing drug based on reasons of medical necessity.		
12. Applicant has appropriate timeframes and "first fill" procedures for non-formulary Part D medications in long-term care and retail settings.		
13. Applicant abides by CMS guidance related to vaccine administration reimbursement under Part D.		

**B. In HPMS, complete the table below:**

<b>If Applicant is intending for its Part D benefit to include the use of a formulary, then Applicant must also provide a P&amp;T committee member list either directly or through its pharmacy benefit manager (PBM). Applicant must attest 'yes' or 'no' that it is using its PBM's P&amp;T committee, in order to be approved for</b>	<b>Yes</b>	<b>No</b>
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a Part D contract. Attest 'yes' or 'no' by clicking the appropriate response in HPMS:		
1. Applicant is using the P&T Committee of its PBM for purposes of the Part D benefit.		
2. If answered yes to B1, Applicant's PBM is operating under a confidentiality agreement for purposes of the P&T Committee (meaning Applicant has no knowledge of the membership of the PBM's P&T Committee). (If not applicable, check "NO.") Note: If answer is YES, then Applicant must complete P&T Committee Certification Statement and PBM must complete the P&T Committee Member List located in the Appendix entitled <i>Applicant Submission of P&amp;T Committee Member List and Certification Statement</i> .		
3. Applicant develops and uses a P&T committee to develop and review the formulary and to ensure that the formulary is appropriately revised to adapt to both the number and types of drugs on the market.  4. <i>Note: While the P&amp;T committee may be involved in providing recommendations regarding the placement of a particular Part D drug on a formulary cost-sharing tier, the ultimate decision maker on such formulary design issues is the Part D plan sponsor, and that decision weighs both clinical and non-clinical factors.</i>		
5. Applicant's P&T committee first looks at medications that are clinically effective. When two or more drugs have the same therapeutic advantages in terms of safety and efficacy, the committee may review economic factors that achieve appropriate, safe, and cost-effective drug therapy.		
6. Applicant assures that the P&T committee uses appropriate scientific and economic considerations to consider utilization management activities that affect access to drugs, such as access to non-formulary drugs, prior authorization, step therapy, generic substitution, and therapeutic interchange protocols.		
7. Applicant's P&T committee reviews and approves all clinical prior authorization criteria, step therapy protocols, and quantity limit restrictions applied to each covered Part D drug.		
8. Applicant adheres to P&T guidelines that will, from time to time, be promulgated with regard to such subject areas as membership, conflict of interest, meeting schedule, meeting minutes, therapeutic classes, drug review and inclusion, formulary management, utilization management and review,		

formulary exceptions, and educational programs for providers.		
9. Applicant's P&T committee makes a reasonable effort to review a new FDA approved drug product within 90 days, and will make a decision on each new drug product within 180 days of its release onto the market, or a clinical justification will be provided if this timeframe is not met. These timeframes also include the review of products for which new FDA indications have been approved.		
10. Applicant's P&T committee approves inclusion or exclusion of the therapeutic classes in the formulary on an annual basis.		
11. The majority of the membership of the Applicant's P&T committee are practicing physicians and/or practicing pharmacists.		
12. The membership of the Applicant's P&T committee includes at least one practicing physician and at least one practicing pharmacist who are both free of conflict with respect to the Applicant organization and pharmaceutical manufacturers.		
13. The membership of the Applicant's P&T committee includes at least one practicing physician and at least one practicing pharmacist who are experts in the care of the elderly or disabled persons.		
14. Applicant's P&T committee recommends protocols and procedures for the timely use of and access to both formulary and non-formulary drug products.		
15. Applicant verifies that their P&T Committee members (listed in 3.2.1 C) do not appear on the HHS Office of Inspector General's Exclusion List. This list can be found at <a href="http://exclusions.oig.hhs.gov/search.html">http://exclusions.oig.hhs.gov/search.html</a>		

**C. If Applicant is intending for its Part D benefit to include use of a formulary, then the members of the P&T committee must be provided either directly by the Applicant or by the Applicant's PBM. The membership of the P&T committee must be comprised as described in items B, 10, 11 and 13 above. If Applicant is providing names of P&T committee directly, then provide the membership in HPMS' Contract Management/Part D Data page. If the PBM operates under a confidentiality agreement (where the Applicant does not know the membership of the PBM's P&T Committee) refer to the Appendix entitled Applicant Submission of P & T Committee Member List and Certification Statement for additional instructions.**

### 3.2.2 Utilization Management Standards 42 CFR §423.153(b); Prescription Drug Benefit Manual, Chapter 6 and Chapter 7

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
1. Applicant maintains policies and procedures to prevent over-utilization and under-utilization of prescribed medications, including but not limited to the following elements: <ul style="list-style-type: none"> <li>• Programs designed to improve adherence/compliance with appropriate medication regimens</li> <li>• Monitoring procedures to discourage over-utilization through multiple prescribers or multiple pharmacies</li> <li>• Quantity versus time edits</li> <li>• Early refill edits</li> </ul>		
2. Applicant maintains methods to ensure cost-effective drug utilization management. Examples of these tools include, but are not limited to: <ul style="list-style-type: none"> <li>• Step therapy</li> <li>• Prior authorization</li> <li>• Tiered cost-sharing</li> </ul>		
3. Applicant makes enrollees aware of utilization management (UM) program requirements through information and outreach materials.		
4. Applicant has incentives to reduce costs when medically appropriate such as, but not limited to encouragement of generic utilization.		
5. Applicant agrees to submit corresponding utilization management criteria for each drug identified on the Applicant's formulary flat file with prior authorization or step therapy via HPMS.		

### 3.2.3 Quality Assurance and Patient Safety Affordable Care Act § 3310; 42 CFR §423.153(c); Prescription Drug Benefit Manual, Chapter 7

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
<p>1. Applicant has a concurrent drug utilization review program that includes but is not limited to, the following checks each time a prescription is dispensed:</p> <ul style="list-style-type: none"> <li>• Screening for potential drug therapy problems due to therapeutic duplication;</li> <li>• Age/gender-related contraindications;</li> <li>• Over-utilization and under utilization;</li> <li>• Drug-drug interactions;</li> <li>• Incorrect drug dosage or duration of drug therapy;</li> <li>• Drug-allergy contraindications; and</li> <li>• Clinical abuse/misuse.</li> </ul>		
2. Applicant performs retrospective drug utilization review.		
3. Applicant develops and implements internal medication error identification and reduction systems.		
4. Applicant reduces wasteful dispensing of outpatient prescription drugs in long-term care facilities by utilizing specific, uniform dispensing techniques, such as weekly, daily, or automated dose dispensing as established by CMS.		

### 3.2.4 Medication Therapy Management 42 CFR §423.153(d); The Affordable Care Act § 10328; Prescription Drug Benefit Manual, Chapter 7;

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
<p>1. Applicant develops and implements a Medication Therapy Management (MTM) Program designed to :</p> <ul style="list-style-type: none"> <li>• Ensure optimum therapeutic outcomes for targeted beneficiaries through improved medication use</li> <li>• For targeted beneficiaries, reduce the risk of adverse events,</li> </ul>		

including adverse drug interactions		
2. Applicant develops the MTM program in cooperation with licensed and practicing pharmacists and physicians.		
<p>3. Applicant targets beneficiaries for enrollment in the MTM program based on all three of the following criteria:</p> <ul style="list-style-type: none"> <li>• Beneficiary must have multiple chronic diseases, with three chronic diseases being the maximum number an Applicant may require for targeted enrollment;</li> <li>• Beneficiary must be taking multiple covered Part D drugs, with eight Part D drugs being the maximum number of drugs an Applicant may require for targeted enrollment; and</li> <li>• Beneficiary must be identified as likely to incur annual costs for covered Part D drugs in an amount greater than or equal to \$3000 increased by the annual percentage specified in 42 CFR § 423.104(d)(5)(iv).</li> </ul>		
4. Applicant has an appropriate MTM enrollment policy which enrolls targeted beneficiaries using an opt-out method of enrollment only.		
5. Applicant has an appropriate MTM enrollment policy which targets beneficiaries for enrollment at least quarterly during each year.		
<p>6. Applicant has appropriate policies and procedures for offering a minimum level of MTM services for each beneficiary enrolled in the MTMP that includes all of the following:</p> <ul style="list-style-type: none"> <li>• Interventions for both beneficiaries and prescribers;</li> <li>• An annual comprehensive medication review (CMR) with written summaries. The CMR must include an interactive, person-to-person , or telehealth consultation performed by a pharmacist or other qualified provider unless the beneficiary is in a long-term care setting. The Summary resulting from the CMR must comply with the requirements for a standardized format as specified by CMS, and</li> <li>• Quarterly targeted medication reviews with follow-up interventions when necessary.</li> </ul>		
7. The Applicant agrees to submit a description of its MTM program including, but not limited to, policies, procedures, services, payments and criteria provided in item #3 above used for identifying beneficiaries eligible for the MTM program. Note:		



<p>Instructions to submit a description of your MTM program will be forthcoming in future guidance from CMS and this description is not due at the time of this application.</p>		
<p>8. Applicant has an appropriate policy on how they will set MTM fees paid to pharmacists or others providing MTM services for covered Part D drugs. The policy will explain how the Applicant's fee or payment structure takes into account the resources used and the time required for those providing MTM services.</p>		
<p>9. The Applicant agrees to submit a description of how they will set MTM fees paid to pharmacists or others providing MTM services for covered Part D drugs. The policy will explain how the Applicant's fee or payment structure takes into account the resources used and the time required for those providing MTM services. Note: Instructions to submit a description of MTM fees with a description of your MTM program will be forthcoming in future guidance from CMS and is not due at the time of this application.</p>		
<p>10. Applicant has appropriate policies and procedures to meet CMS expectations for administering the MTM program, including, but not limited to, services, payments and criteria used for identifying beneficiaries eligible for the MTM program. Such expectations include:</p> <ul style="list-style-type: none"> <li>• Once enrolled, beneficiaries will not be disenrolled from the MTMP program if they no longer meet one or more of the MTMP eligibility criteria (as determined by the organization) and will remain in the MTMP program for the remainder of the calendar year.</li> <li>• Applicant's MTMP will serve and provide interventions for enrollees who meet all three of the required criteria as defined above regardless of setting (e.g., ambulatory, long term care, etc.)</li> <li>• Applicant's MTMP will not include discriminatory exclusion criteria. If an enrollee meets all three of the required criteria as described by your organization, the enrollee should be eligible for MTM intervention.</li> <li>• Applicant will consider the provision of other prescription drug quality improvement interventions to beneficiaries who do not meet all three of the required MTMP criteria as described by your organization, however, these beneficiaries cannot be considered for MTM reimbursement by CMS.</li> <li>• Applicant will put into place safeguards against discrimination</li> </ul>		

<p>based on the nature of their MTM interventions (i.e., TTY if phone based, Braille if mail based, etc.)</p> <ul style="list-style-type: none"> <li>• Applicant will promote continuity of care by performing an end-of-year analysis that identifies current MTM program participants who will continue to meet eligibility criteria for the next program year for the same plan.</li> <li>• Applicant will have procedures in place to drive participation and follow-up with beneficiaries that do not respond to initial offers for MTM services.</li> <li>• Applicant will consider using more than one approach when possible to reach all eligible patients who may wish to receive MTM services.</li> <li>• Applicant will analyze and evaluate their MTMP and make changes to continuously improve their programs.</li> </ul>		
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### 3.2.5 Electronic Prescription Program and Health Information Technology Standards 42 CFR §423.159; Prescription Drug Benefit Manual, Chapter 7; P.L. 111-5 (2009); 2010 Call Letter

A. In HPMS, complete the table below:

<b>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:</b>	<b>Yes</b>	<b>No</b>
1. Applicant supports and complies with electronic prescription standards relating to covered Part D drugs for Part D enrollees.		
2. Applicant has an electronic prescription drug program that complies with final Part D standards for transmitting, directly or through an intermediary, prescriptions and prescription-related information using electronic media for covered Part D drugs for Part D eligible individuals.		
3. Applicant obtains the Prescription Origin Code on original prescriptions submitted via the NCPDP 5.1 option field 419 DJ and reports this code on their PDE submissions.		
4. Applicant agrees that as it implements, acquires, or upgrades health information technology (HIT) systems, where available, the HIT systems and products meet standards and implementation specifications adopted under section 3004 of the Public Health Services Act as added by section 13101 of the American		

Recovery and Reinvestment Act of 2009, P.L. 111-5.		
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### 3.2.6 Bids 42 CFR § 423.104, §423.265 and §423.272

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
1. Applicant limits the number of submitted bids in a service area to those that would demonstrate meaningful differences in benefit packages or plan costs to a beneficiary.		
2. Applicant has reviewed Section 2.4 of this application and understands that for the purpose of assigning autoenrollments, all bids that are below the low income subsidy threshold for all PDP contracts offered by the applicant's parent organization, its affiliates and itself will be counted as one.		
3. Applicant agrees to offer the plan to all Part D eligible beneficiaries residing in the applicant's service area; and at a uniform premium, with uniform benefits and level of cost-sharing throughout the plan service area.		

### 3.3 Service Area/Regions 42 CFR §423.112; 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
1. Applicant offers a prescription drug plan in at least one Part D region (e.g. PDP region, MA-PD region).		
2. For all regions in which the applicant offers a prescription drug plan, the Applicant provides coverage in the entire region.		

**B. 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. PDP and MA-PD region and Territory information may be found on the [www.cms.gov/](http://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.**

### **3.4 General Pharmacy Access 42 CFR §423.120(a); 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
1. Applicant permits in its plan networks any pharmacy that accepts and meets the plans’ standard terms and conditions. However, terms and conditions may vary, particularly with respect to payment terms to accommodate geographical areas (e.g. rural pharmacies) or different types of pharmacies (e.g. mail order and retail), provided that all similarly-situated pharmacies are offered the same standard terms and conditions.		
2. Applicant does not require a pharmacy to accept insurance risk as a condition of participation in the Part D sponsor’s network.		
3. Applicant agrees to notify CMS when the Applicant changes its pharmacy benefit manager.		
4. Applicant agrees to notify CMS about any substantive change in its pharmacy network that may impact its ability to maintain a Part D pharmacy network that meets CMS’ requirements.		

**B. Upload in HPMS a contract template in .pdf format for each for the following types of pharmacies: Retail, Mail Order, Home Infusion, Long-Term Care and I/T/U. The mail order contract template is only necessary if the plan is offering mail order. The I/T/U template is only necessary if the Applicant’s service area includes states in which I/T/U pharmacies reside. If Applicant has contracted with a Pharmacy Benefit Manager to provide a pharmacy network, those downstream contract templates must also be uploaded. If there are several different types of standard terms and conditions for the same type of pharmacy, please provide a contract template for all versions and label according to type of pharmacy. For example, if different terms for retail pharmacies apply depending upon geographic location, a separate template representing each variation must be provided. Each contract template type must contain the unsigned standard terms and conditions, including the provisions listed in the Appendices entitled**

- Crosswalk for Retail Pharmacy Contracts
- Crosswalk for Mail Order Pharmacy Contracts
- Crosswalk for Home Infusion Pharmacy Access Contracts
- Crosswalk for Long-Term Care Pharmacy Access Contracts
- Crosswalk for I/T/U Pharmacy Access Contracts.

**C. Upload in HPMS crosswalks of the Pharmacy Access Contract Citations [for Retail, Mail Order (if offered), Home Infusion, Long-Term Care and I/T/U Pharmacy networks] demonstrating that all applicable requirements are included in such contracts. Submit this data by downloading the Microsoft Excel worksheets from HPMS that are located on the Pharmacy Upload page, complete the worksheets and upload the finished document back into HPMS for each of the Appendices entitled**

- Crosswalk for Retail Pharmacy Contracts
- Crosswalk for Mail Order Pharmacy Contracts
- Crosswalk for Home-Infusion Pharmacy Access Contracts
- Crosswalk for Long-Term Care Pharmacy Access Contracts
- Crosswalk for I/T/U Pharmacy Access Contracts.

### **3.4.1 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:**

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
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:**

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

### **C. Submission of Supporting Discussion in Areas Failing to Meet Access Standards**

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

Provide as an 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.**

<b>Request for a Waiver of Convenient Access Standards for the Territories</b>	<b>Yes</b>	<b>No</b>	<b>N/A</b>
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 3.4.1D. In HPMS, in .pdf format, provide the following information:**

1. Explain why your organization cannot demonstrate compliance with the access standards or why these standards cannot be met.
2. Describe the Applicant's efforts to identify and contract with all of the retail pharmacies in each of the applicable territories.

3. Describe how the pharmacies in the Applicant's contracted network demonstrate convenient access to all eligible Part D individuals enrolled in the Applicant's plan(s) in each of the territories listed above as not meeting the standards in §423.120(a)(1).

### 3.4.2 Out of Network Access 42 CFR §423.124; 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
1. Applicant agrees that enrollees have adequate access to covered Part D drugs dispensed at out-of-network pharmacies when an enrollee cannot reasonably be expected to obtain such drugs at a network pharmacy and provided such enrollees do not access Part D drugs at an out-of-network pharmacy on a routine basis. The coverage rules applicable to covered Part D drugs dispensed at out-of-network pharmacies may generally mirror those applicable to covered Part D drugs dispensed at network pharmacies (to the extent that the out-of-network pharmacy has the ability to effectuate those coverage rules). However, Applicant agrees to develop policies and procedures governing reasonable rules for appropriately limiting out-of-network access (for example, quantity limits, purchase of maintenance medications via mail-order for extended out-of-area travel, or plan notification or authorization processes).		
2. Applicant agrees that enrollees have adequate access to covered Part D drugs dispensed at physician offices for covered Part D drugs that are appropriately dispensed and administered in physician offices (e.g. Part D-covered vaccines).		
3. Applicant abides by 42 CFR §423.124(b) relating to the financial responsibility for out-of-network access to covered Part D drugs and may require its Part D enrollees accessing covered Part D drugs to assume financial responsibility for any differential between the out-of-network pharmacy's usual and customary price and the PDP sponsor plan allowance, consistent with the requirements of 42 CFR §§ 423.104(d)(2)(i)(B) and 423.104(e).		
4. Applicant does not routinely permit coverage of more than a month's supply of medication to be dispensed at an out-of-network pharmacy. Applicant may override the one month limit only on a case-by-case basis when warranted by extraordinary		

circumstances.		
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### 3.4.3 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
1. Applicant offers mail order pharmacy as part of its Part D plans.		
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

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

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

#### A. Home Infusion Pharmacy List

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.



**3.4.5 Long -Term Care (LTC) Pharmacy 42 CFR §423.120(a)(5);  
Prescription Drug Benefit Manual, Chapter 5; CMS issued guidance  
04/28/09**

**A. In HPMS, complete the table below:**

<b>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:</b>	<b>Yes</b>	<b>No</b>
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 attests 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 or her current plan for as long as he/she reside in an LTC facility in Applicant’s service area.		

8. Applicant ensures that LTC pharmacy contracting activity 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. States may not be able to agree to certain clauses in some LTC standard contracts because of constitutional and legal restraints. Applicants should be prepared to negotiate with States to address these issues.		
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**

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.

### **3.4.6 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:**

<b>Applicant must attest 'yes' or 'no' to each of the following qualifications by clicking on the appropriate response in HPMS to be approved for a Part D contract:</b>	<b>Yes</b>	<b>No</b>	<b>N/A</b>
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1. Using the list of I/T/U pharmacies provided at the <a href="http://www.cms.gov/PrescriptionDrugCovContra/">www.cms.gov/PrescriptionDrugCovContra/</a> indicate whether your service area includes at least one state in which an I/T/U pharmacy resides.			
<p><b>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:</b></p>			
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 <a href="http://www.cms.gov/PrescriptionDrugCovContra/">www.cms.gov/PrescriptionDrugCovContra/</a> 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

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 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 and all states within its service area.

To submit I/T/U pharmacy listings to CMS, Applicants must first 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.

### 3.4.7 Specialty Pharmacy 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		
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<b>following qualifications by clicking on the appropriate response in HPMS:</b>	<b>Yes</b>	<b>No</b>
1. Applicant does not restrict access to Part D drugs by limiting distribution through a subset of network pharmacies, except when necessary to meet FDA limited distribution requirements or to ensure the appropriate dispensing of Part D drugs that require extraordinary special handling, provider coordination, or patient education when such extraordinary requirements cannot be met by a network pharmacy. Applicant agrees that additional education or counseling alone does not qualify a drug for limited distribution within the overall pharmacy network.		
2. Applicant does not restrict access solely on the placement of a Part D drug in a “specialty/high cost” tier because this tier placement alone is not indicative of any special requirements associated with such drug. Applicant further agrees that any drug-by-drug requirements for network pharmacies only apply to special handling and dispensing that may be required for a particular “specialty” drug and not to reimbursement or other standard terms and conditions.		
3. Applicant does not require a pharmacy to be a “specialty” pharmacy in order to dispense any drug that requires special handling if the network pharmacy is capable of appropriately dispensing the particular Part D drug or drugs in question.		

### **3.5 Enrollment and Eligibility 42 CFR §423.30; Prescription Drug Benefit Manual, Chapters 3, 4, and 13; Plan Communications User Guide; CMS issued guidance 07/21/09**

**A. In HPMS, complete the table below:**

<b>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:</b>	<b>Yes</b>	<b>No</b>
1. Applicant complies with the CMS Enrollment and Disenrollment Guidance documents that are provided on the <a href="http://www.cms.gov/">www.cms.gov/</a> website.		
2. Applicant complies with CMS operational guidance on Creditable Coverage and the Late Enrollment Penalty.		
3. Applicant permits the enrollment of all Medicare beneficiaries who are eligible for Part D and reside in the PDP service area during allowable enrollment periods according to CMS requirements.		

4. Eligible applicant accepts auto-enrollments and facilitated enrollments in accordance with procedures adopted by CMS and provided in CMS Enrollment and Disenrollment Guidance documents.		
5. Applicant collects and transmits data elements specified by CMS for the purposes of enrolling and disenrolling beneficiaries in accordance with the CMS Eligibility Enrollment and Disenrollment Guidance and CMS systems instructions including technical specifications and format requirements.		
6. Applicant \transmits enrollment and disenrollment and change transactions within the timeframes provided in CMS Enrollment and Disenrollment Guidance and in accordance with the published MARx Processing Calendar.		
7. Applicant provides all current and newly enrolled individuals all required enrollment material and notices within the timeframes provided in the CMS PDP Enrollment and Disenrollment Guidance.		
8. Applicant has and operates a process for enrolling Medicare beneficiaries in the PDP that includes: communicating with beneficiaries who are requesting enrollment in the PDP within timeframes specified by CMS, including requirements for initiating appropriate follow up with beneficiaries who submit incomplete enrollment requests; and making enrollments effective according to the effective date requirements associated with the enrollment period in which the enrollment is received.		
9. Applicant accepts voluntary disenrollment requests in accordance with CMS PDP Enrollment and Disenrollment Guidance only during allowable periods as specified in CMS requirements.		
10. Applicant accepts and processes voluntary disenrollment requests from beneficiaries, including providing all required notices and information to beneficiaries, communicating these requests to CMS, and establishing the disenrollment effective date according to the effective date requirements associated with the enrollment period in which the disenrollment request is received.		
11. Applicant provides advanced notice to all enrollees in the event of a contract termination, describing the implications of the termination and alternatives for obtaining prescription drug coverage under Part D in accordance with Part 423 regulations and CMS non-renewal instructions.		
12. Applicant has and implements policies and procedures (including appropriate notice and due process requirements) for optional		

involuntary disenrollment as permitted by CMS.		
13. Applicant ensures that information necessary to access all plan benefits, such as an ID card, is provided to new enrollees prior to the enrollment effective date, or no later than 10 days after receipt of the enrollment request, according to the timeframes described in the PDP Enrollment and Disenrollment Guidance.		
14. Applicant collects, reviews, and transmits creditable coverage information in accordance with CMS operational guidance and policies.		
15. Applicant has business processes for quickly resolving urgent issues affecting beneficiaries, such as late changes in enrollment or copay status, in collaboration with CMS caseworkers.		
<p>16. For each enrollment request received, Applicant queries the Batch Eligibility Query (BEQ) or the User Interface (UI) prior to the submission of an enrollment transaction to the MARx system to receive:</p> <ul style="list-style-type: none"> <li>• Verification of Medicare Entitlement and Part D Eligibility,</li> <li>• Periods of enrollment in a Medicare plan that provides prescription drug coverage,</li> <li>• Periods of enrollment in a retiree prescription drug plan whose sponsor receives a retiree drug subsidy from Medicare, and</li> <li>• Information regarding the Low Income Subsidy applicable to each new enrollee.</li> </ul>		
17. Applicant uses the information provided by CMS, including the Low-Income Subsidy/Part D Premium Report Data File to determine match rates of their information to that of CMS within 72 hours of receipt. Applicant further agrees that their match rate should achieve 95 percent and that non-matches are resolved within 72 hours.		
18. Applicant adheres to CMS's Best Available Evidence policy under 42 CFR § 423.800(d), under which an individual can provide acceptable evidence supporting a revised cost-sharing amount that the sponsor must accept for the purpose of administering the benefit, and to submit information to CMS with respect to Best Available Evidence in accordance with CMS procedures outlined in Chapter 13 of the Prescription Drug Benefit Manual.		
19. Applicant has a process in place to transmit plan-generated enrollment transactions that include active 4Rx data, and for CMS-generated enrollments, to transmit active 4Rx data on an update		

transaction within 3 business days of receipt of the TRR transmitting the enrollments.		
20. Applicant does not disenroll members for failure to pay premiums (or notify them of impending disenrollment) in cases where the individual is considered to be in premium withhold status by CMS as provided in CMS Enrollment and Disenrollment Guidance and Premium Payment policies.		
21. Applicant does not disenroll a member or initiate the disenrollment process if the organization has been notified that a State Pharmaceutical Assistance Program (SPAP) or other payer intends to pay the entire Part D premium on behalf of an individual.		
22. Applicant downloads at least daily and processes all enrollment elections made via the on-line enrollment center (OEC) hosted by CMS.		
23. Applicant reviews all systems responses, files and reports received from CMS and compares these to its internal data to identify discrepancies and reconcile enrollment information, beneficiary status (such as LIS) and payment data.		
24. Applicant completes the reconciliation of all enrollment, membership and payment data, and submits requests for valid discrepancy corrections in compliance with the 45-day schedule to submit the monthly CEO certification of enrollment data for payment.		
25. Applicant allows a temporary absence from a PDP service area for up to 12 months before disenrollment would be mandatory.		

### 3.6 Complaints Tracking Prescription Drug Benefit Manual, Chapter 7; CMS issued guidance 11/16/06, 07/28/2008, and 12/09/08

A. In HPMS, complete the table below:

<b>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:</b>	<b>Yes</b>	<b>No</b>
1. Applicant resolves 95% of complaints designated as immediate needs complaints via the CMS Complaints Tracking Module within 2 calendar days.		
2. Applicant is expected to resolve at least 95% of complaints designated as "urgent" via the CMS Complaints Tracking Module in		

accordance with CMS issued guidance.		
3. Applicant is expected to resolve at least 95% of complaints without an issue level via the CMS Complaints Tracking Module in accordance with CMS issued guidance.		
4. Applicant monitors and documents complaint resolutions for complaints attributed to their contracts in the CMS' Complaint Tracking Module in accordance with CMS' Standard Operating Procedures for Part D sponsors.		
5. Applicant maintains Standard Operating Procedures that address how its organization will handle and quickly resolve immediate action cases, as well as, outline the steps the organization intends to take to have enrollees call your customer service directly for the prompt resolution of all inquiries.		

### 3.7 Medicare Plan Finder Prescription Drug Benefit Manual, Chapter 7; CMS issued guidance 07/17/06, 11/20/07, 08/21/08, 05/20/10

A. In HPMS, complete the table below:

<b>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:</b>	<b>Yes</b>	<b>No</b>
1. Applicant provides current and accurate calendar year drug pricing and pharmacy network data for publishing on the "Medicare Plan Finder (MPF)" in the format and on a schedule required by CMS.		
2. Applicant performs quality checks for data submitted to CMS for display on the MPF and agrees that failure to conduct quality checks may result in suppression of the Applicant's pricing data from the website.		
3. Applicant agrees that errors or omissions identified by CMS during analyses of the data will also result in the suppression of the Applicant's pricing data from the website.		
4. Applicant agrees to respond to CMS' MPF quality assurance outlier emails as directed by CMS, and agrees that failure to respond in accordance with these directions will result in the suppression of the Applicant's pricing data from the website.		



### 3.8 Grievances 42 CFR Part 423 Subpart M; Prescription Drug Benefit Manual, Chapter 18

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
1. Applicant processes beneficiary grievances consistent with 42 CFR §423 subpart M.		
2. Applicant abides by Chapter 18 of the Prescription Drug Benefit Manual.		
3. Applicant, consistent with 42 CFR §423.564: <ul style="list-style-type: none"> <li>• Tracks and addresses enrollees' grievances,</li> <li>• Processes enrollees' grievances within the appropriate timeframes,</li> <li>• Works with the QIO to resolve quality of care grievances when appropriate,</li> <li>• Provides appropriate and timely notification to enrollees of grievance dispositions, and</li> <li>• Trains relevant staff and first tier, downstream and related entities on all regulatory requirements.</li> </ul>		
4. Applicant informs enrollees aware of the grievance process through information and outreach materials.		
5. Applicant accepts grievances from enrollees at least by telephone and in writing (including facsimile).		
6. Applicant maintains, and provides to CMS upon request, records on all grievances received both orally and in writing. At a minimum, such records must track the: <ul style="list-style-type: none"> <li>• Date of receipt of the grievance</li> <li>• Mode of receipt of grievance (i.e. fax, telephone, letter, etc.)</li> <li>• Person who filed the grievance</li> <li>• Subject of the grievance</li> <li>• Final disposition of the grievance</li> <li>• Date the enrollee was notified of the disposition</li> </ul>		

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

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

### 3.9 Coverage Determinations (including Exceptions) and Appeals 42 CFR Part 423 Subpart M; Prescription Drug Benefit Manual, Chapter 18; Part D QIC Reconsideration Procedures Manual

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
1. Applicant processes beneficiary coverage determinations (including exceptions) and appeals consistent with 42 CFR Part 423 subpart M and relevant provisions of subpart U.		
2. Applicant uses a uniform exceptions and appeals process, including procedures for accepting oral and written requests for coverage determinations and redeterminations per § 423.128(b)(7) and (d)(1)(iii). Applicant ensures access to a uniform model form to request a coverage determination and redetermination, to the extent such model forms have been approved for use by CMS. Applicant provides immediate access to the coverage determination and redetermination processes via an Internet Website.		
3. Applicant employs a medical director who is a physician with a current and unrestricted license to practice medicine in a State, Territory, Commonwealth of the United States, or the District of Columbia, per the requirements set forth in § 423.562(a)(5). The medical director is responsible for ensuring the clinical accuracy of all coverage determinations and redeterminations involving medical necessity.		
4. Applicant retains the services of physicians or other appropriate health care professionals per the requirements in 423.566(d) for medical necessity reviews in cases where the applicant expects to issue a partially or fully adverse coverage determination.		

5. Applicant abides by the coverage determination and appeals policies contained in Chapter 18 of the Prescription Drug Benefit Manual and the Part D QIC Reconsideration Procedures Manual.		
6. Applicant has arrangements with its network pharmacies for the standardized pharmacy notice (“Notice: Your Prescription Cannot be Filled”/CMS-10147) to be distributed to enrollees in accordance with the requirements set out in 42 CFR §§423.562 (a)(3) and 423.128(b)(7)(iii).		
7. Applicant, in accordance with 42 CFR Part 423 subpart M: <ul style="list-style-type: none"> <li>• Tracks coverage determination (including exceptions) and redetermination requests received both orally and in writing,</li> <li>• Processes coverage determinations (including exceptions) and redeterminations within the appropriate timeframes,</li> <li>• Provides appropriate and timely notification to enrollees (and prescribing physicians or other prescribers, when appropriate) of coverage determination (including exceptions) and redetermination decisions, and</li> <li>• Trains relevant staff and first tier, downstream and related entities on all regulatory requirements.</li> </ul>		
8. At a minimum, Applicant must track the: <ul style="list-style-type: none"> <li>• Date and time of receipt of a coverage determination request (including an exception request) or redetermination request,</li> <li>• Mode of receipt (i.e. fax, telephone, letter, etc.),</li> <li>• Person who filed the request,</li> <li>• Type of request made (i.e., standard or expedited),</li> <li>• Date and time of receipt of a physician's or other prescriber's supporting statement (for an exception request),</li> <li>• Disposition of request, and</li> <li>• Date and time of decision notice to the enrollee and/or prescriber.</li> </ul>		
9. Applicant notifies the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of an expedited coverage determination for benefits as expeditiously as the enrollee's health condition requires, but no later than 24 hours after receipt of the request.		
10. Applicant ensures that an enrollee is notified of a standard coverage determination for benefits as expeditiously as the enrollee's health		

condition requires, but no later than 72 hours after receipt of the request.		
11. Applicant ensures that an enrollee is notified of a standard coverage determination regarding reimbursement and receives reimbursement (when appropriate) no later than 14 calendar days after receipt of the request.		
12. Applicant ensures that an enrollee is notified of a decision on an exception request in accordance with regulatory timelines applicable to coverage determinations. For exceptions involving requests for benefits, the processing timeframe begins upon receipt of the physician's or other prescriber's supporting statement. For exceptions involving requests for payment, the processing timeframe begins upon receipt of the request for payment.		
13. Applicant notifies the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of an expedited redetermination as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receipt of the request.		
14. Applicant ensures that an enrollee is notified of standard redeterminations as expeditiously as the enrollee's health condition requires, but no later than 7 calendar days after receipt of the request.		
15. Applicant automatically forwards coverage determination (including exception) and redetermination requests to the Independent Review Entity (IRE) when the notification timeframes are not met, consistent with the rules set forth in Chapter 18 of the Medicare Prescription Drug Benefit Manual. Applicant auto-forwards cases timely to the proper IRE filing location and notifies the enrollee that the case has been sent to the IRE.		
16. Applicant maintains an exceptions process that includes a written description of how the organization will provide for standard and expedited tiering exception requests and non-formulary exception requests (including exceptions to utilization management tools), and how the organization will comply with such description. Such policies and procedures will be made available to CMS on request.		
17. Applicant complies with 42 CFR §423.578(a) and (b) which require a PDP sponsor to: <ul style="list-style-type: none"> <li>• Grant a tiering or non-formulary exception (including an exception to a utilization management tool) when it is medically appropriate to do so, and</li> <li>• Provide the criteria for evaluating whether approval is appropriate.</li> </ul>		

These requirements also apply to exceptions requests by Medicare eligible children for off-formulary Part D pediatric drugs and doses that are medically appropriate.		
18. Applicant's exceptions process is not overly burdensome or onerous. For example, a Part D Sponsor may not require that ALL exception requests be accompanied by laboratory evidence.		
19. Applicant's approved non-formulary drugs are assigned to a single existing tier, unless Applicant elects to apply a second less expensive level of cost sharing for approved formulary exceptions for generic drugs, so long as the second level of cost sharing is associated with an existing formulary tier and is applied uniformly to all approved formulary exceptions for generic drugs. Applicant may not create a tier specifically designed for non-formulary exceptions.		
20. Applicant does not restrict the number of exception requests submitted by an enrollee.		
21. Applicant will: <ul style="list-style-type: none"> <li>• Timely effectuate favorable decisions issued by the IRE, an Administrative Law Judge, the Medicare Appeals Council, or a federal court, and</li> <li>• Timely notify the IRE when a favorable decision has been effectuated.</li> </ul>		
22. Applicant will timely forward case files to the IRE (upon request by the IRE) when an enrollee requests a reconsideration by the IRE and will prepare and submit the case file consistent with instructions in the Part D QIC's Reconsideration Procedures Manual.		
23. Applicant informs its enrollees about the coverage determination (including exceptions) and appeals process through information provided in the Evidence of Coverage and outreach materials.		
24. Applicant makes available to CMS upon request, coverage determination (including exceptions) and appeals records and is able to track all levels of appeal by the appeal number assigned by the adjudicator (e.g., IRE).		

### **3.10 Coordination of Benefits 42 CFR Part 423 Subpart J; Prescription Drug Benefit Manual, Chapter 14**

**A. In HPMS, complete the table below:**

<b>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</b>		
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following qualifications by clicking on the appropriate response in HPMS:	Yes	No
1. Applicant complies with Chapter 14 of the Prescription Drug Benefit Manual.		
2. Applicant has a system for notifying enrollees when CMS' systems indicate other prescription drug coverage, and requesting enrollees to concur with new/changed information.		
3. Applicant permits SPAPs, ADAPs, IHS, and other third party payers to coordinate benefits as required by the regulations in 42 CFR Part 423, Subpart J, and Chapter 14 of the Prescription Drug Benefit Manual. For example, an SPAP may require agreements be signed in order for the state to pay premiums on behalf of a beneficiary. CMS expects Part D sponsors to execute these trading partner agreements within a reasonable timeframe.		
4. Applicant pays user fees as required under 42 CFR §423.6 and as may be required under 42 CFR §423.464 (c).		
5. Applicant does not impose fees on SPAPs or other third-party insurers that are unreasonable and/or unrelated to the cost of coordination of benefits.		
6. Applicant sends updated information captured in the beneficiary COB notification process about its enrollees' other sources of prescription drug coverage via electronic updates to the COB contractor.		
7. Applicant agrees to receive COB files from CMS and update its systems with these data at least weekly in accordance with the most current version of the Plan Communications User Guide.		
<p>8. When a supplemental payer wishes to pay premiums on behalf of plan enrollees, Applicant:</p> <ul style="list-style-type: none"> <li>• As may be required by a supplemental payer, enters into agreements with, and accept premium payments made by these supplemental payers;</li> <li>• Suppresses premium billing to the beneficiaries for whom it accepts premium payments from supplemental payers;</li> <li>• Informs enrollees not to use the SSA withhold when another payer is paying their premium (in whole or in part); and</li> <li>• Ensures that, the overall premium payment made by or on behalf of a beneficiary does not vary among plan enrollees (e.g., Sponsor cannot charge a different premium to SPAPs for their members versus all</li> </ul>		

other enrollees).		
9. If Applicant agrees to enter into an agreement with SPAPs, accepting a risk-based, per capita amount to administer a wrap-around benefit on behalf of the beneficiary, the Applicant must follow the requirements set forth in Chapter 14 of the Prescription Drug Benefit Manual.		
10. When the Applicant's service area includes States that subsidize a portion of beneficiary cost-sharing through their SPAPs through a non-risk lump-sum contract with reconciliation, Applicant: <ul style="list-style-type: none"> <li>• Enters into an agreement to receive such subsidies;</li> <li>• Applies such subsidies to the first dollar of beneficiary cost sharing under the Applicant's Part D plan; and</li> <li>• Submits claims information to the State to support reconciliation.</li> </ul>		
11. Applicant provides clear and prominently displayed information identifying the SPAP as a co-sponsor of benefits when the Applicant participates in a risk- or non-risk lump sum per capita contract with an SPAP to provide wrap-around benefits to Part D enrollees.		
12. Applicant receives and processes plan to plan reconciliation reports on a monthly basis.		
13. Applicant coordinates the reconciliation of claims when a Part D sponsor other than the Part D sponsor of record paid claims or when a non-Part D payer (e.g., SPAP) paid claims and should not have paid at all or paid out of the correct payer order in accordance with Chapter 14 of the Prescription Drug Benefit Manual.		
14. Applicant coordinates benefits with SPAPs, other entities providing prescription drug coverage, beneficiaries, and others paying on the beneficiaries' behalf for a period not to exceed three years from the date on which the prescription for a covered Part D drug was filled.		

### 3.11 Tracking Out-of Pocket Costs (TrOOP) Affordable Care Act § 3314; 42 CFR Part 423 Subpart J; Prescription Drug Benefit Manual, Chapters 13 and Chapter 14

A. In HPMS, complete the table below:

<b>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:</b>	<b>Yes</b>	<b>No</b>
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1. Applicant tracks each enrollee's true out of pocket (TrOOP) costs reflecting the amount the enrollee has spent out of pocket during a program year on covered Part D drugs.		
2. Applicant accepts data concerning third party payers in a format specified by CMS and uses these data in the Applicant's TrOOP calculation process.		
3. Applicant processes claims and tracks TrOOP in real time using the current HIPAA-approved NCPDP standard.		
4. Applicant provides enrollees with a report on their TrOOP status at least monthly if the enrollee's TrOOP status has changed.		
5. Applicant provides enrollees daily access to their current TrOOP status through the organization's toll-free customer service phone number.		
6. In the event of disenrollment, Applicant provides the TrOOP status of the beneficiary as of the effective date of the disenrollment to the beneficiary, if there has been a change in these data since the last report to the beneficiary.		
7. Applicant retroactively adjusts claims and recalculates TrOOP balances based on Nx transactions received from the TrOOP Facilitation Contractor that were created based on other than real-time TrOOP-eligible claims.		
8. Applicant retroactively adjusts claims and recalculates TrOOP balances based on receipts received from its Medicare enrollees that reflect amounts the enrollee paid on other than real-time TrOOP-eligible claims.		
9. Applicant agrees that when it receives an Nx transaction, but has no supplemental payer information on file to identify the payer, the Applicant contacts the beneficiary to identify the payer and sends the payer information to the COB Contractor via ECRS verification.		
10. Applicant retroactively adjusts claims, recalculates TrOOP balances, and reimburses other payers (when applicable) whenever it receives information (e.g., an LIS status change) that affects how the Applicant previously adjudicated a claim, or that indicates an error in the order of payment when another payer(s) was involved.		
11. Applicant may count other payer paid amounts as satisfying the Part D deductible whether or not the entire amount counts toward TrOOP.		



12. Applicant has the systems capability to receive and respond to real-time (or batch) transactions requesting TrOOP-related data for disenrolling Part D beneficiaries as well as to receive these data for newly enrolling Part D beneficiaries transferring mid-year from another plan.		
13. Applicant agrees that, when an exception to the ATBT process is required, the Applicant sends TrOOP-related data manually for disenrolling Part D beneficiaries as well as receives these data manually for newly enrolling Part D beneficiaries transferring mid-year from another plan.		
14. Applicant has the capacity to integrate data received via electronic transactions (as well as data received manually when the exception process is required) into those systems that track and apply beneficiary-level TrOOP and gross covered prescription drug costs.		
15. Applicant treats costs incurred by AIDS Drug Assistance Programs and Indian Health Services in providing prescription drugs toward the annual out-of-pocket threshold.		

NOTE: For information regarding the TrOOP facilitator, Applicant may link to [http://medifacd.ndchealth.com/home/medifacd\\_home.htm](http://medifacd.ndchealth.com/home/medifacd_home.htm)

### 3.12 Medicare Secondary Payer 42 CFR §423.462; Prescription Drug Benefit Manual, Chapter 14

A. In HPMS, complete the table below:

<b>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:</b>	<b>Yes</b>	<b>No</b>
1. Applicant is familiar with rules that determine when other payers are primary or secondary to Medicare as referenced in 42 CFR §423.462.		
2. Applicant adheres to MSP laws and any other Federal and State laws in establishing payers of last resort.		
3. Applicant follows the Rules for Coordination of Benefits adopted in the most current National Association of Insurance Commissioner Coordination of Benefits Model Regulation.		
4. Applicant processes claims in real time to support the TrOOP facilitation process when it is a secondary payer in accordance with		

the application of MSP rules.		
5. Applicant collects mistaken primary payment from insurers, group health plans, employer sponsors, enrollees and other entities.		
6. Applicant agrees that in situations involving workers' compensation, Black Lung, No-Fault, or Liability coverage to make conditional primary payment and recover any mistaken payments, unless the Applicant is already aware that the enrollee has workers' compensation, Black Lung, No-Fault, or Liability coverage and has previously established that a certain drug is being used exclusively to treat a related injury.		

### 3.13 Marketing/Beneficiary Communications 42 CFR §423.128; 42 CFR §423.505; Prescription Drug Benefit Manual, Chapter 2

A. In HPMS, complete the table below:

<b>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:</b>	<b>Yes</b>	<b>No</b>
1. Applicant complies with marketing guidelines and approval procedures that are contained with Chapter 2 of the Prescription Drug Benefit Manual and posted on the <a href="http://www.cms.gov/">www.cms.gov/</a> website, including the requirements of the File and Use Certification process.		
2. Applicant makes available to beneficiaries only those marketing materials, notices, and other standardized letters that comply with CMS' marketing guidelines and have been appropriately filed with CMS through HPMS.		
3. Annually and at the time of enrollment, the Applicant provides enrollees information about the following Part D features, as described in the marketing guidelines: <ul style="list-style-type: none"> <li>• Enrollment and Disenrollment Procedures</li> <li>• Beneficiary Procedural Rights</li> <li>• Potential for Contract Termination</li> <li>• Benefits</li> <li>• Types of Pharmacies in the Pharmacy Network</li> <li>• Out-of-network Pharmacy Access</li> <li>• Formulary</li> </ul>		

<ul style="list-style-type: none"> <li>• Premiums and cost-sharing</li> <li>• Service Area</li> <li>• Plan ratings information</li> </ul>		
4. Applicant provides general coverage information, as well as information concerning utilization, grievances, appeals, exceptions, quality assurance, and sponsor financial information to any beneficiary upon request.		
5. Applicant discloses to its enrollees and potential enrollees information concerning the organization's performance and contract compliance deficiencies as described by CMS.		
6. Applicant makes marketing materials available in any language that is the primary language of at least 5% of the general population in an Applicant's plan benefit package service area.		
<p>7. Applicant maintains a toll-free customer service call center that provides customer telephone service to current and prospective enrollees in compliance with CMS standards. This means that the Applicant complies with at least the following:</p> <ul style="list-style-type: none"> <li>• Call center operates during normal business hours, seven days a week from 8:00 AM to 8:00 PM for all time zones in which the Applicant offers a Part D plan during the annual enrollment period and 45 days thereafter.</li> <li>• On Saturdays, Sundays and holidays, from February 15 until the following annual enrollment period, a customer service representative or an automated phone system may answer beneficiary calls.</li> <li>• If a beneficiary is required to leave a message in voice mail box due to the utilization of an automated phone system, the applicant ensures that a return call to a beneficiary is made in a timely manner, but no later than one business day from the leaving of the message by the beneficiary.</li> <li>• The average hold time for a beneficiary to reach a customer service representative is two minutes or less.</li> <li>• The disconnect rate of all incoming customer calls does not exceed 5 percent.</li> <li>• Call center provides thorough information about the Part D benefit plan, including co-payments, deductibles, and network pharmacies.</li> <li>• Call center features an explicit process for handling customer complaints.</li> <li>• Call center provides service to non-English speaking, limited English</li> </ul>		

proficient (LEP), and hearing impaired beneficiaries.		
8. Applicant operates an Internet Web site that includes all items identified in Chapter 2 of the Prescription Drug Benefit Manual and 42 CFR §423.505..		
9. Applicant ensures that the marketed and adjudicated formularies are consistent with the HPMS approved formulary file.		
10. Applicant provides its plan enrollees, in a form understandable to enrollees and on at least a monthly basis for those months in which the enrollees use their Part D benefits, an explanation of benefits that states a) the item or service for which payment was made; b) notice of the enrollee's right to an itemized statement; c) a year-to-date statement of the total Part D benefits provided in relation to deductibles, coverage limits, and annual out-of-pocket thresholds; d) cumulative year-to-date total of incurred costs; and e) applicable formulary changes.		
11. Applicant does not include co-branding names and/or logos of contracted providers or names and/or logos that are substantially similar to a contracted provider's name and/or logo on member identification cards.		
12. Applicant agrees that the subsequent CY Annual Notice of Change (ANOC) / Summary of Benefits (SB) / Formulary must be received by members (if applicable) no later than 15 days prior to the start of the annual election period.		
13. Applicant notifies its enrollees that the Applicant will release the enrollee's information, including the enrollee's prescription drug event data, to CMS which may release it for research and other purposes consistent with all applicable Federal statutes and regulations.		
14. Applicant provides initial and renewal compensation to a broker or agent for the sale of a prescription drug plan consistent with CMS-established requirements in 42 CFR §423.2274.		
15. Applicant ensures that brokers and agents selling Medicare products are trained and tested on Medicare rules and the specifics of the plans they are selling, and that they pass with a minimum score as specified in CMS guidance.		

### **3.14 Provider Communications Prescription Drug Benefit Manual, Chapter 2**

**A. In HPMS, complete the table below:**

<b>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:</b>	<b>Yes</b>	<b>No</b>
<p>1. Applicant operates a toll-free call center to respond to inquiries from pharmacies and providers regarding the Applicant’s Medicare prescription drug benefit. Inquiries will concern such operational areas as claims processing, benefit coverage, claims submission, and claims payment. This means that the Applicant complies with at least the following:</p> <ul style="list-style-type: none"> <li>• Be available 24 hours a day when the pharmacy network includes pharmacies that are open 24 hours a day;</li> <li>• The average hold time for a pharmacist to reach a customer service representative is two minutes or less.</li> <li>• The disconnect rate of all incoming calls does not exceed 5 percent.</li> </ul>		
<p>2. Applicant agrees that it has a “one-stop” area on its website that provides needed information on the procedures, the forms and the contact information for their prior authorization, coverage determination (including exceptions), and appeals processes.</p>		
<p>3. Applicant operates a toll-free call center to respond to physicians and other prescribers for information related to prior authorizations, coverage determinations (including exceptions), and appeal requests. The call center operates during normal business hours and never less than 8:00 a.m. to 6:00 p.m., Monday through Friday according to the time zones for the regions in which their plans operate.</p> <p>Applicant may use voicemail provided the message:</p> <ul style="list-style-type: none"> <li>• Indicates that the mailbox is secure.</li> <li>• Lists the information that must be provided so the case can be worked (e.g., provider identification, beneficiary identification, type of request (coverage determination, exception, or appeal), and whether the request is an expedited or standard request).</li> <li>• For coverage determination (including exception) requests: articulates and follows a process for resolution within 24 hours of call for expedited requests, or 72 hours for standard requests.</li> <li>• For appeal requests: articulates and follows a process for resolution within 72 hours for expedited appeals, and 7 calendar days for standard appeals.</li> <li>• Provides and follows a process for immediate access in situations</li> </ul>		

where an enrollee's life or health is in serious jeopardy.		
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### 3.15 Reporting Requirements Affordable Care Act § 6005; 42 CFR §423.514; 2010 Reporting Requirements

A. In HPMS, complete the table below:

Applicant must attest 'yes' to each of the following qualifications to be approved for a Part D contract. Attest 'yes' or 'no' to each of the following qualifications by clicking on the appropriate response in HPMS:	Yes	No
<b>Reporting Requirements Guidance</b>		
1. Applicant complies with the Reporting Requirements Guidance that is posted on the <a href="http://www.cms.gov/">www.cms.gov/</a> website.		
2. Applicant agrees that an individual with authority to sign on behalf of your organization attests that the reporting requirements data has been audited internally for accuracy.		
3. Applicant subjects reporting requirement data to a yearly independent audit to determine its reliability, validity, completeness, and comparability in accordance with CMS guidance.		
<b>Business Transactions and Financial Requirements</b>		
4. Applicant reports, consistent with 42 CFR §423.514(b), information related to significant business transactions between the Part D plan sponsor and a party in interest within 120 days of the end of each fiscal year. This qualification includes combined financial statements, where required under 42 CFR §423.514(b)(2).		
5. Applicant notifies CMS of any loans or other special financial arrangements made with contractors, first tier, downstream and related entities as that term is defined in 42 CFR §423.501.		
6. Applicant submits audited financial statements to CMS annually.		
<b>Claims Data</b>		
7. The Applicant or the Applicant's representative, such as a first tier, downstream or related entity, has data management processes and data systems capable of collecting, storing and protecting electronic eligibility and claims data. Data to be collected encompasses quantity, type, and costs of pharmaceutical prescriptions filled for enrollees. The plan must link this information to Medicare beneficiary		

identification numbers (HIC#s).		
8. The Applicant or the Applicant's representative, such as a first tier, downstream or related entity, has data management processes and data systems capable of creating and submitting PDE records for Medicare enrollees for every Part D drug prescription in the format required by CMS, using batch submission processes. Data to be submitted encompasses quantity, type and costs of pharmaceutical prescriptions filled for enrollees. The plan must link this information to Medicare beneficiary identification numbers (HIC#s).		
9. The Applicant or the Applicant's representative, such as a first tier, downstream or related entity, has data management processes and data systems capable of submitting data to CMS via the Medicare Data Communications Network (MDCN).		
10. The Applicant or the Applicant's representative, such as a first tier, downstream or related entity, has data management processes and data systems capable of performing data edit and quality control procedures (including resolution of rejected claims) to ensure accurate and complete prescription drug data.		
11. The Applicant or the Applicant's representative, such as a first tier, downstream or related entity, has data management processes and data systems capable of correcting all data errors identified by CMS.		
12. The Applicant or the Applicant's representative, such as a first tier, downstream or related entity, has data management processes and data systems capable of collecting data for dates of service within the coverage year with a 3-month closeout window for the submission of remaining unreported claims data.		
13. The Applicant or the Applicant's representative, such as a first tier, downstream or related entity, has data management processes and data systems capable of providing additional information for the purposes of reconciliation of risk factors, low income subsidy payments, reinsurance payments, and risk corridor as required by CMS.		
<b>Rebate Data</b>		
14. The Applicant reports direct and indirect remuneration (DIR) dollars for payment reconciliation on an annual basis at the Plan Benefit Package (PBP) level/plan level in the manner specified by CMS. In addition, the Applicant maintains records and documentation to verify the DIR data reported to CMS.		

Other Data		
15. Applicant reports at a frequency determined by CMS specified data (pursuant to 42 CFR §423.514(a)) on a variety of measures to support payment, program integrity, program management, and quality improvement activities in a manner prescribed by CMS. Such data submissions will be accurate and timely.		
16. The Applicant provides CMS with routine administrative reports (pursuant to 42 CFR §423.514 (a)) on a variety of measures that concern the Applicant's performance in the administration of the Part D benefit. Such reports shall be submitted according to instructions issued with timely notice by CMS.		
Supporting <a href="http://www.medicare.gov">www.medicare.gov</a>		
17. The Applicant submits pricing and pharmacy network information to be publicly reported on <a href="http://www.medicare.gov">www.medicare.gov</a> in order to provide Medicare beneficiaries with necessary information regarding prescription drug costs under the respective plans. Details regarding this data requirement are posted on <a href="http://www.cms.gov">www.cms.gov</a> by April of the prior year.		
Conflict of Interest		
18. The Applicant provides financial and organizational conflict of interest reports to CMS.		
PBM Transparency		
19. The Applicant's PBM provides information related to PBM transparency as specified in Section 6005 of the Affordable Care Act.		

### 3.16 Data Exchange between Part D Sponsor and CMS 42 CFR §423.505(c) and (k)

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
HPMS		
1. Applicant uses HPMS to communicate with CMS in support of the application process, formulary submission process, bid submission		



process, ongoing operations of the Part D program, and reporting and oversight activities. Part D sponsors are required to secure access to HPMS in order to carry out these functions.		
<b>Enrollment &amp; Payment</b>		
2. Applicant establishes connectivity to CMS as noted in the instructions provided by the MAPD Help Desk at 1-800-927-8069 or via the MAPD HelpDesk webpage, <a href="http://www.cms.gov/mapdhelpdesk">www.cms.gov/mapdhelpdesk</a> , in the Plan Reference Guide for CMS Part C/D Systems link.		
3. Applicant obtains CMS User ID and Password.		
4. Applicant submits enrollment, disenrollment and change transactions to communicate membership information to CMS within the timeframes provided by CMS.		
5. Applicant reconciles Part D data to CMS enrollment/payment reports received daily, weekly and monthly.		
6. Applicant completes the review of monthly reports, including submitting all requests for discrepancy corrections, and submits the CEO Certification of enrollment data for plan payment within 45 days of CMS monthly membership payment report availability.		
7. Applicant participates in connectivity testing and other system testing measures as provided to the Applicants prior to contract execution to validate system setup.		
8. Applicant has system(s) to process enrollment and payment transactions as exchanged with CMS in accordance with system development lifecycle standards.		
9. Applicant ensures appropriate security safeguards and protocols are in place to protect the protected health information in the system(s).		
10. Applicant maintains all pertinent system security and disaster recovery plans and procedures.		
11. In accordance with 42 CFR §423.322, the Applicant provides CMS with any data required to ensure accurate prospective, interim, and/or final reconciled payments including, but not limited to, the following: test data, Prescription Drug Event (PDE) records, enrollment transactions, Direct and Indirect Remuneration (DIR) data, discrepancy records, and premium payment data.		

**3.17 Health Insurance Portability and Accountability Act of 1996 (HIPAA), Health Information Technology for Economic and Clinical Health Act (HITECH), and Related CMS Requirements 45 CFR Parts 160, 162, and 164; CMS issued guidance 08/15/2006 and 08/26/08**

**A. In HPMS, complete the table below:**

<b>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:</b>	<b>Yes</b>	<b>No</b>
1. Applicant complies with all applicable standards, implementation specifications, and requirements in the Standards for Privacy of Individually Identifiable Health Information, and Security Standards under 45 CFR Parts 160, 162, and 164.		
2. Applicant encrypts all hard drives or other storage media within the device as well as all removable media.		
3. Applicant has policies addressing the secure handling of portable media that is accessed or used by the organization.		
4. Applicant complies with all applicable standards, implementation specifications, and requirements in the Standard Unique Health Identifier for Health Care Providers final rule under 45 CFR Parts 160 and 162.		
5. Applicant agrees that when its organization receives a National Provider Identifier (NPI) in prescription drug event data, that the organization must report an NPI.		
6. Applicant agrees to implement a contingency plan related to compliance with the NPI provisions.		
7. Applicant complies with all applicable standards, implementation specifications, and requirements in the Standards for Electronic Transactions under 45 CFR Parts 160 and 162.		
8. Applicant transmits payment and remittance advice consistent with the HIPAA-adopted ACS X12N 835, Version 4010/4010A1: Health Care Claim Payment and Remittance Advice Implementation Guide (“835”).		
9. Applicant submits the Offshore Subcontract Information and Attestation via HPMS for each offshore subcontractor (first tier,		

downstream and related entities) (including downstream offshore subcontractors' first tier, downstream and related entities) that receive, process, transfer, handle, store, or access Medicare beneficiary protected health information (PHI) by the last Friday in September for the upcoming contract year.		
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### 3.18 Prohibition on Use of SSN or Medicare ID number on Enrollee ID Cards Prescription Drug Benefit Manual, Chapter 2

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
1. Applicant does not use an enrollee's Social Security Number (SSN) or Medicare ID Number on the enrollee's identification card.		

### 3.19 Record Retention 42 CFR §423.505(d)

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
1. The Applicant maintains books, records, documents, and other evidence of accounting procedures and practices consistent with 42 CFR §423.505(d).		
2. Applicant has pharmacies, contracted for the Part D benefit, maintain prescription records in their original format for the greater of 3 years or the period required by State law and allow those records to be transferred to an electronic format that replicates the original prescription for the remaining 7 years of the 10 year record retention requirement.		
3. Applicant keeps all other records—except prescription records—that must be retained for Medicare under Part C and Part D in the format(s) required by State law or at the Applicant's discretion.		

**3.20 Prescription Drug Event (PDE) Records; 42 CFR Part 423 Subpart G; CMS issued guidance 04/27/2006, 06/23/2006, 12/17/2010, 03/01/2011, 03/04/2011, 04/28/2011, 05/16/2011**

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
1. Applicant abides by CMS guidance related to PDE data. Such guidance includes the 2008 Regional Prescription Drug Event Data Participant Training Guide and Technical Assistance Resource Guide which can be found at <a href="http://www.csscooperations.com/new/pdic/pdd-training/pdd-training.html">www.csscooperations.com/new/pdic/pdd-training/pdd-training.html</a> .		
2. Applicant submits data and information necessary for CMS to carry out payment provisions.		
3. Applicant submits PDE data on the schedule required by applicable regulations and CMS guidance.		
4. Applicant submits the PDE data in the format described by CMS and in accordance with the National Council for Prescription Drug Programs (NCPDP) industry standard format.		
5. Applicant meets all data submission deadlines.		
6. Applicant pays all Plan-to-Plan payables on time.		
7. Applicant complies with Medicare Coverage Gap Discount Program requirements.		
8. Applicant complies with timely response requirements for PDE Data Quality Reviews posted on the Data Quality Validation website.		

**3.21 Claims Processing; 42 CFR §423.120(c)(4); 42 CFR §423.466; CMS issued guidance 04/26/2006, 01/13/2010, and 03/29/2010**

**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
1. Applicant has an on-line claims processing system that operates in real time to ensure accurate and timely payment of all claims		

<p>submitted by network pharmacies on behalf of Part D plan enrollees. System operates according to the following standards:</p> <ul style="list-style-type: none"> <li>• 98% response within 4 seconds;</li> <li>• 99% of all claims paid with no errors;</li> <li>• 99% system availability.</li> </ul>		
<p>2. Applicant has a system designed to:</p> <ul style="list-style-type: none"> <li>• Pay non-electronic claims submissions from network pharmacies in accordance with 42 CFR §423.520; and</li> <li>• Pay requests for reimbursement from beneficiaries in accordance with 42 CFR §423.568(b).</li> </ul>		
<p>3. Applicant has available for CMS inspection a complete description of your claims adjudication system including:</p> <ul style="list-style-type: none"> <li>• Hardware and software;</li> <li>• Operating system;</li> <li>• Commercial organization from which Applicant receives pricing files, including file revision history;</li> <li>• Number of sites processing claims (including disaster recovery back-up system);</li> <li>• System volume in covered lives, including the number of transactions the system can support per day and per hour.</li> </ul>		
<p>4. Applicant has available to CMS upon request policies and procedures that include a complete description and flow chart detailing the claims adjudication process for each:</p> <ul style="list-style-type: none"> <li>• Contracted network pharmacies;</li> <li>• Paper claims;</li> <li>• Out-of-network pharmacy claims submitted by beneficiaries;</li> <li>• Non-electronic claims submitted by network pharmacies, and other payers seeking to coordinate benefits;</li> <li>• Batch-processed claims; and</li> <li>• Manual claim entry (e.g. for processing direct member reimbursement).</li> </ul>		
<p>5. Applicant has available to CMS upon request policies and procedures that include a complete description of claim detail management, including:</p>		

<ul style="list-style-type: none"> <li>• The length of time that detailed claim information is maintained online (not less than 12 months);</li> <li>• The data storage process after it is no longer online; and</li> <li>• The length of time that detailed claim information is stored when it is no longer online (not less than 10 years).</li> </ul>		
<p>6. Applicant has available to CMS upon request policies and procedures that include a complete description of the accessibility of this information for data capture purposes and flow chart of the claims data retrieval process for each:</p> <ul style="list-style-type: none"> <li>• Entire claims history file;</li> <li>• File claims adjustments including records of reimbursements and recoveries due to network pharmacies and beneficiaries; and</li> <li>• Deductible files/ TrOOP/ and gross covered prescription drug cost accumulator.</li> </ul>		
<p>7. Applicant has a robust testing process that will identify and correct any plan configuration errors prior to implementation.</p>		
<p>8. Applicant uses HIPAA compliant transactions where applicable.</p>		
<p>9. Applicant documents the manner and extent to which it has tested benefit designs such as drug exclusions or quantity limitations and plan parameters such as co-payments and benefit intervals (phases).</p>		
<p>10. Applicant rapidly adopts any new messaging approved by the NCPDP Workgroup to adjudicate a Part D claim and appropriately coordinate benefits in real time.</p>		
<p>11. Applicant regularly updates their systems with the most current information on sanctioned providers and has processes in place to identify and prevent payment of Part D claims at point-of-sale when such claims have been prescribed by excluded providers.</p>		
<p>12. Applicant assigns and exclusively uses unique Part D identifiers (RxBin or RxBin/RxPCN) for each individual Part D member.</p>		
<p>13. Applicant agrees when it receives information that necessitates a retroactive claims adjustment, the applicant processes the adjustment and issues refunds or recovery notices within 45 days of the applicant's receipt of complete information regarding the claims adjustment.</p>		

### 3.22 Premium Billing 42 CFR §423.293; CMS issued guidance 03/08/2007

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
1. Applicant takes steps to ensure that members are not over billed or double billed for their monthly premiums. The Applicant will promptly refund members when billing errors occur.		
2. Applicant agrees it cannot prevent excessive billing when a member exercises their right to have Social Security withholding and has a secondary payer (e.g., SPAP) paying part of their premium. In such cases the Applicant promptly reimburses members for overpayments.		
3. Applicant does not direct bill a member when the member is already in Premium Withholding status until the status change with both CMS and SSA has been confirmed.		
4. Applicant agrees that when a member is in Premium Withholding status and the withheld amount has not been issued by CMS in the monthly plan payments, the Applicant resolves the matter with CMS not with the member.		

### 3.23 Consumer Assessment of Healthcare Providers and Systems (CAHPS) Survey Administration 42 CFR §423.156

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
1. Applicant agrees once its enrollment is more than 600 enrollees (as of July in the preceding contract year), it will contract with an approved CAHPS survey vendor and pay for the CAHPS data collection costs.		
2. Applicant agrees to abide by CMS guidance to the process for contracting with approved CAHPS survey vendors.		

**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 Part D contract.

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Authorized Representative Name (printed)

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Title



Authorized Representative Signature

Date (MM/DD/YYYY)

## **5 APPENDICES**

## APPENDIX I – Attestation for Employer/Union-Only Group Waiver Plans (800-Series)

### DESIGNATION OF APPLICATION AS “800 SERIES” EGWP ONLY (NO INDIVIDUAL PLANS WILL BE OFFERED)

*Checking the box below is optional. Only check the box below if you are applying to only offer “800 series” plans under this contract (no plans to individual beneficiaries will be offered). Do not check the box below if you intend to offer plans to individual beneficiaries and “800 series” plans under this contract number.*

☐ I am hereby designating this application as one which will only offer “800 series” plans. No plans will be offered to individual Medicare beneficiaries under this contract number.

{Entity MUST complete if it is applying to only offer “800 series” EGWPs (no plans will be offered to individual Medicare beneficiaries under this contract number).}

**EGWP Attestation for Contract \_\_\_\_\_**

#### 1. EGWP SERVICE AREA & PHARMACY ACCESS REQUIREMENTS

PDP Sponsor Applicants may provide coverage to employer group members wherever they reside (i.e., nationwide). However, in order to provide coverage to retirees wherever they reside, PDP Sponsor Applicants must set their service areas to include all areas where retirees may reside during the plan year (i.e., set national service areas).

##### ***New PDP Sponsors Offering Individual and “800 Series” Plans – Pharmacy Access:***

PDP Sponsors will not initially be required to have retail and other pharmacy networks in place for those designated EGWP service areas outside of their individual plan service areas. However, in accordance with employer group waiver pharmacy access policy, pharmacy access sufficient to meet the needs of enrollees must be in place once the PDP Sponsor enrolls members of an employer or union group residing in particular geographic locations outside of its individual plan service area.

##### ***New PDP Sponsors Only Offering “800 Series” Plans – Pharmacy Access:***

PDP Sponsors only offering “800 series” plans (i.e., no plans will be offered to individual Medicare beneficiaries under this contract number) will be required to submit retail and other pharmacy access information (mail order, home infusion, long-term care, I/T/U) for the entire defined EGWP service area during the application process and demonstrate sufficient access in these areas in accordance with employer group waiver pharmacy access policy.

☐ I certify that I am an authorized representative, officer, chief executive officer, or general partner of the business organization that is applying for qualification to offer employer/union-only group waiver plans in association with my organization’s Prescription Drug Plan Contract with CMS. I have read, understand, and agree to comply with the above statement about service areas and pharmacy access. If I need further information, I will contact one of the individuals listed in the instructions for this application.

{Entity MUST complete for a complete application.}

## 2. CERTIFICATION

This appendix, along with the underlying *2013 Solicitation for Applications for New Prescription Drug Plans (PDP) Sponsors*, comprises the entire “800 series” EGWP application for PDP Sponsor. All provisions of the *2013 Solicitation for Applications for New Prescription Drug Plans (PDP) Sponsors* apply to all employer/union-only group waiver plan benefit packages offered by PDP Sponsor except where the provisions are specifically modified and/or superseded by particular employer/union-only group waiver guidance, including those waivers/modifications set forth below (specific sections of the *2013 Solicitation for Applications for New Prescription Drug Plans (PDP) Sponsor* that have been waived or modified for new PDP Sponsor Applicants are noted in parentheses).

For existing PDP Sponsors, this appendix comprises the entire “800 series” EGWP application for PDP Sponsor. All provisions of the PDP Sponsor’s existing contract with CMS apply to all employer/union-group waiver plan benefit packages offered by PDP Sponsor except where the provisions are specifically modified and/or superseded by particular employer/union-only group waiver guidance, including those waivers/modifications set forth below.

### **I, the undersigned, certify to the following:**

- 1) Applicant is applying to offer new employer/union-only group waiver (“800 series”) prescription drug plans (PDPs) and agrees to be subject to and comply with all CMS employer/union-only group waiver guidance.

In order for new PDP Sponsors to be eligible for the CMS employer group waiver that allows PDP Sponsors to offer employer/union-only group waiver plan benefit packages without offering plans to individual beneficiaries, Applicant must complete the underlying *2013 Solicitation for Applications for New Prescription Drug Plans (PDP) Sponsors* in addition to this appendix.

In order for new PDP Sponsors to be eligible for the CMS employer group waiver that allows PDP Sponsors to offer employer/union-only group waiver plan benefit packages without offering plans to individual beneficiaries, Applicant must be licensed in at least one state. (Section 3.1.2B)

Applicant understands and agrees that it is not required to submit a 2013 Part D bid (i.e., bid pricing tool) to offer its employer/union-only group waiver plans. (Section 3.2.6A1)

In order for new PDP Sponsors to be eligible for the CMS employer group waiver that allows PDP Sponsors to offer employer/union-only group waiver plan benefit packages without offering plans to individual beneficiaries, Applicant understands and agrees that as part of its completion of the *2013 Solicitation for Applications for New Prescription Drug Plan (PDP) Sponsors*, it submits retail pharmacy lists and other pharmacy access submissions (mail order, home infusion, long-term

care, I/T/U) required at the time of application in Section 3.4 for its entire designated service area. (Section 3.4)

PDP Sponsor Applicants applying to offer employer/union-only group waiver plans and plans to individual beneficiaries understand and agree that they are not initially required to have networks in place for those designated EGWP service areas outside of their individual plan service areas or submit retail pharmacy and other pharmacy access submissions (mail order, home infusion, long-term care, I/T/U) required in Section 3.4 for its designated EGWP service area. However, access sufficient to meet the needs of enrollees must be in place once an Applicant enrolls members of an employer or union group residing in particular geographic locations outside of its individual plan service area. (Section 3.4)

- 2) In order to be eligible for the CMS retail pharmacy access waiver of 42 CFR §423.120(a)(1), Applicant attests that its retail pharmacy network is sufficient to meet the needs of its enrollees throughout the employer/union-only group waiver PDP's service area, including situations involving emergency access, as determined by CMS. Applicant acknowledges and understands that CMS may review the adequacy of the Applicant's pharmacy networks and potentially require expanded access in the event of beneficiary complaints or for other reasons it determines in order to ensure that the Applicant's network is sufficient to meet the needs of its employer group population. (Section 3.4.1A)
- 3) Applicant agrees to restrict enrollment in its employer/union-only group waiver PDPs to those Part D eligible individuals eligible for the employer's/union's employment-based retiree prescription drug coverage. (Section 3.5A3)
- 4) Applicant understands that its employer/union-only group waiver PDPs are not included in the processes for auto-enrollment (for full-dual eligible beneficiaries) or facilitated enrollment (for other low income subsidy eligible beneficiaries). (Section 3.5A4)
- 5) Applicant understands that its employer/union-only group waiver plans are not subject to the requirements contained in 42 CFR §423.48 to submit information to CMS, including the requirements to submit information (e.g., pricing and pharmacy network information) to be publicly reported on [www.medicare.gov](http://www.medicare.gov) and the Medicare Plan Finder. (Sections 3.7A and 3.16A17)
- 6) Applicant understands that dissemination materials for its employer/union-only group waiver PDPs are not subject to the requirements contained in 42 CFR §423.128 to be submitted for review and approval by CMS prior to use. However, Applicant agrees to submit these materials to CMS at the time of use in accordance with the procedures outlined in Chapter 12 of the Prescription Drug Benefit Manual. Applicant also understands CMS reserves the right to review these materials in the event of beneficiary complaints or for any other reason it determines to ensure the information accurately and adequately informs Medicare beneficiaries about their rights and obligations under the plan. (Section 3.13A1)
- 7) Applicant understands that its employer/union-only group waiver PDPs is not subject to the requirements regarding the timing for issuance of certain dissemination materials, such as the Annual Notice of Change/ Evidence of Coverage (ANOC/EOC), Summary of Benefits

(SB), Formulary, and LIS rider when an employer's or union's open enrollment period does not correspond to Medicare's Annual Coordinated Election Period. For these employers and unions, the timing for issuance of the above dissemination materials should be appropriately based on the employer/union sponsor's open enrollment period. For example, the Annual Notice of Change/Evidence of Coverage (ANOC/EOC), Summary of Benefits (SB), LIS rider, and Formulary are required to be received by beneficiaries no later than 15 days before the beginning of the employer/union group health plan's open enrollment period. The timing for other dissemination materials that are based on the start of the Medicare plan (i.e., calendar) year should be appropriately based on the employer/union sponsor's plan year. (Section 3.13A12)

- 8) Applicant understands that the dissemination requirements set forth in 42 CFR §423.128 do not apply to its employer/union-only group waiver PDPs when the employer/union sponsor is subject to alternative disclosure requirements (e.g., the Employee Retirement Income Security Act of 1974 ("ERISA")) and complies with such alternative requirements. Applicant complies with the requirements for this waiver contained in employer/union-only group waiver guidance, including those requirements contained in Chapter 12 of the Prescription Drug Benefit Manual. (Sections 3.13A1-A2, A10)
- 9) Applicant understands that its employer/union-only group waiver plans is not subject to the Part D beneficiary customer service call center hours and call center performance requirements. Applicant ensures that a sufficient mechanism is available to respond to beneficiary inquiries and provides customer service call center services to these members during normal business hours. However, CMS may review the adequacy of these call center hours and potentially require expanded beneficiary customer service call center hours in the event of beneficiary complaints or for other reasons in order to ensure that the entity's customer service call center hours are sufficient to meet the needs of its enrollee population. (Section 3.13A7)
- 10) Applicant understands that CMS has waived the requirement that the employer/union-only group waiver plans must provide beneficiaries the option to pay their premium through Social Security withholding. Thus, the premium withhold option is not available for enrollees in Applicant's employer/union-only group waiver plans. (Sections 3.5A20 and 3.23A2-A4)
- 11) This Certification is deemed to incorporate any changes that are required by statute to be implemented during the term of the contract, and any regulations and policies implementing or interpreting such statutory provisions.
- 12) 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 CMS immediately and in writing.
- 13) 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.
- 14) 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.

**15)** 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 comply with such guidance at the time of the application submission date.

☐ I certify that I am an authorized representative, officer, chief executive officer, or general partner of the business organization that is applying for qualification to offer employer/union-only group waiver plans ("800 series" EGWPs) in association with my organization's PDP Contract with CMS. I have read and agree to comply with the above certifications.

{Entity MUST check box for a complete application.}

{Entity MUST create 800-series PBPs during plan creation and designate EGWP service areas.}

## APPENDIX II—Direct Contract PDP Attestation

Direct Contract PDP Attestations For Contract \_\_\_\_\_

### 1. SERVICE AREA & PHARMACY ACCESS REQUIREMENTS

In general, Part D plans can only cover beneficiaries in the service areas in which they are licensed and approved by CMS to offer benefits. CMS has waived this requirement for Direct Contract PDP Sponsors. Direct Contract PDP Sponsors can extend coverage to all of their retirees, regardless of whether they reside in one or more other PDP regions in the nation. In order to provide coverage to retirees wherever they reside, Direct Contract PDP Sponsors must set their service areas to include all areas where retirees may reside during the plan year (**no mid-year service area expansions will be permitted**). Applicants are required to submit retail and other pharmacy access information (mail order, home infusion, long-term care, I/T/U) for the entire defined service area during the application process and demonstrate sufficient access in these areas in accordance with employer group waiver pharmacy access policy.

☐ I certify that I am an authorized representative, officer, chief executive officer, or general partner of the business organization that is applying for qualification to offer employer/union-only Direct Contract PDP. I have read, understand, and agree to comply with the above statement about service areas and pharmacy access. If I need further information, I will contact one of the individuals listed in the instructions for this application.  
{Entity MUST complete for a complete application.}

### 2. CERTIFICATION

All provisions of the underlying *2013 Solicitation for Applications for New Prescription Drug Plans (PDP) Sponsors* apply to all plan benefit packages offered by PDP Sponsor except where the provisions are specifically modified and/or superseded by particular employer/union-only group waiver guidance, including those waivers/modifications set forth below (specific sections of the underlying application that have been waived or modified for new PDP Sponsor Applicants are noted in parentheses).

**I, the undersigned, certify to the following:**

- 1) Applicant is applying to offer new employer/union Direct Contract prescription drug plans (PDPs) and agrees to be subject to and comply with all CMS employer/union-only group waiver guidance.
- 2) Applicant must complete and submit the underlying 2013 Solicitation for Applications for New Prescription Drug Plans (PDP) Sponsors in addition to this Appendix in its entirety. The 2013 Solicitation for Applications for New Prescription Drug Plans (PDP) Sponsors along with the Appendix entitled “Part D Financial Solvency & Capital Adequacy Documentation” and this attestation comprise a new Direct Contract PDP Sponsor Applicant’s entire application.
- 3) A Part D Sponsor must be organized and licensed under State law as a risk-bearing entity eligible to offer health insurance or health benefits coverage in each State in which it offers its coverage (42 CFR §423.504(b)(2)). However, CMS has waived the state licensing requirement for all Direct Contract PDP Sponsors along with the requirement to be a nongovernmental legal entity (42 CFR §423.4). As a condition of this waiver, Applicant



meets the financial solvency and capital adequacy standards contained in the Appendix entitled “Part D Financial Solvency and Capital Adequacy Documentation” of this application. (Sections 3.1.1A1 and 3.1.2)

- 4) Applicant is not required to submit a 2013 Part D bid (i.e., bid pricing tool) to offer its Direct Contract PDP. (Section 3.2.6A1)
- 5) Applicant restricts enrollment in its Direct Contract PDP to those Part D eligible individuals eligible for the Direct Contract PDP’s employment-based retiree prescription drug coverage. Applicant does not enroll active employees into its Direct Contract PDP. (Sections 3.5A3)
- 6) In order to be eligible for the CMS retail pharmacy access waiver of 42 CFR §423.120(a)(1), Applicant attests that its retail pharmacy network is sufficient to meet the needs of its enrollees throughout the Direct Contract PDP’s service area, including situations involving emergency access, as determined by CMS. Applicant acknowledges and understands that CMS reviews the adequacy of the Applicant’s pharmacy networks and may potentially require expanded access in the event of beneficiary complaints or for other reasons it determines in order to ensure that the Applicant’s network is sufficient to meet the needs of its employer group population. (Section 3.4.1A1)
- 7) Applicant understands and agrees that as part of its completion of the underlying 2013 Solicitation for Applications for New Prescription Drug Plans (PDP) Sponsors, submits retail pharmacy access and other pharmacy access submissions (mail order, home infusion, long-term care, I/T/U) required at the time of application in Section 3.4 for its entire designated service area. (Section 3.4)
- 8) Applicant understands that its Direct Contract PDP is not included in the processes for auto-enrollment (for full-dual eligible beneficiaries) or facilitated enrollment (for other low income subsidy eligible beneficiaries). (Sections 3.2.6A2 and 3.5A4)
- 9) Applicant understands that CMS has waived the requirement that the Direct Contract PDP provide beneficiaries the option to pay their premium through Social Security withholding. Thus, the premium withhold option is not available for enrollees in Applicant’s Direct Contract PDP. (Sections 3.5.A20 and 3.23A2-A4)
- 10) Applicant understands that dissemination materials for its Direct Contract PDP are not subject to the requirements contained in 42 CFR §423.128 to be submitted for review and approval by CMS prior to use. However, Applicant agrees to submit these materials to CMS at the time of use in accordance with the procedures outlined in Chapter 12 of the Prescription Drug Benefit Manual. Applicant also understands that CMS reserves the right to review these materials in the event of beneficiary complaints or for any other reason it determines to ensure the information accurately and adequately informs Medicare beneficiaries about their rights and obligations under the plan. (Section 3.13A1)
- 11) Applicant understands that its Direct Contract PDP is not subject to the requirements regarding the timing for issuance of certain dissemination materials, such as the Annual Notice of Change/ Evidence of Coverage (ANOC/EOC), Summary of Benefits (SB), Formulary, and LIS rider when an employer’s or union’s open enrollment period does not correspond to Medicare’s Annual Coordinated Election Period. For these employers and unions, the timing for issuance of the above dissemination materials should be appropriately based on the employer/union sponsor’s open enrollment period. For example, the Annual

Notice of Change/Evidence of Coverage (ANOC/EOC), Summary of Benefits (SB), LIS rider, and Formulary are required to be received by beneficiaries no later than 15 days before the beginning of the employer/union group health plan's open enrollment period. The timing for other dissemination materials that are based on the start of the Medicare plan (i.e., calendar) year should be appropriately based on the employer/union sponsor's plan year. (Section 3.13A12)

- 12)** Applicant understands that the dissemination requirements set forth in 42 CFR §423.128 do not apply to its Direct Contract PDP when the employer/union sponsor is subject to alternative disclosure requirements (e.g., the Employee Retirement Income Security Act of 1974 ("ERISA")) and complies with such alternative requirements. Applicant complies with the requirements for this waiver contained in employer/union-only group waiver guidance, including those requirements contained in Chapter 12 of the Prescription Drug Benefit Manual. (Sections 3.13A1-A2, A10)
- 13)** Applicant understands that its Direct Contract PDP is not subject to the requirements contained in 42 CFR §423.48 to submit information to CMS, including the requirements to submit information (e.g., pricing and pharmacy network information) to be publicly reported on [www.medicare.gov](http://www.medicare.gov) and the Medicare Plan Finder. (Sections 3.7A and 3.16A17)
- 14)** Applicant understands that its Direct Contract PDP is not subject to the Part D beneficiary customer service call center hours and call center performance requirements. Applicant has a sufficient mechanism available to respond to beneficiary inquiries and provides customer service call center services to these members during normal business hours. However, CMS may review the adequacy of these call center hours and potentially require expanded beneficiary customer service call center hours in the event of beneficiary complaints or for other reasons in order to ensure that the entity's customer service call center hours are sufficient to meet the needs of its enrollee population. (Section 3.13A7)
- 15)** Applicant understands that the management and operations requirements of 42 CFR §423.504(b)(4)(i)-(iii) are waived if the employer or union (or to the extent applicable, the business associate with which it contracts for prescription drug benefit services) is subject to ERISA fiduciary requirements or similar state or federal law standards. However, Applicant understands that it (or its business associates) are not relieved from the record retention standards applicable to other Part D Sponsors set forth in 42 CFR §423.505(d). (Section 3.20A1-A3)
- 16)** In general, Part D plan Sponsors must report certain information to CMS, to their enrollees, and to the general public (such as the cost of their operations and financial statements) under 42 CFR §423.514(a). Applicant understands that in order to avoid imposing additional and possibly conflicting public disclosure obligations that would hinder the offering of employer sponsored group plans, CMS modifies these reporting requirements for Direct Contract PDPs to allow information to be reported to enrollees and to the general public to the extent required by other law (including ERISA or securities laws), or by contract. (Section 3.16.A15-A16)
- 17)** This Certification is deemed to incorporate any changes that are required by statute to be implemented during the term of the contract, and any regulations and policies implementing or interpreting such statutory provisions.

- 18)** 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 CMS immediately and in writing.
- 19)** 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.
- 20)** 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.
- 21)** 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 at the time of the application submission date.
- ☐ I certify that I am an authorized representative, officer, chief executive officer, or general partner of the business organization that is applying for qualification to offer employer/union-only Direct Contract plans in association with my organization's PDP Contract with CMS. I have read and agree to comply with the above certifications.

{Entity MUST check box for a complete application.}

## APPENDIX III -- Part D Financial Solvency & Capital Adequacy Documentation

(For Direct PDP Contract applicants only)

### Background and Instructions:

A PDP Sponsor generally must be licensed by at least one state as a risk-bearing entity (42 CFR §423.401(a)(1)). CMS has waived the requirement for Direct Contract PDP Sponsors. Direct Contract PDP Sponsors are not required to be licensed, but must meet CMS Part D financial solvency and capital adequacy requirements. Each Direct Contract PDP Sponsor Applicant must demonstrate that it meets the requirements set forth in this Appendix and provide all required information set forth below. CMS may in its discretion approve, on a case-by-case basis, waivers of such requirements upon a demonstration from the Direct Contract PDP Sponsor Applicant that its fiscal soundness is commensurate with its financial risk and that through other means the entity can assure that claims for benefits paid for by CMS and beneficiaries will be covered. In all cases, CMS requires that the employer's/union's contracts and sub-contracts provide beneficiary hold harmless provisions.

The information required in this Appendix must be submitted electronically through HPMS as a supporting documentation upload to the Licensure and Solvency section of the Part D supporting file section in accordance with the instructions contained in this application.

### **I. EMPLOYER/UNION ORGANIZATIONAL INFORMATION**

#### **A. Complete the information in the table below.**

<b>IDENTIFY YOUR ORGANIZATION BY PROVIDING THE FOLLOWING INFORMATION:</b>
Organization's Full Legal Name:
Full Address of Your Organization's Headquarters ( <i>Street, City, State, Zip</i> ):
Type of Entity (place a checkmark in <u>all</u> applicable boxes):  <input type="checkbox"/> Employer  <input type="checkbox"/> Fund established by one or more employers or labor organizations  <input type="checkbox"/> Union  <input type="checkbox"/> Government

<input type="checkbox"/> Church Group <input type="checkbox"/> Publicly-Traded Corporation <input type="checkbox"/> Privately- Held Corporation <input type="checkbox"/> Other (list type) _____	
Name of Your Organization's Parent Organization, if any:	
Is Applicant subject to ERISA? <input type="checkbox"/> Yes <input type="checkbox"/> No	Tax Status: <input type="checkbox"/> For Profit <input type="checkbox"/> Not-for-Profit
State in Which your Organization is Incorporated or Otherwise Organized to do Business:	

## B. Summary Description

Briefly describe the organization in terms of its history and its present operations. Cite significant aspects of its current financial, general management, and health services delivery activities. Please include the following:

1.
2.
3.
4.



health benefit plan services) is subject to ERISA fiduciary requirements or similar state or federal laws and standards. However, such entities (or their business associates) are not relieved from the record retention standards applicable to other PDP Sponsors. In accordance with the terms of this waiver, please provide the following information:

1. List the members of the organization's policymaking body (name, position, address, telephone number, occupation, term of office and term expiration date). Indicate whether any of the members are employees of the Applicant.
2. If the Applicant is a line of business versus a legal entity, does the Board of Directors of the corporation serve as the policymaking body of the organization? If not, describe the policymaking body and its relationship to the corporate Board.
3. Does the Federal Government or a State regulate the composition of the policymaking body? If yes, please identify all Federal and State regulations that govern your policymaking body (e.g., ERISA).

## **II. FINANCIAL DOCUMENTATION**

### **A. Minimum Net Worth: \$1.5 Million - Documentation of Minimum Net Worth**

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

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

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

### **B. Liquidity**

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

1. In determining the ability of a Direct Contract PDP Applicant 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 remedies:
- a) If a PDP Sponsor fails to pay obligations as they become due, CMS will require the PDP Sponsor to initiate corrective action to pay all overdue obligations.
  - 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 outside resources, CMS will require the PDP Sponsor to obtain funding from alternative financial resources.

### **C. Methods of Accounting**

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

### **D. Bonding and Insurance**

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

### **E. Additional Information**

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

1. **Self-Insurance/Self Funding:** If the Direct Contract PDP Applicant's health plan(s) are self-insured or self-funded, it must forward proof of stop-loss coverage (if any) through copies of policy declarations.



2. **Trust:** If the Direct Contract PDP Applicant maintains one or more trusts with respect to its health plan(s), a copy of the trust documents, and if the trust is intended to meet the requirements of Section 501(c)(9) of the Internal Revenue Code, the most recent IRS approval letter.
3. **Forms 5500 and M-1:** The two most recent annual reports on Forms 5500 and M-1 (to the extent applicable) for the Direct Contract PDP Applicant's health plans that cover prescription drugs for retirees that are Part D eligible individuals.
4. **ERISA Section 411(a) Attestation:** Each applicant (including an applicant that is exempt from ERISA) must provide a signed attestation that no person serves as a fiduciary, administrator, trustee, custodian, counsel, agent, employee, consultant, adviser or in any capacity that involves decision-making authority, custody, or control of the assets or property of any employee benefit plan sponsored by the Direct Contract PDP Applicant if he or she has been convicted of, or has been imprisoned as a result of his or her conviction of, one of the felonies set forth in ERISA Section 411(a), for 13 years after such conviction or imprisonment (whichever is later).
5. **Defined Benefit Pension Plan:** If the Direct Contract PDP Applicant sponsors one or more defined benefit pension plans (within the meaning of ERISA Section 3(35)) that is subject to the requirements of Title IV of ERISA, the latest actuarial report for each such plan.
6. **Multi-Employer Pension Plan:** If the Direct Contract PDP Applicant is a contributing employer with respect to one or more multi-employer pension plans within the meaning of ERISA Section 3(37), the latest estimate of contingent withdrawal liability.
7. **Tax-Exempt Applicants Only:** A copy of the most recent IRS tax-exemption.

### III. INSOLVENCY REQUIREMENTS

#### A. Hold Harmless and Continuation of Coverage/Benefits

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

#### B. Insolvency Deposit

A Direct Contract PDP Applicant generally must forward confirmation of its establishment and maintenance of an insolvency deposit of at least \$100,000, to be held in accordance with CMS requirements by a qualified U. S. Financial Institution. A "qualified financial institution" means an institution that:

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

A Direct Contract PDP Applicant may request a waiver in writing of this requirement.

#### **IV. GUARANTEES (only applies to an Applicant that utilizes a Guarantor)**

##### **A. General Policy**

A Direct Contract PDP Applicant, or the legal entity of which the Direct Contract PDP Applicant is a component, may apply to CMS to use the financial resources of a Guarantor for the purpose of meeting the requirements of a Direct Contract PDP Applicant set forth above. CMS has the sole discretion to approve or deny the use of a Guarantor.

##### **B. Request to Use a Guarantor**

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

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

##### **C. Requirements for Guarantor**

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

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

##### **D. Guarantee Document**

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

1. State the financial obligation covered by the guarantee;

2. Agree to:

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

**E. Ongoing Guarantee Reporting Requirements**

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

**F. Modification, Substitution, and Termination of a Guarantee**

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

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

**G. Nullification**

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

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

**V. ONGOING REPORTING REQUIREMENTS**

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

## APPENDIX IV – Federal Waiver of State Licensure

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: <i>(Street, City, State, Zip – No Post Office Boxes):</i>	
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: <i>(Street, City, State, Zip – No Post Office Boxes):</i>	
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 1, 2011. 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 V – Financial Solvency Documentation for Applicant Not Licensed as a Risk-bearing Entity in Any State**

(For individual market applicants only)

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.
- (a) "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.

- (b) The letter of credit also shall indicate that it is not subject to any condition or qualifications any other agreement, documents or entities.
  - (c) 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.
  - (d) 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:

- (i) 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:
  - (a) 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
  - (b) Resources to cover 100% of any projected losses, if the business plan projects losses greater than 7.5% of the aggregated projected target amount.
- (ii) The applicant must upload in HPMS with the application, a worksheet calculating the aggregated projected target amount as defined above.
- (iii) 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.
3. 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 waived 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: Net worth means the excess of total admitted assets over total liabilities, but the liabilities shall not include fully subordinated debt.
      - (i) 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.
      - (ii) 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).
2. In addition, the PDP Sponsor shall submit an annual independently audited financial statement with management letter.
3. 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) 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.
4. 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.

## **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.

## **APPENDIX VI—Organization Background and Structure**

Instructions: Applicants must complete and upload in HPMS the following information.

### **A. Legal Entity Background**

Date Legal Entity Established: \_\_\_\_\_

State of Incorporation

(Applicant must upload proof of incorporation, such as articles of incorporation or a certificate of good standing from the state of incorporation.)

### **B. Management of Legal Entity**

Identify the staff with legal authority to sign/enter into contracts on behalf of the legal entity

Identify all covered persons of the legal entity. “Covered persons”, as defined at 42 CFR §§423.507(a)(4), 423.508(f), and 423.510(e)(2), include:

- All owners of nonrenewed or terminated organizations who are natural persons, other than shareholders who have an ownership interest of less than 5 percent;
- An owner of a whole or part interest in a mortgage, deed of trust, note, or other obligation secured (in whole or in part) by the organization, or by any property or assets thereof, which whole or part interest is equal to or exceeds 5 percent of the total property and assets of the organization; and
- A member of the board of directors or board of trustees of the entity, if the organization is organized as a corporation.

### **C. Parent Organization Information**

Name of Parent Organization

Date Parent Organization established

### **D. Organizational Charts**

Provide an organizational chart of the legal entity’s parent organization, affiliates, subsidiaries and related entities.

Provide an organizational chart solely of the internal structure of the legal entity by department (i.e., marketing, compliance, pharmacy network/contracting, and claims adjudication). Do not provide the internal structure of the parent organization.

## **APPENDIX VII – Crosswalks of Section 3.1.1D Requirements in Subcontracts submitted as Attachments to Section 3.1.1**

**INSTRUCTIONS:** Applicants must complete and upload in HPMS the following chart for each contract/administrative services agreement submitted under Section 3.1.1D.

Applicants must identify where specifically (i.e., the pdf page number) in each contract/administrative services agreement the following elements are found.

<b>Section</b>	<b>Requirement</b>	<b>Location in Subcontract by Page number and Section</b>
3.1.1D1	The parties to the contract	
3.1.1D2	The functions to be performed by the first tier, downstream, or related entity. Describe the reporting requirements the first tier, downstream, or related entity identified in Section 3.1.1C of the application has to the applicant. 42 CFR §423.505(i)(4)(i)	
3.1.1D3	Language clearly indicating that the first tier, downstream, or related entity has agreed to participate in your Medicare Prescription Drug Benefit program (except for a network pharmacy if the existing contract would allow participation in this program).	
3.1.1D4	Contains flow-down clauses requiring the first tier, downstream, or related entity's activities to be consistent and comply with the Applicant's contractual obligations as a Part D sponsor. 42 CFR §423.505(i)(3)(iii)	
3.1.1D5	The payment the first tier, downstream, or related entity will receive for performance under the contract, if applicable.	
3.1.1D6	Are for a term of at least the one-year contract period for which application is submitted. Note: Where the contract is for services or products to be used in preparation for the next contract year's Part D operations (marketing, enrollment), the initial term of such contract must include this period of performance (e.g., contracts for enrollment-related services must have a term beginning no later than October 15 extending through the full contract year ending on December 31 of the next year).	

3.1.1D7	Are signed by a representative of each party with legal authority to bind the entity.	
3.1.1D8	Language obligating the first tier, downstream, or related entity to abide by all applicable Federal laws and regulations and CMS instructions. 42 CFR §423.505(i)(4)(iv)	
3.1.1D9	Language obligating the first tier, downstream, or related entity to abide by State and Federal privacy and security requirements, including the confidentiality and security provisions stated in the regulations for the program at 42 CFR §423.136.	
3.1.1D10	Language ensuring that the first tier, downstream, or related entity will make its books and other records available in accordance with 42 CFR 423.505(e)(2) and 42 CFR 423.505(i)(2). Generally stated these regulations give HHS, the Comptroller General, or their designees the right to audit, evaluate and inspect any books, contracts, records, including medical records and documentation involving transactions related to CMS' contract with the Part D sponsor and that these rights continue for a period of 10 years from the final date of the contract period or the date of audit completion, whichever is later. 42 CFR §423.505	
3.1.1D11	Language stating that the first tier, downstream, or related entity will ensure that beneficiaries are not held liable for fees that are the responsibility of the Applicant. 42 CFR §423.505(i)(3)(i)	
3.1.1D12	Language ensuring that if the Applicant, upon becoming a Part D sponsor, delegates an activity or responsibility to the first tier, downstream, or related entity, that such activity or responsibility may be revoked if CMS or the Part D sponsor determines the first tier, downstream, or related entity has not performed satisfactorily. Note: The contract/administrative services agreement may include remedies in lieu of revocation to address this requirement. 42 CFR §423.505(i)(4)(ii)	
3.1.1D13	Language specifying that the Applicant, upon becoming a Part D sponsor, will monitor the performance of the first tier, downstream, or related entity on an ongoing basis. 42 CFR §423.505(i)(4)(iii)	



3.1.1D14	Language that the Part D sponsor retains the right to approve, suspend, or terminate any arrangement with a pharmacy if the first tier, downstream, or related entity will establish the pharmacy network or select pharmacies to be included in the network. 42 CFR §423.505(i)(5)	
3.1.1D15	Language that if the first tier, downstream, or related entity will establish the pharmacy network or select pharmacies to be included in the network contain language that payment to such pharmacies (excluding long-term care and mail order) shall be issued, mailed, or otherwise transmitted with respect to all clean claims submitted by or on behalf of pharmacies within 14 days for electronic claims and within 30 days for claims submitted otherwise. 42 CFR §423.505(i)(3)(vi)	
3.1.1D16	Language that if the first tier, downstream, or related entity will establish the pharmacy network or select pharmacies to be included in the network and a prescription drug pricing standard is used for reimbursement, identifies the source used by the Part D sponsor for the prescription drug pricing standard of reimbursement. 42 CFR §423.505(i)(3)(viii)(B)	
3.1.1D17	If the first tier, downstream, or related entity will establish the pharmacy network or select pharmacies to be included in the network and a prescription drug pricing standard is used for reimbursement, a provision requiring that updates to such a standard occur not less frequently than once every 7 days beginning with an initial update on January 1 of each year, to accurately reflect the market price of acquiring the drug. 42 CFR §423.505(i)(3)(viii)(A)	
3.1.1D18	If the first tier, downstream, or related entity will establish the pharmacy network or select pharmacies to be included in the network, language requiring the network pharmacies to submit claims to the Part D sponsor or first tier, downstream or related entity whenever the membership ID card is presented or on file at the pharmacy unless the enrollee expressly requests that a particular claim not be submitted. 42 CFR §423.120(c)(3)	

3.1.1D19	Language that if the first tier, downstream, or related entity will adjudicate and process claims at the point of sale and/or negotiate with prescription drug manufacturers and others for rebates, discounts, or other price concessions on prescription drugs contain language requiring that the first tier, downstream, or related entity will comply with the reporting requirements established in Section 6005 of the Affordable Care Act.	
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## APPENDIX VIII – Crosswalk for Retail Pharmacy Access Contracts

<b>INSTRUCTIONS:</b> Applicants must complete and upload in HPMS the following chart (which contains applicable Section 3.11D requirements AND additional requirements specific to Pharmacy Access) for each Retail pharmacy contract template submitted under Section 3.4. Applicants must identify where <u>specifically</u> (i.e., the .pdf page number) in each contract template the following elements are found.		
<b>The provisions listed below must be in all pharmacy contracts. If contracts reference policies and procedures to which the pharmacy must comply, provide the relevant documentation as evidence and cite this documentation accordingly.</b>		
Section	Requirement	Citation
3.1.1D2	The functions to be performed by the first tier, downstream, or related entity. Describes the reporting requirements the first tier, downstream, or related entity identified in Section 3.1.1C of the application has to the Applicant. 42 CFR §423.505(i)(4)(i)	
3.1.1D8	Language obligating the first tier, downstream, or related entity to abide by all applicable Federal laws and regulations and CMS instructions. 42 CFR §423.505(i)(4)(iv)	
3.1.1D9	Language obligating the first tier, downstream, or related entity to abide by State and Federal privacy and security requirements, including the confidentiality and security provisions stated in the regulations for the program at 42 CFR §423.136.	
3.1.1D10	Language ensuring that the first tier, downstream, or related entity will make its books and other records available in accordance with 42 CFR 423.505(e)(2) and 42 CFR 423.505(i)(2). Generally stated these regulations give HHS, the Comptroller General, or their designees the right to audit, evaluate and inspect any books, contracts, records, including medical records and documentation involving transactions related to CMS' contract with the Part D sponsor and that these rights continue for a period of 10 years from the final date of the contract period or the date of audit completion, whichever is later. 42 CFR §423.505	

3.1.1D11	Language stating that the first tier, downstream, or related entity will ensure that beneficiaries are not held liable for fees that are the responsibility of the Applicant. 42 CFR §423.505(i)(3)(i)	
3.1.1D12	Language ensuring that if the Applicant, upon becoming a Part D sponsor, delegates an activity or responsibility to the first tier, downstream, or related entity, that such activity or responsibility may be revoked if CMS or the Part D sponsor determines the first tier, downstream, or related entity has not performed satisfactorily. Note: The contract may include remedies in lieu of revocation to address this requirement. 42 CFR §423.505(i)(4)(ii)	
3.1.1D13	Language specifying that the Applicant, upon becoming a Part D sponsor, will monitor the performance of the first tier, downstream, or related entity on an ongoing basis. 42 CFR §423.505(i)(4)(iii)	
3.1.1D15	Provisions requiring that payment shall be issued, mailed or otherwise transmitted with respect to all clean claims submitted by or on behalf of pharmacies within 14 days for electronic claims and within 30 days for claims submitted otherwise. 42 CFR §423.505(i)(3)(vi)	
3.1.1D16	For those contracts that use a prescription drug pricing standard for reimbursement, a provision indicating the source used by the Part D sponsor for the prescription drug pricing standard of reimbursement. 42 CFR §423.505(i)(3)(viii)(B)	
3.1.1D17	For those contracts that use a prescription drug pricing standard for reimbursement, a provision that updates to such a standard occur not less frequently than once every 7 days beginning with an initial update on January 1 of each year, to accurately reflect the market price of acquiring the drug. 42 CFR §423.505(i)(3)(viii)(A)	
3.1.1D18	Language requiring the network pharmacy to submit claims to the Part D sponsor or first tier, downstream or related entity whenever the membership ID card is presented or on file at the pharmacy unless the enrollee expressly requests that a particular claim not be submitted. 42 CFR §423.120(c)(3)	

3.4A3	Provisions governing submitting claims to a real-time claims adjudication system. 42 CFR §423.505(j) and §423.505(b)(17)  Note: Applicant may indicate for I/T/U pharmacies and for certain pharmacies that are allowed to submit claims in the X 12 format that these may be batch processed.	
3.4A4	Provisions governing providing Part D enrollees access to negotiated prices as defined in 42 CFR 423.100. 42 CFR §423.104(g)	
3.4A5	Provisions regarding charging/applying the correct cost-sharing amount. 42 CFR §423.104	
3.4A6	Provisions governing informing the Part D enrollee at the point of sale (or at the point of delivery for mail order drugs) of the lowest-priced, generically equivalent drug, if one exists for the beneficiary's prescription, as well as any associated differential in price. 42 CFR §423.132	

## APPENDIX IX – Crosswalk for Mail Order Pharmacy Access Contracts

<b>INSTRUCTIONS:</b> Applicants must complete and upload in HPMS the following chart (which contains applicable Section 3.1.1D requirements AND additional requirements specific to Pharmacy Access) for each Mail Order pharmacy contract template submitted under Section 3.4. Applicants must identify where <u>specifically</u> (i.e., the .pdf page number) in each contract template the following elements are found.		
<b>The provisions listed below must be in all pharmacy contracts. If contracts reference policies and procedures with which the pharmacy must comply, provide the relevant documentation as evidence and cite this documentation accordingly.</b>		
Section	Requirement	Citation
3.1.1D2	The functions to be performed by the first tier, downstream, or related entity, and describes the reporting requirements the first tier, downstream, or related entity identified in Section 3.1.1C of the application has to the Applicant. 42 CFR §423.505(i)(4)(i)	
3.1.1D8	Language obligating the first tier, downstream, or related entity to abide by all applicable Federal laws and regulations and CMS instructions. 42 CFR §423.505(i)(4)(iv)	
3.1.1D9	Language obligating the first tier, downstream, or related entity to abide by State and Federal privacy and security requirements, including the confidentiality and security provisions stated in the regulations for the program at 42 CFR §423.136.	
3.1.1D10	Language ensuring that the first tier, downstream, or related entity will make its books and other records available in accordance with 42 CFR 423.505(e)(2) and 42 CFR 423.505(i)(2). Generally stated these regulations give HHS, the Comptroller General, or their designees the right to audit, evaluate and inspect any books, contracts, records, including medical records and documentation involving transactions related to CMS' contract with the Part D sponsor and that these rights continue for a period of 10 years from the final date of the contract period or the date of audit completion,	

	whichever is later. 42 CFR §423.505	
3.1.1D11	Language stating that the first tier, downstream, or related entity will ensure that beneficiaries are not held liable for fees that are the responsibility of the Applicant. 42 CFR §423.505(i)(3)(i)	
3.1.1D12	Language ensuring that if the Applicant, upon becoming a Part D sponsor, delegates an activity or responsibility to the first tier, downstream, or related entity, that such activity or responsibility may be revoked if CMS or the Part D sponsor determines the first tier, downstream, or related entity has not performed satisfactorily. Note: The contract may include remedies in lieu of revocation to address this requirement. 42 CFR §423.505(i)(4)(ii)	
3.1.1D13	Language specifying that the Applicant, upon becoming a Part D sponsor, will monitor the performance of the first tier, downstream, or related entity on an ongoing basis. 42 CFR §423.505(i)(4)(iii)	
3.1.1D16	For those contracts that use a prescription drug pricing standard for reimbursement, a provision indicating the source used by the Part D sponsor for the prescription drug pricing standard of reimbursement. 42 CFR §423.505(i)(3)(viii)(B)	
3.1.1D17	For those contracts that use a prescription drug pricing standard for reimbursement, a provision that updates to such a standard occur not less frequently than once every 7 days beginning with an initial update on January 1 of each year, to accurately reflect the market price of acquiring the drug. 42 CFR §423.505(i)(3)(viii)(A)	
3.1.1D18	Language requiring the network pharmacy to submit claims to the Part D sponsor or first tier, downstream or related entity whenever the membership ID card is presented or on file at the pharmacy unless the enrollee expressly requests that a particular claim not be submitted. 42 CFR	

	§423.120(c)(3)	
3.4A3	<p>Provisions governing submitting claims to a real-time claims adjudication system. 42 CFR §423.505(j) and §423.505(b)(17)</p> <p>Note: Applicant may indicate for I/T/U pharmacies and for certain pharmacies that are allowed to submit claims in the X 12 format that these may be batch processed.</p>	
3.4A4	Provisions governing providing Part D enrollees access to negotiated prices as defined in 42 CFR 423.100. 42 CFR §423.104(g)	
3.4A5	Provisions regarding charging/applying the correct cost-sharing amount. 42 CFR §423.104	
3.4A6	Provisions governing informing the Part D enrollee at the point of sale (or at the point of delivery for mail order drugs) of the lowest-priced, generically equivalent drug, if one exists for the beneficiary's prescription, as well as any associated differential in price. 42 CFR §423.132	



## APPENDIX X – Crosswalk for Home Infusion Pharmacy Access Contracts

<b>INSTRUCTIONS:</b> Applicants must complete and upload in HPMS the following chart (which contains applicable Section 3.1.1D requirements AND additional requirements specific to Pharmacy Access) for each Home Infusion pharmacy contract template submitted under Section 3.4. Applicants must identify where <u>specifically</u> (i.e., the .pdf page number) in each contract template the following elements are found.		
<b>The provisions listed below must be in all pharmacy contracts. If contracts reference policies and procedures with which the pharmacy must comply, provide the relevant documentation as evidence and cite this documentation accordingly.</b>		
Section	Requirement	Citation
3.1.1D2	The functions to be performed by the first tier, downstream, or related entity, and describes the reporting requirements the first tier, downstream, or related entity identified in Section 3.1.1C of the application has to the Applicant. 42 CFR §423.505(i)(4)(i)	
3.1.1D8	Language obligating the first tier, downstream, or related entity to abide by all applicable Federal laws and regulations and CMS instructions. 42 CFR §423.505(i)(4)(iv)	
3.1.1D9	Language obligating the first tier, downstream, or related entity to abide by State and Federal privacy and security requirements, including the confidentiality and security provisions stated in the regulations for the program at 42 CFR §423.136.	
3.1.1D10	Language ensuring that the first tier, downstream, or related entity will make its books and other records available in accordance with 42 CFR 423.505(e)(2) and 42 CFR 423.505(i)(2). Generally stated these regulations give HHS, the Comptroller General, or their designees the right to audit, evaluate and inspect any books, contracts, records, including medical records and documentation involving transactions related to CMS' contract with the Part D sponsor and that these rights continue for a period of 10 years from the final date of the contract period or the date of audit completion, whichever is later. 42 CFR §423.505	

3.1.1D11	Language stating that the first tier, downstream, or related entity will ensure that beneficiaries are not held liable for fees that are the responsibility of the Applicant. 42 CFR §423.505(i)(3)(i)	
3.1.1D12	Language ensuring that if the Applicant, upon becoming a Part D sponsor, delegates an activity or responsibility to the first tier, downstream, or related entity, that such activity or responsibility may be revoked if CMS or the Part D sponsor determines the first tier, downstream, or related entity has not performed satisfactorily. Note: The contract may include remedies in lieu of revocation to address this requirement. 42 CFR §423.505(i)(4)(ii)	
3.1.1D13	Language specifying that the Applicant, upon becoming a Part D sponsor, will monitor the performance of the first tier, downstream, or related entity on an ongoing basis. 42 CFR §423.505(i)(4)(iii)	
3.1.1D15	Provisions requiring that payment shall be issued, mailed or otherwise transmitted with respect to all clean claims submitted by or on behalf of pharmacies within 14 days for electronic claims and within 30 days for claims submitted otherwise. 42 CFR §423.505(i)(3)(vi)	
3.1.1D16	For those contracts that use a standard for reimbursement, a provision indicating the source used by the Part D sponsor for the standard of reimbursement. 42 CFR §423.505(i)(3)(viii)(B)	
3.1.1D17	For those contracts that use a standard for reimbursement, a provision that updates to such a standard occur not less frequently than once every 7 days beginning with an initial update on January 1 of each year, to accurately reflect the market price of acquiring the drug. 42 CFR §423.505(i)(3)(viii)(A)	
3.1.1D18	Language requiring the network pharmacy to submit claims to the Part D sponsor or first tier, downstream or related entity whenever the membership ID card is presented or on file at the pharmacy unless the enrollee expressly requests that a particular claim not be submitted. 42 CFR §423.120(c)(3)	

3.4A3	Provisions governing submitting claims to a real-time claims adjudication system. 42 CFR §423.505(j) and §423.505(b)(17)  Note: Applicant may indicate for I/T/U pharmacies and for certain pharmacies that are allowed to submit claims in the X 12 format that these may be batch processed.	
3.4A4	Provisions governing providing Part D enrollees access to negotiated prices as defined in 42 CFR 423.100. 42 CFR §423.104(g)	
3.4A5	Provisions regarding charging/applying the correct cost-sharing amount. 42 CFR §423.104	
3.4A6	Provisions governing informing the Part D enrollee at the point of sale (or at the point of delivery for mail order drugs) of the lowest-priced, generically equivalent drug, if one exists for the beneficiary's prescription, as well as any associated differential in price. 42 CFR §423.132	
3.4.4A5	Provisions ensuring that before dispensing home infusion drugs, pharmacy ensures that the professional services and ancillary supplies are in place.423.120(a)(4)(iii)	
3.4.4A6	Provisions ensuring that a pharmacy that delivers home infusion drugs provides delivery of home infusion drugs within 24 hours of discharge from an acute care setting, or later if so prescribed. 423.120(a)(4)(iv)	

## APPENDIX XI – Crosswalk for Long-Term Care Pharmacy Access Contracts

<b>INSTRUCTIONS:</b> Applicants must complete and upload in HPMS the following chart (which contains applicable Section 3.1.1D requirements AND additional requirements specific to Pharmacy Access) for each Long-Term Care pharmacy contract template submitted under Section 3.4. Applicants must identify where <u>specifically</u> (i.e., the .pdf page number) in each contract template the following elements are found.		
<b>The provisions listed below must be in all pharmacy contracts. If contracts reference policies and procedures with which the pharmacy must comply, provide the relevant documentation as evidence and cite this documentation accordingly.</b>		
Section	Requirement	Citation
3.1.1D2	The functions to be performed by the first tier, downstream, or related entity, and describes the reporting requirements the first tier, downstream, or related entity identified in 3.1.1C of the application has to the Applicant. 42 CFR §423.505(i)(4)(i)	
3.1.1D8	Language obligating the first tier, downstream, or related entity to abide by all applicable Federal laws and regulations and CMS instructions. 42 CFR §423.505(i)(4)(iv)	
3.1.1D9	Language obligating the first tier, downstream, or related entity to abide by State and Federal privacy and security requirements, including the confidentiality and security provisions stated in the regulations for the program at 42 CFR §423.136. 42 CFR §423.136	
3.1.1D10	Language ensuring that the first tier, downstream, or related entity will make its books and other records available in accordance with 42 CFR 423.505(e)(2) and 42 CFR 423.505(i)(2). Generally stated these regulations give HHS, the Comptroller General, or their designees the right to audit, evaluate and inspect any books, contracts, records, including medical records and documentation involving transactions related to CMS' contract with the Part D sponsor and that these rights continue for a period of 10 years from the final date of the contract period or the date of audit completion, whichever is later. 42 CFR §423.505	

3.1.1D11	Language stating that the first tier, downstream, or related entity will ensure that beneficiaries are not held liable for fees that are the responsibility of the Applicant. 42 CFR §423.505(i)(3)(i)	
3.1.1D12	Language ensuring that if the Applicant, upon becoming a Part D sponsor, delegates an activity or responsibility to the first tier, downstream, or related entity, that such activity or responsibility may be revoked if CMS or the Part D sponsor determines the first tier, downstream, or related entity has not performed satisfactorily. Note: The contract may include remedies in lieu of revocation to address this requirement. 42 CFR §423.505(i)(4)(ii)	
3.1.1D13	Language specifying that the Applicant, upon becoming a Part D sponsor, will monitor the performance of the first tier, downstream, or related entity on an ongoing basis. 42 CFR §423.505(i)(4)(iii)	
3.1.1D16	For those contracts that use a standard for reimbursement, a provision indicating the source used by the Part D sponsor for the standard of reimbursement. 42 CFR §423.505(i)(3)(viii)(B)	
3.1.1D17	For those contracts that use a standard for reimbursement, a provision that updates to such a standard occur not less frequently than once every 7 days beginning with an initial update on January 1 of each year, to accurately reflect the market price of acquiring the drug. 42 CFR §423.505(i)(3)(viii)(A)	
3.1.1D18	Language requiring the network pharmacy to submit claims to the Part D sponsor or first tier, downstream or related entity whenever the membership ID card is presented or on file at the pharmacy unless the enrollee expressly requests that a particular claim not be submitted. 42 CFR 423.120(c)(3)	
3.4A3	Provisions governing submitting claims to a real-time claims adjudication system. 42 CFR §423.505(j) and §423.505(b)(17)  Note: Applicant may indicate for I/T/U pharmacies and for certain pharmacies that are allowed to submit claims in the X 12 format that these may be batch processed.	
3.4A4	Provisions governing providing Part D enrollees access to negotiated prices as defined in 42 CFR 423.100. 42 CFR §423.104(g)	

3.4A5	Provisions regarding charging/applying the correct cost-sharing amount. 42 CFR §423.104	
3.4A6	Provisions governing informing the Part D enrollee at the point of sale (or at the point of delivery for mail order drugs) of the lowest-priced, generically equivalent drug, if one exists for the beneficiary's prescription, as well as any associated differential in price. 42 CFR §423.132	
	Provide that long-term care pharmacies must have not less than 30 days, nor more than 90 days, to submit to the Part D Sponsor claims for reimbursement under the plan. 42 CFR § 423.504(b)(20)	
	Provisions requiring that long-term care pharmacies dispense drugs and report information as required by 42 CFR §423.154.	
<b>Elements Specific to Long-Term Care Contracts</b> Note: CMS Long-Term Care Guidance included in Chapter 5 of the Prescription Drug Benefit Manual contains an updated list of performance and service criteria for contracting with long-term care pharmacies. Applicants must, at a minimum, incorporate these criteria in ALL LTC pharmacy network contracts.		
<b>Performance and Service Criteria</b>		<b>Citation</b>
<i>Comprehensive Inventory and Inventory Capacity</i> – Network Long Term Care Pharmacies [NLTCPs] must provide a comprehensive inventory of Plan formulary drugs commonly used in the long term care setting. In addition, NLTCPs must provide a secured area for physical storage of drugs, with necessary added security as required by federal and state law for controlled substances. This is not to be interpreted that the pharmacy will have inventory or security measures outside of the normal business setting.		
<i>Pharmacy Operations and Prescription Orders</i> -- NLTCPs must provide services of a dispensing pharmacist to meet the requirements of pharmacy practice for dispensing prescription drugs to LTC residents, including but not limited to the performance of drug utilization review (DUR). In addition, the NLTCP pharmacist must conduct DUR to routinely screen for allergies and drug interactions, to identify potential adverse drug reactions, to identify inappropriate drug usage in the LTC population, and to promote cost effective therapy in the LTC setting. The NLTCP must also be equipped with pharmacy software and systems sufficient to meet the needs of prescription drug ordering and distribution to an LTC facility. Further, the		

<p>NLTCP must provide written copies of the NLTCP's pharmacy procedures manual and said manual must be available at each LTC facility nurses' unit. NLTCPs are also required to provide ongoing in-service training to assure that LTC facility staff is proficient in the NLTCP's processes for ordering and receiving of medications. NLTCP must be responsible for return and/or disposal of unused medications following discontinuance, transfer, discharge, or death as permitted by State Boards of Pharmacy. Controlled substances and out of date substances must be disposed of within State and Federal guidelines.</p>	
<p><i>Special Packaging</i> -- NLTCPs must have the capacity to provide specific drugs in Unit of Use Packaging, Bingo Cards, Cassettes, Unit Dose or other special packaging commonly required by LTC facilities. NLTCPs must have access to, or arrangements with, a vendor to furnish supplies and equipment including but not limited to labels, auxiliary labels, and packing machines for furnishing drugs in such special packaging required by the LTC setting.</p>	
<p><i>IV Medications</i> -- NLTCPs must have the capacity to provide IV medications to the LTC resident as ordered by a qualified medical professional. NLTCPs must have access to specialized facilities for the preparation of IV prescriptions (clean room). Additionally, NLTCPs must have access to or arrangements with a vendor to furnish special equipment and supplies as well as IV trained pharmacists and technicians as required to safely provide IV medications.</p>	
<p><i>Compounding /Alternative Forms of Drug Composition</i> -- NLTCPs must be capable of providing specialized drug delivery formulations as required for some LTC residents. Specifically, residents unable to swallow or ingest medications through normal routes may require tablets split or crushed or provided in suspensions or gel forms, to facilitate effective drug delivery.</p>	
<p><i>Pharmacist On-call Service</i> -- NLTCP must provide on-call, 24 hours a day, 7 days a week service with a qualified pharmacist available for handling calls after hours and to provide medication dispensing available for emergencies, holidays and after hours of normal operations.</p>	
<p><i>Delivery Service</i> -- NLTCP must provide for delivery of medications to the LTC facility up to seven days each week (up to three times per day) and in-between regularly scheduled visits. Emergency delivery service must be available 24 hours a day, 7 days a week. Specific delivery arrangements will be determined through an agreement between the NLTCP and the LTC facility. NLTCPs must provide safe and secure exchange systems for delivery of medication to the LTC facility. In addition, NLTCP must provide medication cassettes, or other standard delivery systems, that may be exchanged on a routine basis for automatic restocking. The NLTCP</p>	

delivery of medication to carts is a part of routine “dispensing”.	
<i>Emergency Boxes</i> -- NLTCPs must provide “emergency” supply of medications as required by the facility in compliance with State requirements.	
<i>Emergency Log Books</i> -- NLTCP must provide a system for logging and charging medication used from emergency/first dose stock. Further, the pharmacy must maintain a comprehensive record of a resident’s medication order and drug administration.	
<i>Miscellaneous Reports, Forms and Prescription Ordering Supplies</i> -- NLTCP must provide reports, forms and prescription ordering supplies necessary for the delivery of quality pharmacy care in the LTC setting. Such reports, forms and prescription ordering supplies may include, but will not necessarily be limited to, provider order forms, monthly management reports to assist the LTC facility in managing orders, medication administration records, treatment administration records, interim order forms for new prescription orders, and boxes/folders for order storage and reconciliation in the facility.	



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

**INSTRUCTIONS:** Applicants must complete and upload in HPMS the following chart (which contains applicable Section 3.1.1D requirements AND additional requirements specific to Pharmacy Access) for each I/T/U pharmacy contract template submitted under Section 3.4. Applicants must identify where specifically (i.e., the .pdf page number) in each contract template the following elements are found.

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

Section	Requirement	Citation
3.1.1D2	The functions to be performed by the first tier, downstream, or related entity, and describes the reporting requirements the first tier, downstream, or related entity identified in Section 3.1.1C of the application has to the Applicant. 42 CFR §423.505(i)(4)(i)	
3.1.1D8	Language obligating the first tier, downstream, or related entity to abide by all applicable Federal laws and regulations and CMS instructions. 42 CFR §423.505(i)(4)(iv)	
3.1.1D9	Language obligating the first tier, downstream, or related entity to abide by State and Federal privacy and security requirements, including the confidentiality and security provisions stated in the regulations for the program at 42 CFR §423.136.	
3.1.1D10	Language ensuring that the first tier, downstream, or related entity will make its books and other records available in accordance with 42 CFR 423.505(e)(2) and 42 CFR 423.505(i)(2). Generally stated these regulations give HHS, the Comptroller General, or their designees the right to audit, evaluate and inspect any books, contracts, records, including medical records and documentation involving transactions related to CMS' contract with the Part D sponsor and that these rights continue for a period of 10 years from the final date of the contract period or the date of audit completion, whichever is later. 42 CFR §423.505	

3.1.1D11	Language stating that the first tier, downstream, or related entity will ensure that beneficiaries are not held liable for fees that are the responsibility of the Applicant. 42 CFR §423.505(i)(3)(i)	
3.1.1D12	Language ensuring that if the Applicant, upon becoming a Part D sponsor, delegates an activity or responsibility to the first tier, downstream, or related entity, that such activity or responsibility may be revoked if CMS or the Part D sponsor determines the first tier, downstream, or related entity has not performed satisfactorily. Note: The contract may include remedies in lieu of revocation to address this requirement. 42 CFR §423.505(i)(4)(ii)	
3.1.1D13	Language specifying that the Applicant, upon becoming a Part D sponsor, will monitor the performance of the first tier, downstream, or related entity on an ongoing basis. 42 CFR §423.505(i)(4)(iii)	
3.1.1D15	Provisions requiring that payment shall be issued, mailed or otherwise transmitted with respect to all clean claims submitted by or on behalf of pharmacies within 14 days for electronic claims and within 30 days for claims submitted otherwise. 42 CFR §423.505(i)(3)(vi)	
3.1.1D16	For those contracts that use a standard for reimbursement, a provision indicating the source used by the Part D sponsor for the standard of reimbursement. 42 CFR §423.505(i)(3)(viii)(B)	
3.1.1D17	For those contracts that use a standard for reimbursement, a provision that updates to such a standard occur not less frequently than once every 7 days beginning with an initial update on January 1 of each year, to accurately reflect the market price of acquiring the drug.42 CFR §423.505(i)(3)(viii)(A)	
3.1.1D18	Language requiring the network pharmacy to submit claims to the Part D sponsor or first tier, downstream or related entity whenever the membership ID card is presented or on file at the pharmacy unless the enrollee expressly requests that a particular claim not be submitted. 42 CFR §423.120(c)(3)	

3.4A3	Provisions governing submitting claims to a real-time claims adjudication system. 42 CFR §423.505(j) and §423.505(b)(17)  Note: Applicant may indicate for I/T/U pharmacies and for certain pharmacies that are allowed to submit claims in the X 12 format that these may be batch processed.	
3.4A4	Provisions governing providing Part D enrollees access to negotiated prices as defined in 42 CFR 423.100. 42 CFR §423.104(g)	
3.4A5	Provisions regarding charging/applying the correct cost-sharing amount. 42 CFR §423.104	
<b>Elements Specific to Indian Tribe and Tribal Organization, and Urban Indian Organization (I/T/U) Pharmacy Contracts</b>  <b>Note: Provisions listed below are in the model I/T/U Addendum, located at Appendix XV and at <a href="http://www.cms.gov/10_RxContracting_SpecialGuidance.asp#TopOfPage">www.cms.gov/10_RxContracting_SpecialGuidance.asp#TopOfPage</a> and all I/T/U Contracts must contain language consistent with the model addendum that addresses the following.</b>		
Item 1	Supersession of the addendum from underlying agreement.	
Item 3	The description of the provider.	
Item 4	Counting of costs paid for by provider toward any deductibles.	
Item 5	Persons eligible for services of the provider.	
Item 6	The applicability of certain Federal law.	
Item 7	The non-taxable status of the provider.	
Item 8	Insurance and indemnification.	
Item 9	Applicability of state licensing law to provider's employees.	
Item 10	Provider eligibility for payments	

Item 11	Dispute resolution.	
Item 12	Federal law as the governing law.	
Item 13	The contract will apply to all pharmacies and dispensaries operated by the provider.	
Item 14	The contract will not affect the provider's acquisition of pharmaceuticals.	
Item 15	The provider's point of sale processing capabilities.	
Item 16	Claims processing.	
Item 17	Reasonable and appropriate payment rates.	
Item 18	Any information, outreach or enrollment materials prepared by the Applicant will be supplied at no cost to the provider.	
Item 19	The provider determines the hours of service for the pharmacies or dispensaries of the provider.	
Item 20	Endorsement	
Item 21	Sovereign Immunity	

## **APPENDIX XIII – Applicant Submission of P&T Committee Member List and Certification Statement**

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

### **I. P&T Committee Member Disclosure to CMS**

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

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

### **II. Instructions to Plans and PBMs**

- A.** If the Part D Applicant sub-contracts with a PBM for its P&T Committee and operates under a Confidentiality Agreement (such that its members are not disclosed to the Part D Applicant) then the Applicant must (1) complete the attached Certification in HPMS, and (2) forward the attached P&T Committee Member Disclosure form to the sub-contracted PBM and direct the PBM to submit the form to CMS by February 21, 2012. The PBM should email the P&T Committee Member Disclosure form to the following email box: [drugbenefitimpl@cms.hhs.gov](mailto:drugbenefitimpl@cms.hhs.gov).
- B.** In the event of any future changes to the membership of the Part D Sponsor's P&T Committee or the PBM's P&T Committee, Part D Sponsors must (or in the case of a confidentiality agreement the Part D Sponsor) assure that the PBM will notify the appropriate CMS account manager (to be assigned at a future date) and make the

correct changes in HPMS on the Contract Management/Part D Data page within 30 days of the effective date of such change.

### III. PHARMACY AND THERAPEUTICS COMMITTEE MEMBER DISCLOSURE

PBM must email the following form to [drugbenefitimpl@cms.hhs.gov](mailto:drugbenefitimpl@cms.hhs.gov) by February 21, 2012.

Name of Part D Plan or PBM: \_\_\_\_\_

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

Contact Person: \_\_\_\_\_

Phone Number: \_\_\_\_\_

Email: \_\_\_\_\_

#### A. Complete the table below.

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

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

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

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

ADDITIONAL ROWS AS NECESSARY.		
Organization Name	Type of Application	Contract Number(s)

Applicant must upload in HPMS:

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

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

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

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

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

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

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

I agree that CMS may inspect the records and premises of my organization or my subcontractor (first tier, downstream and related entities) to ensure compliance with the statements to which I have attested above.

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



Part D Applicant's Contract Number: \_\_\_\_\_

\_\_\_\_\_  
Authorized Representative Name (printed)

\_\_\_\_\_  
Title

\_\_\_\_\_  
Authorized Representative Signature

\_\_\_\_\_  
Date (MM/DD/YYYY)

## **APPENDIX XIV – I/T/U Revised Addendum**

Note: All Part D sponsors will be required to use the attached revised version of the I/T/U Addendum.

### **Indian Health Addendum to Medicare Part D Plan Agreement**

#### **1. Purpose of Indian Health Addendum; Supersession.**

The purpose of this Indian Health Addendum is to apply special terms and conditions to the agreement by and between \_\_\_\_\_ (herein “Part D Sponsor”) and \_\_\_\_\_ (herein “Provider”) for administration of Medicare Prescription Drug Benefit program at pharmacies and dispensaries of Provider authorized by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, and implementing regulations in Parts 403, 411, 417, 422, and 423 of Title 42, Code of Federal Regulations. To the extent that any provision of the Part D Sponsor’s agreement or any other addendum thereto is inconsistent with any provision of this Indian Health Addendum, the provisions of this Indian Health Addendum shall supersede all such other provisions.

#### **2. Definitions.**

For purposes of the Part D Plan Sponsor's agreement, any other addendum thereto, and this Indian Health Addendum, the following terms and definitions shall apply:

(a) The term "Part D Plan Sponsor" means a nongovernmental entity that is certified under 42 CFR 417.472, 42 CFR Part 423 or 42 CFR Part 422 as meeting the requirements and standards that apply to entities that offer Medicare Part D plans.

(b) The terms "Part D Plan" means prescription drug coverage that is offered under a policy, contract, or plan that has been approved as specified in 42 CFR 423.272, 42 CFR 422.502 or 42 CFR 417.472 and that is offered by a PDP sponsor that has a contract with the Centers for Medicare and Medicaid Services that meets the contract requirements under subpart K of 42 CFR Part 423 or subpart K of 42 CFR Part 422.

(c) The term "Provider" means the Indian Health Service (IHS) and all pharmacies and dispensaries operated by the IHS, or an Indian tribe, tribal organization or urban Indian organization which operates one or more pharmacies or dispensaries, and is identified by name in Section 1 of this Indian Health Addendum.

(d) The term "Centers for Medicare and Medicaid Services" means the agency of that name within the U.S. Department of Health and Human Services.

(e) The term "Indian Health Service" means the agency of that name within the U.S. Department of Health and Human Services established by Sec. 601 of the Indian Health Care Improvement Act (“IHCIA”), 25 USC §1661.

(f) The term "Indian tribe" has the meaning given that term in Sec. 4 of the IHCIA, 25 USC §1603.

(g) The term "tribal organization" has the meaning given than term in Sec. 4 of the IHCA, 25 USC §1603.

(h) The term "urban Indian organization" has the meaning given that term in Sec. 4 of the IHCA, 25 USC §1603.

(i) The term "Indian" has the meaning given to that term in Sec. 4 of the IHCA, 25 USC §1603.

(j) The term "dispensary" means a clinic where medicine is dispensed by a prescribing provider.

### **3. Description of Provider.**

The Provider identified in Section 1 of this Indian Health Addendum is (check appropriate box):

☐ IHS operated health care facilities located within the geographic area covered by the Provider Agreement, including hospitals, health centers and one or more pharmacies or dispensaries ("IHS Provider"). Where an IHS Provider operates more than one pharmacy or dispensary all such pharmacies and dispensaries are covered by this Addendum.

☐ An Indian tribe that operates a health program, including one or more pharmacies or dispensaries, under a contract or compact with the Indian Health Service issued pursuant to the Indian Self-Determination and Education Assistance Act, 25 USC §450 *et seq.*

☐ A tribal organization authorized by one or more Indian tribes to operate a health program, including one or more pharmacies or dispensaries, under a contract or compact with the Indian Health Service issued pursuant to the Indian Self-Determination and Education Assistance Act, 25 USC §450 *et seq.*

☐ An urban Indian organization that operates a health program, including one or more pharmacies or dispensaries, under a grant from the Indian Health Service issued pursuant to Title V of the IHCA.

### **4. Deductibles; Annual Out-of-Pocket Threshold.**

The cost of pharmaceuticals provided at a pharmacy or dispensary of Provider or paid for by the Provider through a referral to a retail pharmacy shall count toward the deductible and the annual out-of-pocket threshold applicable to an IHS beneficiary enrolled in a Part D Plan.

### **5. Persons eligible for services of Provider.**

(a) The parties agree that the IHS Provider is limited to serving eligible IHS beneficiaries pursuant to 42 CFR Part 136 and section 813(a) and (b) of the IHCA, 25 USC §1680(a) and (b), who are also eligible for Medicare Part D services pursuant to Title XVIII, Part D of the Social Security Act and 42 CFR Part 423. The IHS Provider

may provide services to non-IHS eligible persons only under certain circumstances set forth in IHClA section 813(c) and in emergencies under section 813(d ) of the IHClA.

(b) The parties agree that the persons eligible for services of the Provider who is an Indian tribe or a tribal organization or a Provider who is an urban Indian organization shall be governed by the following authorities:

- (1) Title XVIII, Part D of the Social Security Act and 42 CFR Part 423;
- (2) IHClA sections 813, 25 USC §1680c;
- (3) 42 CFR Part 136; and
- (4) The terms of the contract, compact or grant issued to the Provider by the IHS for operation of a health program.

(c) No clause, term or condition of the Part D Plan Sponsor's agreement or any addendum thereto shall be construed to change, reduce, expand or alter the eligibility of persons for services of the Provider under the Part D Plan that is inconsistent with the authorities identified in subsection (a) or (b).

## **6. Applicability of other Federal laws.**

Federal laws and regulations affecting a Provider include but are not limited to the following:

(a) An IHS provider:

- (1) The Anti-Deficiency Act 31 U.S.C. § 1341;
- (2) The Indian Self Determination and Education Assistance Act ("ISDEAA"); 25 USC § 450 *et seq.*;
- (3) The Federal Tort Claims Act ("FTCA"), 28 U.S.C. § 2671-2680;
- (4) The Federal Medical Care Recovery Act, 42 U.S.C. §§ 2651-2653;
- (5) The Federal Privacy Act of 1974 ("Privacy Act"), 5 U.S.C. § 552a, 45 CFR Part 5b;
- (6) Confidentiality of Alcohol and Drug Abuse Patient Records, 42 CFR Part 2;
- (7) The Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), 45 CFR Parts 160 and 164; and
- (8) The IHClA, 25 U.S.C. § 1601 *et seq.*

(b) A Provider who is an Indian tribe or a tribal organization:

- (1) The ISDEAA, 25 USC §450 *et seq.*;
- (2) The IHClA, 25 USC §1601, *et seq.*;
- (3) The FTCA, 28 USC §§2671-2680;
- (4) The Privacy Act, 5 USC §552a and regulations at 45 CFR Part 5b;

- (5) The HIPAA and regulations at 45 CFR parts 160 and 164; and
- (6) Sec. 206(e)(3) of the IHClA, 25 USC § 1624e(e)(3), regarding recovery from tortfeasors.

(c) A Provider who is an urban Indian organization:

- (1) The IHClA, 25 USC §1601, *et seq.*;
- (2) The Privacy Act, 5 USC §552a and regulations at 45 CFR Part 5b;
- (3) The HIPAA and regulations at 45 CFR parts 160 and 164; and
- (4) Sec. 206(e)(3) of the IHClA, 25 USC §1621e(e)(3), regarding recovery from tortfeasors, as made applicable to urban Indian organizations by Sec. 206(i) of the IHClA.

## **7. Non-taxable entity.**

To the extent the Provider is a non-taxable entity, the Provider shall not be required by a Part D Plan Sponsor to collect or remit any Federal, State, or local tax.

## **8. Insurance and indemnification.**

(a) As an IHS provider, FTCA coverage obviates the requirement that IHS carry private malpractice insurance as the United States consents to be sued in place of federal employees for any damages to property or for personal injury or death caused by the negligence or wrongful act or omission of federal employees acting within the scope of their employment. 28 U.S.C. § 2671-2680. Nothing in the Part D Plan Sponsor's Agreement shall be interpreted to authorize or obligate any IHS employee to perform any act outside the scope of his/her employment. The IHS Provider shall not be required to acquire insurance, provide indemnification, or guarantee that the Plan will be held harmless from liability.

(b) A Provider which is an Indian tribe or a tribal organization shall not be required to obtain or maintain professional liability insurance to the extent such Provider is covered by the Federal Tort Claims Act (FTCA) pursuant to Federal law (Pub.L. 101-512, Title III, §314, as amended by Pub.L. 103-138, Title III, §308 (codified at 25 USC §450 F note); and regulations at 25 CFR Part 900, Subpt. M. To the extent a Provider that is an urban Indian organization is covered by the FTCA pursuant to section 224(g)-(n) of the Public Health Service Act, as amended by the Federally Supported Health Centers Assistance Act, Pub.L. 104-73, (codified at 42 USC §233(g)-(n)) and regulations at 42 CFR Part 6, such Provider shall not be required to obtain or maintain professional liability insurance. Further, nothing in the Part D Plan Sponsor's agreement or any addendum thereto shall be interpreted to authorize or obligate Provider or any employee of such Provider to operate outside of the scope of employment of such employee, and Provider shall not be required to indemnify the Part D Plan Sponsor.

## **9. Licensure.**

(a) States may not regulate the activities of IHS-operated pharmacies nor require that the IHS pharmacists be licensed in the State where they are providing services, whether the IHS employee is working at an IHS-operated facility or has been assigned to a pharmacy or dispensary of a tribe, tribal organization, or urban Indian organization. The parties agree that during the term of the Part D Plan Sponsor's Agreement, IHS pharmacists shall hold state licenses in accordance with applicable federal law, and that the IHS facilities where the pharmacies and dispensaries are located shall be accredited in accordance with federal statutes and regulations. During the term of the Part D Plan Sponsor's Agreement, the parties agree to use the IHS facility's Drug Enforcement Agency (DEA) number consistent with federal law.

(b) Federal law (Sec. 221 of the IHClA) provides that a pharmacist employed directly by a Provider that is an Indian tribe or tribal organization is exempt from the licensing requirements of the state in which the tribal health program is located, provided the pharmacist is licensed in any state. Federal law (Sec. 408 of the IHClA) further provides that a health program operated by an Indian tribe or tribal organization shall be deemed to have met a requirement for a license under state or local law if such program meets all the applicable standards for such licensure, regardless of whether the entity obtains a license or other documentation under such state or local law. The parties agree that these federal laws apply to the Part D Plan Sponsor's Agreement and any addenda thereto. This provision shall not be interpreted to alter the requirement that a pharmacy hold a license from the Drug Enforcement Agency.

(c) To the extent that any directly hired employee of an urban Indian Provider is exempt from State regulation, such employee shall be deemed qualified to perform services under the Part D Plan Sponsor's agreement and all addenda thereto, provided such employee is licensed to practice pharmacy in any State. Federal law (Sec. 408 of the IHClA) provides that a health program operated by an urban Indian organization shall be deemed to have met a requirement for a license under state or local law if such program meets all the applicable standards for such licensure, regardless of whether the entity obtains a license or other documentation under such state or local law. This provision shall not be interpreted to alter the requirement that a pharmacy hold a license from the Drug Enforcement Agency.

## **10. Provider eligibility for payments.**

To the extent that the Provider is exempt from State licensing requirements, the Provider shall not be required to hold a State license to receive any payments under the Part D Plan Sponsor's agreement and any addendum thereto.

## **11. Dispute Resolution.**

**a. For IHS Provider.** In the event of any dispute arising under the Participating Part D Plan Sponsor's Agreement or any addendum thereto, the parties agree to meet and confer in good faith to resolve any such disputes. The laws of the United States shall apply to any problem or dispute hereunder that cannot be resolved by and

between the parties in good faith. Notwithstanding any provision in the Part D Plan Sponsor's Agreement or any addendum thereto to the contrary, IHS shall not be required to submit any disputes between the parties to binding arbitration.

**b. For Tribal and Urban Providers.** In the event of any dispute arising under the Participating Part D Plan Sponsor's Agreement or any addendum thereto, the parties agree to meet and confer in good faith to resolve any such disputes. Any dispute hereunder that cannot be resolved by and between the parties in good faith shall be submitted to the dispute resolution procedure pursuant to the Participating Part D Plan Sponsor's Agreement.

## **12. Governing Law.**

The Part D Plan Sponsor's agreement and all addenda thereto shall be governed and construed in accordance with Federal law of the United States. In the event of a conflict between such agreement and all addenda thereto and Federal law, Federal law shall prevail. Nothing in the Part D Plan Sponsor's agreement or any addendum thereto shall subject an Indian tribe, tribal organization, or urban Indian organization to State law to any greater extent than State law is already applicable.

## **13. Pharmacy/Dispensary Participation.**

The Part D Plan Sponsor's agreement and all addenda thereto apply to all pharmacies and dispensaries operated by the Provider, as listed on the attached Schedule ----- to this Indian Health Addendum. A pharmacy is required to use a National Provider Identifier (NPI) number.

## **14. Acquisition of Pharmaceuticals.**

Nothing in the Part D Plan Sponsor's agreement and all addenda thereto shall affect the Provider's acquisition of pharmaceuticals from any source, including the Federal Supply Schedule and participation in the Drug Pricing Program of Section 340B of the Public Health Service Act. Nor shall anything in such agreement and all addenda thereto require the Provider to acquire drugs from the Part D Plan Sponsor or from any other source.

## **15. Drug Utilization Review/Generic Equivalent Substitution.**

Where the Provider lacks the capacity to comply with the information technology requirements for drug utilization review and/or generic equivalent substitution set forth in the Part D Plan Sponsor's agreement, the Provider and Part D Plan Sponsor agree that the Provider shall comply with the Part D Plan Sponsor's drug utilization review and/or generic equivalent substitution policies and procedures through an alternative method. Nothing in this paragraph shall be interpreted as waiving the applicability of the drug utilization review and/or generic equivalent substitution policies and procedures adopted by Part D sponsor in accordance with 42 C.F.R. §§ 423.153(b) and (c), as approved by CMS, to covered Part D drugs dispensed by the Provider to enrollees in the Part D Plan[s]. As specified at 42 C.F.R. §423.132(c)(3), the requirements related to notification of price differentials is waived for the Provider .

#### **16. Claims.**

The Provider may submit claims to the Part D Plan by telecommunication through an electronic billing system or by calling a toll-free number for non-electronic claims; in the case of the latter, Provider shall submit a confirmation paper claim.

#### **17. Payment Rate.**

Claims from the provider shall be paid at rates that are reasonable and appropriate.

#### **18. Information, Outreach, and Enrollment Materials.**

(a) All materials for information, outreach, or enrollment prepared for the Part D Plan shall be supplied by the Part D Plan Sponsor to Provider in paper and electronic format at no cost to the Provider.

(b) All marketing or informational material listing a provider as a pharmacy must refer to the special eligibility requirements necessary for service to be provided, consistent with the eligibility requirements as described in this Indian health addendum in paragraphs 5(a) for IHS providers and 5(b) for tribal and urban providers.

#### **19. Hours of Service.**

The hours of service of the pharmacies or dispensaries of Provider shall be established by Provider. At the request of the Part D Plan Sponsor, Provider shall provide written notification of its hours of service.

#### **20. Endorsement**

An endorsement of a non-Federal entity, event, product, service, or enterprise may be neither stated nor implied by the IHS provider or IHS employees in their official capacities and titles. Such agency names and positions may not be used to suggest official endorsement or preferential treatment of any non-Federal entity under this agreement.



## **21. Sovereign Immunity**

Nothing in the Part D Plan Sponsor's Agreement or in any addendum thereto shall constitute a waiver of federal or tribal sovereign immunity.

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Signature of Authorized Representative

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Printed Name of Authorized Representative

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Title of Authorized Representative

## APPENDIX XV – Compliance Program Crosswalk

<b>INSTRUCTIONS:</b> Applicants must complete and upload in HPMS the following chart (which contains the requirements for a Compliance Plan). Applicants must identify where <u>specifically</u> (i.e., the .pdf page number) in its compliance plan the following elements are found.	
Compliance Plan Elements	Page, paragraph where element located
<b>A. Written policies, procedures, and standards of conduct must include the following seven components:</b>	<b>§ 423.504(b)(4)(vi)(A)</b>
1. Articulate the applicant's commitment to comply with all applicable Federal and State standards.	
2. Describe compliance expectations as embodied in the standards of conduct.	
3. Describe the implementation and operation of the compliance program.	
4. Provide guidance to employees and others on dealing with potential compliance issues.	
5. Identify how to communicate compliance issues to appropriate compliance personnel.	
6. Describe how potential compliance issues will be investigated and resolved by the applicant.	
7. Include a policy of non-intimidation and non-retaliation for good faith participation in the compliance program, including, but not limited to, reporting potential issues, investigating issues, conducting self-evaluations, audits and remedial actions, and reporting to appropriate officials.	
<b>B. Designation of a compliance officer and a compliance committee who report directly to and are accountable to applicant's chief executive or senior management and include the following three components:</b>	<b>§ 423.504(b)(4)(vi)(B)</b>
1. The compliance officer, vested with the day-to-day operations of the compliance program, must be an employee of the MA applicant, parent organization or corporate affiliate. The	

compliance officer may not be an employee of the MA applicant's first tier, downstream or related entity.	
2. The compliance officer and the compliance committee must periodically report directly to the governing body of the MA applicant on the activities and status of the compliance program, including issues identified, investigated, and resolved by the compliance program.	
3. The governing body of the MA applicant must be knowledgeable about the content and operation of the compliance program and must exercise reasonable oversight with respect to the implementation and effectiveness of the compliance programs.	
<b>C. Establish, implement and provide effective training and education for employees including the chief executive and senior administrators or managers, governing body members, first tier, downstream, and related entities must include the following components:</b>	<b>§ 423.504(b) (4)(vi)(C)</b>
1. Training and education must occur at least annually and must be part of the orientation for new employees, new first tier, downstream and related entities, and new appointments to chief executive, senior administrator, or governing body member.	
2. An indication that first tier, downstream, and related entities who have met the fraud, waste, and abuse certification requirements through enrollment into the Medicare program or accreditation as a Durable Medical Equipment, Prosthetics, Orthotics, and supplies (DMEPOS) are deemed to have met the training and educational requirements for fraud, waste, and abuse.	
<b>D. Establishment and implementation of effective lines of communication, ensuring confidentiality, between:</b>	<b>§ 423.504(b) (4)(vi)(D)</b>
1. The compliance officer, members of the compliance committee, the MA applicant's employees, managers and governing body.	
2. The MA applicant's first tier, downstream, and related entities.	
3. Such lines of communication must be accessible to all.	
4. Allow compliance issues to be reported, including a method for anonymous and confidential good faith reporting of potential compliance issues, as they are identified.	
<b>E. Well-publicize disciplinary standards and implementation of</b>	<b>§ 423.504(b)</b>

<b>procedures, which encourage good faith participation in the compliance program by all affected individuals, that are enforced and include the following three policies:</b>	<b>(4)(vi)(E)</b>
1. Articulate expectations for reporting compliance issues and assist in their resolution.	
2. Identify non-compliance or unethical behavior.	
3. Provide for timely, consistent, and effective enforcement of the standards when noncompliance or unethical behavior is determined.	
<b>F. Establish and implementation of an effective system for routine monitoring and identification of compliance risks. The system should include: internal monitoring and audits and, as appropriate, external audits, to evaluate the MA applicant, including first tier entities', compliance with CMS requirements and the overall effectiveness of the compliance program.</b>	<b>§ 423.504(b) (4)(vi)(F)</b>
<b>G. Establishment and implementation of procedures and a system for <u>promptly</u> responding to compliance issues as they are raised, investigating potential compliance problems identified in the course of self-evaluations and audits, correcting such problems promptly and thoroughly to reduce the potential for recurrence, and ensure ongoing compliance with CMS requirements. The procedures must include the following components:</b>	<b>§ 423.504(b) (4)(vi)(G)</b>
1. If the MA applicant discovers evidence of misconduct related to payment or delivery of items or services under the contract, it must conduct a timely, reasonable inquiry into that conduct.	
2. The MA applicant must conduct appropriate corrective actions (e.g., repayment of overpayments and disciplinary actions against responsible individuals) in response to the potential violation.	
3. The MA applicant should have procedures to voluntarily self-report potential fraud or misconduct related to the MA program to CMS or its designee.	