MEDICARE PRESCRIPTION DRUG BENEFIT

Solicitation for Applications for New Medicare Advantage - Prescription Drug Plans (MA-PD) Sponsors

2011 Contract Year

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1.

General Information

1.1. Purpose of Solicitation

The Centers for Medicare & Medicaid Services is seeking applications from Medicare Advantage organizations to enter into contracts to offer qualified prescription drug coverage 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 already has a Medicare Advantage-Prescription Drug (MA-PD) contract with CMS to offer the Part D benefit, and you are expanding your service area offered under the existing contract please refer to the www.cms.hhs.gov/ website for the Part D Service Area Expansion application for instructions to complete an application for a Service Area Expansion (SAE). If your organization, or your parent or affiliated organization already has a MA-PD or Cost Plan contract with CMS to offer the Part D benefit, and you are seeking a PDP contract, you are required to complete the PDP application package.

If your organization or your parent or affiliated organization already has a MA-PD contract with CMS to offer the Part D benefit, and you are seeking to offer a new product line under a new contract, then you are required to complete this application.

1.2. Background

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

1.3. Objectives and Structure

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. 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. If the MA-PD sponsor meets the basic requirement,

then it may also offer supplemental benefits through enhanced alternative coverage for an additional premium. MA organizations approved to offer Part D benefits (hereinafter referred to as "MA-PD sponsors") must offer Part D coverage throughout their approved MA service area.

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

This solicitation is only for entities seeking to operate a MA-PD plan (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 PDP Plans, for entities offering Cost Plans with a Part D benefit, and for entities offering PACE Plans with a Part D benefit.

Only specific types of MA organizations (i.e., entities offering Medicare coordinated care plans or Medicare private fee-for-service plans) may submit a Part D application in response to this solicitation. Medicare reasonable cost plans (as defined under Section 1876 of the Social Security Act), Program of All Inclusive Care for the Elderly (PACE) organizations (as defined in section 1894 of the Social Security Act), and employer groups may also offer pharmacy benefits under the MMA. Those entities must not complete this Part D qualification application, but should refer to the separate applications posted on the CMS website.

It is important to note that MA organizations offering coordinated care plans must qualify to offer at least one plan that includes both Part C and Part D benefits throughout the organization's approved Part C service area. Similarly, MA organizations offering a preferred provider organization (PPO) plan must offer Part D coverage throughout the PPO regions in which they are approved to offer a Part C plan. However, MA organizations offering private fee-for-service plans may, but are not required to, offer a Part D benefit.

CMS payment to MA organizations for provision of Part C services to their enrollees is calculated separately from the payment for the Part D benefit. Like PDP sponsors, MA-PD 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 2.7.1 of this application for information regarding the submission of formulary materials). The plans also may include supplemental benefits coverage such that the total value of the coverage exceeds the value of basic prescription drug coverage.

1.4. Schedule

APPLICATION REVIEW PROCESS

Date	**Milestone**
November 17, 2009	Submit Notice of Intent to Apply Form to CMS
December 2, 2009	CMS User ID form due to CMS
January 5, 2010	Final Applications posted by CMS
February 25, 2010	Applications due
March 29, 2010	Release of Health Plan Management System (HPMS) formulary submissions module
April 9, 2010	Plan Creation module, Plan Benefit Package (PBP), and Bid Pricing Tool (BPT) available on HPMS
April 19, 2010	Formulary submission due to CMS Transition Policy Attestations due to CMS
May/June 2010	CMS sends Part D contract eligibility determination to Applicants, based on review of application. Applicant's bids must still be negotiated (see below)
May 21, 2010	PBP/BPT Upload Module available on HPMS
June 7, 2010	All bids due
Early August 2010	CMS publishes national average Part D premium
September 2010	CMS completes review and approval of bid data. CMS executes Part D contracts to those organizations who submit an acceptable bid
November 15, 2010	2011 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 MA-PD Sponsor Role and Responsibilities

Key aspects of each MA-PD Sponsor shall include the ability to:

- Submit a formulary (considered an element of the bid) each year for CMS approval.

- As part of the annual bidding process MA Coordinated Care Plans (CCPs) must submit at least one MA-PD plan for CMS approval. An MA organization offering a coordinated care plan must offer at least one MA-PD plan throughout its approved MA service area. An MA private fee-for-service (MA-PFFS) contractor may, but is not required to, offer a Part D Benefit to beneficiaries within its service area.
- Enroll all eligible Medicare beneficiaries who apply and reside within the MA-PD sponsor's approved service area.
- 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, 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.
- MA-PDs (except Medicare private fee-for-service plans meeting certain criteria) must feature a contracted retail pharmacy network, providing enrollees convenient access to retail pharmacies as specified in 42 CFR §423.120.
- Process claims at the point of sale.
- All MA-PDs must operate quality assurance programs. MA-PDs, except MA-PFFS plans meeting specific requirements, must also provide drug utilization review, and medication therapy management programs.
- Administer coverage determinations, grievances, exceptions, and an appeals process consistent with CMS requirements.
- Provide customer service to beneficiaries, including enrollment assistance, toll-free telephone customer service help, and education about the Part D benefit.
- Protect the privacy of beneficiaries and beneficiary-specific health information.
- Develop marketing materials and conduct outreach activities consistent with CMS standards.
- Develop and/or maintain systems to support enrollment, provide claims-based data to CMS, accept CMS payment (including subsidies for low-income beneficiaries), track true out-of-pocket costs 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 Prescription Drug 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 reviews the applications submitted on or by February 25, 2010 to determine whether the Applicant meets the qualifications we have established to enter into a Part D addendum to the Applicant's Part C contract.

The second phase has two steps – the formulary upload which begins March 29, 2010 and the bid upload which begins May 21, 2010. The formulary review entails determining that the proposed formulary (if one is used) has at least two drugs in every therapeutic category and class (unless special circumstances exist that would allow only one drug); does not substantially discourage enrollment by certain types of Part D eligible individuals; includes adequate coverage of the types of drugs most commonly needed by Part D enrollees; and includes an appropriate transition policy. CMS will contact Applicants if any issues are identified during the review for discussion and resolution. The intent is to provide an opportunity for Applicants to make any necessary corrections prior to the Part D bid submission date which is on the first Monday in June each year. The second step involves the bid review and negotiations with applicants to 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 addendum as a result of successfully completing phase one and two will be offered a Part D addendum to their Medicare managed care 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. This monitoring system was developed in coordination with CMS personnel responsible for oversight of the Medicare Advantage program to minimize duplication of effort. 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.hhs.gov/ website. (NOTE: Part D sponsors, as covered entities under the Health Insurance Portability and Accountability Act of 1996, are subject to investigation and penalties for findings of HIPAA violations as determined by the Department of Health and Human Services Office for Civil Rights and the Department of Justice.)

We monitor compliance, through the analysis of data we collect from Part D sponsors, CMS contractors, and our own systems. The types of data we collect from sponsors include: certain benefit data, 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 MA-PD sponsors' grievance processes as well as conduct periodic site visits to verify MA-PP 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 Prescription Drug 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, 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 Prescription Drug Plan Finder assists beneficiaries in finding a plan to meet their specific needs; refer to the www.medicare.gov/MPDPF website. CMS displays data that allow comparisons of plans' costs, quality and operational performances. These data may also be used for monitoring purposes.

1.6.4. Marketing Guidelines and Review

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

marketing strategy. Review of MA-PD plan materials will be conducted in conjunction with review of Part C marketing materials under 42 CFR §422.80 and 42 CFR §423.50. MA-PD sponsors are required to submit materials to CMS based on the Medicare 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.hhs.gov/ website.

1.6.6. General Enrollment Processing

CMS has a system to receive and process enrollment, disenrollment and membership information provided by MA organizations. Beneficiaries enrolled in an MA plan must obtain qualified prescription drug coverage through that plan (42 CFR §423.30(b)), unless they are enrolled in a MA private fee-for-service plan that does not provide qualified prescription drug coverage (42 CFR §423.30(b)(1)), or they are enrolled in a MSA plan (42 CFR §423.30(b)(2)).

CMS reviews an individual's status as a Medicare beneficiary. CMS tracks subsidy status and auto-enrollments of full-benefit dual eligible beneficiaries in Part D plans and "facilitated enrollments" for other low-income Medicare beneficiaries. Full-benefit dual eligible beneficiaries who do not enroll in Part D plans are automatically enrolled into a stand-alone drug plan, and other low-income beneficiaries are enrolled through "facilitated enrollment". Finally, CMS tracks dis-enrollments from Part D plans and will deny new enrollments during any given year unless the enrollment occurs during an allowable enrollment period. For additional information regarding enrollment processing, refer to the www.cms.hhs.gov/ website.

1.6.7. Payment to Part D Sponsors

CMS provides payment to MA-PD sponsors in the form of advance monthly payments (consisting of the MA-PD plan's standardized bid, risk adjusted for health status, minus the beneficiary monthly premium), estimated reinsurance subsidies, and estimated low-income subsidies (low-income cost sharing and premiums). After the end of the payment year, CMS reconciles the actual amounts of low-income cost sharing subsidies and reinsurance 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.csscoperations.com and on the www.cms.hhs.gov website.

2. INSTRUCTIONS

2.1. Overview

This application is to be completed by those MA organizations that intend to offer a new MA-PD during 2011. This application is to be submitted to CMS in conjunction with the documents required for participation in the Part C program during 2011. Please refer to the guidance for MA and Cost Plan sponsors posted on the CMS web site for instructions on the type of MA documentation your organization must provide to CMS to qualify to operate an MA plan during 2011.

2.2. Other Technical Support

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

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

2.3. Health Plan Management System (HPMS) Data Entry

MA-PD and/or Regional Preferred Provider Organizations (RPPOs) that submit a Notice of Intent to Apply form are assigned a pending contract number (H/R number) to use throughout the application and subsequent operational processes. Once the contract number is assigned, MA-PD and/or RPPO Applicants apply for and receive their CMS User ID(s) and password(s) for HPMS access and need to input contact and other related information into the HPMS (see section 3.1.4). Applicants are required to provide prompt entry and ongoing maintenance of data in HPMS. By keeping the information in HPMS current, the Applicant facilitates the tracking of their application throughout the review process and ensures that CMS has the most current information for application updates, guidance and other types of correspondence.

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

2.4. Instructions and Format of Qualifications

Applications may be submitted until February 25, 2010. Applicants must use the 2011 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. 2010 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 3.0 of this solicitation, please mark “Yes” or “No” or “Not Applicable” in sections organized with that format within HPMS.

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

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

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 timelines 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, Applicant that upload contract crosswalks instead of contracts, or Applicants that fail to upload any pharmacy access reports. CMS will notify any Applicants that are determined to have provided invalid submissions.

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

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

CMS has established that all aspects of the program that the Applicant attests to must be ready for operation by the contract signature date. As with all aspects of a MA-PD sponsor’s operations under its contract with CMS, we may verify a sponsor’s compliance with qualifications it attests it will meet, through on-site visits at the MA-PD 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 MA-PD 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 4.0. 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 25, 2010. 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 2011 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 25, 2010; 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 Part D 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 the 2011 Application Instructions for MA Organizations to Offer New Employer/Union-Only Group Waiver Plans. The 2011 Application Instructions for MA Organizations to Offer New Employer/Union-Only Group Waiver Plans provides the Applicant with the ability to choose between only offering “800 series” plans and participating in both the individual and group markets for Private Fee-For-Service products. The document further specifies those individual market requirements that are not applicable in the employer market. The document is available on the cms.hhs.gov website.

Applicants Offering Individual and “800 Series” Plans – Pharmacy Access

Applicants offering both individual and “800 series” plans are not required to submit separate GeoNetworks® retail pharmacy reports (Appendix X- Retail Pharmacy Network Access Instructions) or other pharmacy access submittals (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. Applicants 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 Applicant enrolls members of an employer or union group residing in particular geographic locations outside of its individual plan service area.

Applicants (PFFS) Only Offering “800 Series” Plans – Pharmacy Access

Applicants 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 PFFS

New Direct Contract PFFS 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 PFFS Sponsors. Direct Contract PFFS Sponsors can extend coverage to all of their retirees, regardless of whether they reside in one or more regions in the nation. In order to provide coverage to retirees wherever they reside, Direct Contract PFFS Applicants must set their service areas to include all areas where retirees may reside during the plan year.

Direct Contract PFFS 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 PFFS Sponsors for their Medicare-eligible retirees must complete the following materials:

- The 2011 Medicare Advantage Application

- The 2011Solicitation for Applications for New Medicare Advantage Prescription Drug Plan (MA-PD) Sponsors
- The 2011 Initial Application for Employer/Union Direct Contract Private Fee-For-Service (PFFS) Medicare Advantage Organization
- T he 2011 Financial Solvency & Capital Adequacy Documentation for Direct Contract MA-PD Applicants (submitted electronically through fiscal soundness section for the MA Supporting Files; Appendix can be found in the 2011 Initial Application for Employer/Union Direct Contract Private Fee-For-Service (PFFS) Medicare Advantage Organization
- Appendix II—2011 Direct Contract PFFS 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

When reviewing MA-PD applications from potential MA Regional PPO sponsors (RPPOs), 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 MA-PD 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 service area 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 addendum to the Applicant's Medicare Advantage contract to offer a RPPO, and approval of the bid(s) submitted by the joint enterprise, CMS will enter into a multiple-party MA Part D addendum 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 Medicaid benefits, and who fail to enroll in a Part D plan, will be enrolled automatically in a Part D plan, unless the individual declines the enrollment. As such, CMS requires that MA organizations offering both MA-PD and MA-only plans have a process for auto- and facilitated enrollment. All low-income eligible individuals who elect an MA plan without Medicare prescription drug benefits (MA-only plan) will be auto- or facilitated enrolled into the MA-PD plan in the same organization with the lowest combined Part C and Part D premium amount. If more than one MA-PD plan have the same lowest premium amount, enrollment must be random among the available MA-PD plans. For PFFS plans, if the organization offers a stand-alone PDP in the same region with a basic benefit and a premium at or below the low-income premium subsidy amount for that reqion, the organization may auto/facilitate enrollment into that PDP. The MA organization's auto- and facilitated enrollment processes will occur monthly.

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 MA_Applications@cms.hhs.gov and 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 requested letter.

2.4.8. Technical Assistance

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

Marla Rothouse by email at marla.rothouse@cms.hhs.gov, or by phone at 410-786-8063 or Linda Anders by email at linda.anders@cms.hhs.gov, or by phone at 410-786-0459. As stated in section 2.4.1, Applicants must contact the HPMS Help Desk if they are experiencing technical difficulties uploading any part of this solicitation within HPMS prior to the submission deadline.

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 29, 2010. The deadline for formulary submission to CMS is 11:59 PM EDT on April 19, 2010. 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 21, 2010 and the CY 2011- bid deadline of June 7, 2010. 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 2010.

2.6. System Access and Data Transmissions with CMS

2.6.1. HPMS

MA-PD 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. MA-PD applicants are required to secure access to HPMS in order to carry out these functions.

2.6.2. Enrollment and Payment

All MA-PD 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, MA-PD 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.hhs.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, weekly and monthly, CMS provides responses to Sponsor submitted information and reports to each MA-PD sponsor for each of their plans with member and plan-level

information. MA-PD 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 provided by CMS for that purpose. Each MA-PD sponsor must complete and submit the monthly CEO certification of enrollment data by 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 www.cms.hhs.gov/MedicareMangCareSys/). The MAPD Help Desk also provides additional system and technical information at www.cms.hhs.gov/mapdhelpdesk/.

2.6.3. Payment for MA–PD 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).

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

2.7. Summary Instruction and Format for Individual Market Bids

Each MA-PD 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 risk Part D plans. Applicants must submit their formularies to HPMS on or before April 19, 2010 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 29-April 19, 2010. 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 an individual delegated with the authority to sign on behalf of one of these officers, and who reports directly to such officer, must certify (based on best knowledge, information and belief) that the information in the bid submission, and assumptions related to projected reinsurance and low-income cost sharing subsidies, is accurate, complete, and truthful, and fully conforms to the requirements in section 42 CFR §423.265 of the regulations. In addition, consistent with section 43 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 only when they represents a meaningful variation based on plan characteristics that will provide beneficiaries with substantially different options. In general, CMS expects that more than three bids from a sponsoring organization would not provide meaningful variation. CMS reviews multiple bids received from a Part D Applicant as a whole and applies a reasonableness test to determine examples of a strong likelihood of incompetence and/or 'gaming', including, but not limited to: a) multiple bid submissions that would fail a reasonableness test; b) multiple bid submissions based on different formulary drug lists; c) multiple bid submissions based on different levels of utilization management control; and d) multiple bid submissions that reflect a significant unexplained variation in costs between the plans, particularly between plans offered to the group versus the individual market.

2.7.2. CMS Review of Bids

CMS evaluates the bids based on four broad areas: 1) administrative costs, 2) aggregate costs, 3) benefit structure, and 4) plan management. CMS evaluates the administrative costs for reasonableness in comparison to other bidders. CMS also examines aggregate costs to determine whether the revenue requirements for qualified prescription drug coverage are reasonable and equitable. In addition, CMS reviews the steps the MA-PD 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 MA-PD 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 TRICARE standards were developed and are 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.

Section 3.5.1 of this Solicitation includes a reference to the Appendix entitled Retail Pharmacy Network Access Instructions that provides Applicants with detailed instructions to complete the retail pharmacy network access portion of this submission. For purposes of meeting the 2011 Pharmacy Access requirements, Applicants may use their contracted PBM's existing 2010 Part D network to demonstrate compliance. If an Applicant is creating a new Part D network, the submission must be based on executed contracts for Year 2011. CMS conducts the review of Retail Pharmacy Access based on the service area that the Applicant has provided in HPMS by February 25, 2010. To the extent that the service area is reduced during the application review process, the pharmacy access submission reports must pass a full and complete CMS review, including a review that ensures the access submission matches the service area in HPMS at one of the following points in time:

- 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.

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

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

2.8.2. 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 3.5.4). 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 3.5.5). CMS uses this pharmacy listing, as well as information reported as part of Applicant's 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.hhs.gov/PrescriptionDrugCovContra/ website.

2.8.5. Waivers Related to Pharmacy Access

Waivers for MA-PD Plans. CMS guidance regarding waivers of the pharmacy access and any willing pharmacy requirements for certain MA-PD sponsors is contained at sections 50.7 and 50.8.1 of Chapter 5 of the Prescription Drug Benefit Manual. These waivers are described below. **Waiver of Retail Convenient Access Standards for MA-PDs**

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

Waiver of Convenient Access Standards for MA-PFFS

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

Waiver of Any Willing Pharmacy Requirements for MA-PD

As described in section 50.8.2 of Chapter 5 of the Prescription Drug Benefit Manual, the requirement that MA-PD sponsors must offer a network pharmacy contract to any willing pharmacy that agrees to accept MA-PD sponsor's standard terms and conditions is waived for MA-PD sponsors that own and operate the pharmacies in their network. MA-PD sponsors must demonstrate at the plan level that at least 98% of prescriptions are filled through pharmacies that are owned and operated by plan sponsor in order to be granted the waiver.

Waivers for Plans in the Territories.

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 to be waived or modified either through an Applicant's request or at CMS' own determination. Under that authority, CMS will consider waiving the convenient access requirements for a plan's Part D contracted retail pharmacy network, found in 42 CFR §423.120(a)(1) for the Territories, if an Applicant requests such a waiver, and demonstrates that it has made a good faith effort to meet the requirements described in Section 3.5.1F of this solicitation.

2.9. Waivers Related to Attestations for MA-PD EGWP and PFFS 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.

2.10. Standard Contract with MA-PD Sponsors

Successful Applicants will be deemed qualified to enter into a Part D addendum to their Medicare Advantage contract after CMS has reviewed the Applicant's entire submission. Under this addendum the MA-PD sponsor will be authorized to operate one or more Medicare prescription drug plans. Only after the qualified Applicant and CMS have reached agreement on the Applicant's bid submissions will the Applicant be asked to execute its Part D addendum. 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.

2.12. Waivers

CMS is authorized to grant waivers of Part D program requirements where such a requirement conflicts with or duplicates a Part C requirement, or where granting such a waiver would improve the MA-PD sponsor's coordination of Part C and Part D benefits. Accordingly, CMS has identified the waivers it is granting to all MA-PD sponsors in the chart shown in ***Summary of Medicare Part D Regulatory Requirements Fulfilled under Part C for Medicare Advantage Prescription Drug (MA-PD) Applicants*** (Appendix II). As a result of these CMS-granted waivers, the MA-PD sponsor application is less comprehensive than the PDP sponsor application. These waivers will be reflected in each MA-PD sponsor's Part D addendum.

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

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

1. The Part D regulation reference.

2. The appropriate waiver criteria (e.g., duplicative, conflicts, improves benefit coordination).

3. A discussion of how the requested waiver meets at least one of the three waiver criteria.

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

Where this application directs the Applicant to attest that it will meet a particular Part D requirement for which the Applicant has requested a waiver, the Applicant should check both the "Yes" box and the "Waiver Requested" box within HPMS. In the event that CMS does not approve a particular waiver, the Applicant will still have attested that it will meet all the applicable Part D program requirements and remain eligible to enter into a Part D addendum upon approval of its bids. This process will prevent Applicants from having to submit additional application responses after the original February 25, 2010 deadline. If, as a result of CMS' denial of its waiver request, the Applicant no longer intends to offer a Part D benefit plan, the Applicant must notify CMS in writing on or before June 30, 2010. CMS will not execute a Part D addendum with Applicants that submit such a notice. This notice of withdrawal should be sent to:

Centers for Medicare & Medicaid Services (CMS)

Center for Drug and Health Plan Choice

Attention: Application Withdrawal

7500 Security Boulevard

Mail Stop C1-26-12

Baltimore, Maryland 21244-1850

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 MA-PD 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 will comply with such guidance should they be approved for a Part D contract. Applicants must visit the CMS web site periodically to stay informed about new or revised guidance documents.

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

A. In HPMS, complete the table below:

Applicant must attest 'yes' to each of the following qualifications to be approved for a Part D contract. Attest 'yes' or 'no' to each of the following qualifications by clicking on the appropriate response in HPMS:	**Yes**	**No**	**Requesting Waiver?** ***Yes or No***
1. Applicant is a legal entity that intends to enter into a Medicare Prescription Drug Plan addendum to its Medicare Advantage contract with CMS.			

2. Applicant agrees to abide by all applicable Federal laws, regulations and CMS instructions.			
3. Applicant maintains contracts or other legal arrangements between or among the entities combined to meet the functions identified in subsection 3.1.1C.			

B. Upload in HPMS a .pdf document that provides a brief summary of the history, structure and ownership of your organization (including the identification of the parent organization). Include a chart showing the structure of ownership, subsidiaries, and business affiliations. Additionally, include a chart showing the organizational structure of your organization that clearly depicts the placement of the Part D operations within your legal entity.

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 each of the functions listed in this chart: (Indicate with "name of Applicant's Organization" where applicant will perform those functions)	Function	First tier, Downstream and Related entities
	A pharmacy benefit program that performs adjudication and processing of pharmacy claims at the point of sale.	
	A pharmacy benefit program that performs negotiation with prescription drug manufacturers and others for rebates, discounts, or other price concessions on prescription drugs.	
	A pharmacy benefit program that performs administration and tracking of enrollees' drug benefits in real time, including TrOOP balance processing.	
	A pharmacy benefit program that performs coordination with other drug benefit programs, including, for example, Medicaid, state pharmaceutical assistance programs, or other insurance.	

	A pharmacy benefit program that develops and maintains a pharmacy network.	
	A pharmacy benefit program that operates an enrollee grievance and appeals process	
	A pharmacy benefit program that performs customer service functionality, that includes serving seniors and persons with a disability.	
	A pharmacy benefit program that performs pharmacy technical assistance service functionality.	
	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 and related entities identified in Sections 3.1.1 C that:

1. Clearly identify the parties to the contract (or letter of agreement).
2. Describe the functions to be performed by the first tier, downstream or related entity. 42 CFR §423.505(i)(4)(i)
3. Describe the reporting requirements the first tier, downstream, or related entity has to the Applicant. 42 CFR §423.505(i)(4)(i)
4. 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).
5. Contains flow-down clauses requiring their activities be consistent and comply with the Applicant's contractual obligations as a Part D sponsor. 42 CFR §423.505(i)(3)(iii)
6. Describe the payment the first tier, downstream, or related entity will receive for performance under the contract, if applicable.

7. Clearly indicates 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 November 15 extending through the full contract year ending on December 31 of the next year).
8. Are signed by a representative of each party with legal authority to bind the entity.
9. 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)
10. 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.
11. 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(i)(2)
12. 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)
13. Contain language that the first tier, downstream, or related entity indicates clearly that any books, contracts, records, including medical records and documentation relating to the Part D program will be provided to either the sponsor to provide to CMS or its designees, or will be provided directly to CMS or its designees. 42 CFR §423.505(i)(3)(iv)
14. 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)
15. 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)
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 the Part D

sponsor retains the right to approve, suspend, or terminate any arrangement with a pharmacy. 42 CFR §423.505(i)(5)

17. 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)
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 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(i)(3)(viii)(B)
19. 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)

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*.

F. 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 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. Experience and Capabilities

A. In HPMS, complete the table below:

Applicant must attest 'yes' to each of the following qualifications to be approved for a Part D contract. Attest 'yes' or 'no' to each of the following qualifications by clicking on the appropriate response in HPMS:	**Yes**	**No**	**Requesting Waiver?** ***Yes or No***
1. Applicant and/or one of its first tier, downstream, or related entities currently operate a pharmacy benefit program that performs adjudication and processing of pharmacy claims at the point of sale.			
2. Applicant and/or one of its first tier, downstream, or related entities currently operates a pharmacy benefit program that performs negotiation with prescription drug manufacturers and others for rebates, discounts, or other price concessions on prescription drugs.			
3. Applicant and/or one of its first tier, downstream, or related entities currently operate a pharmacy benefit program that performs administration and tracking of enrollees' drug benefits in real time, including tracking of enrollee's TrOOP, as applicable.			
4. Applicant and/or one of its first tier, downstream, or related entities currently operates a pharmacy benefit program that performs coordination with other drug benefit programs, including, for example, Medicaid, state pharmaceutical assistance programs, or other insurance.			
5. Applicant and/or one of its first tier, downstream, or related entities currently develop and maintain a pharmacy network.			
6. Applicant and/or one of its first tier, downstream, or related entities currently operate a pharmacy benefit program that operates an enrollee grievance and appeals process.			
7. Applicant and/or one of its first tier, downstream, or related entities currently operate a pharmacy benefit program that performs customer service functionality, which includes serving seniors and persons with a			

disability.			
8. Applicant and/or one of its first tier, downstream, or related entities currently operate a pharmacy benefit program that performs pharmacy technical assistance service functionality.			
9. Applicant and/or one of its first tier, downstream, or related entities) currently operate a pharmacy benefit program that maintains a pharmaceutical and therapeutic committee.			
10. Applicant and/or one of its first tier, downstream, or related entities currently operate a pharmacy benefit program that performs enrollment processing.			

3.1.3. Business Integrity 2 CFR Part 376; Prescription Drug Benefit Manual, Chapter 9

A. In HPMS, complete the table below:

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:	**Yes**	**No**	**Requesting Waiver?** ***Yes or No***
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. Please note that this includes any member of its board of directors, and any key management or executive staff or any major stockholder.			
2. Applicant has any past or pending investigations, legal actions, administrative actions, or matters subject to arbitration brought involving the Applicant (and Applicant's parent firm if applicable), including any key management or executive staff, by a government agency (state or federal including CMS) over the past three years on matters relating to payments from governmental entities, both federal and state, for healthcare and/or prescription drug services.			

3. Applicant's Pharmacy Benefit Manager (PBM) (and PBM's parent firm if applicable) has any past or pending investigations, legal actions, administrative actions, or matters subject to arbitration brought involving the PBM (and PBM's parent firm if applicable), including any key management or executive staff, by a government agency (state or federal including CMS) over the past three years on matters relating to payments from governmental entities, both federal and state, for healthcare and/or prescription drug services.			

B. If Applicant answered Yes to 3.1.4A2 and/or 3.1.4A3, upload in HPMS as a .pdf document, all past or pending, if known, investigations, legal actions, or matters subject to arbitration brought by a government agency (state or federal including CMS) over the past three years relating to payments from government entities, for healthcare and/or prescription drug services involving the following:

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

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

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

3.1.4. 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, and 08/04/09

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	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				

Patient Safety Contact				
Part D Benefits Contact				
Part D Quality Assurance Contact				
Part D Application Contact				
Pharmacy Director				
HIPAA Security Officer				
HIPAA Privacy Officer				
Part D Price File Contact (Primary)				
Part D Price File Contact (Back-up)				
Part D Appeals				
Government Relations Contact				
Emergency Part D Contact				
Pharmacy Technical Help Desk Contact				
Processor Contact				
CMS Casework Communication Contact				
Part D Exceptions Contact				
EOB Transfer Contact				
Coordination of Benefits Contact				

CEO – CMS Administrator Contact				
Plan to Plan Reconciliation Contact				
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 Requirements Contact				
Fraud Investigations Contact				

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

Applicant must attest 'yes' to each of the following qualifications to be approved for a Part D contract. Attest 'yes' or 'no' to each of the following qualifications by clicking on the appropriate response in HPMS:	**Yes**	**No**	**Requesting Waiver?** ***Yes or No***
1. Applicant 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 42 CFR §423.120(b), 42 CFR §423.272(b)(2); Prescription Drug Benefit Manual, Chapter 6; 2010 Call Letter

A. In HPMS, complete the table below:

Applicant must attest 'yes' to each of the following qualifications to be approved for a Part D contract. Attest 'yes' or 'no' to each of the following qualifications by clicking on the appropriate response in HPMS:	**Yes**	**No**	**Requesting Waiver?** ***Yes or No***
1. Applicant 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 agrees to comply 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 other related formulary guidance.			
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 must include 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 the 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 will provide for an appropriate transition for new enrollees prescribed Part D drugs that are not on its formulary. This transition process must satisfy the requirements specified in Chapter 6 of the Prescription Drug Benefit Manual.			
7. Applicant agrees to attest 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 to CMS upon request.			
9. Applicant agrees, where appropriate, to extend transition periods beyond 30 days for enrollees using non-formulary drugs that have not been transitioned to a formulary drug or gone through the plan exception process within 30 days.			
10. Applicant agrees to ensure that staff are trained and information systems are in place to accommodate administration of the transition policy. This includes adoption of necessary information system overrides.			
11. Applicant will establish 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 will establish appropriate timeframes and "first fill" procedures for non-formulary Part D medications in long-term care and retail settings.			
13. Applicant will abide by CMS guidance related to vaccine administration reimbursement under Part D.			

B. In HPMS, complete the table below:

If Applicant is intending for its Part D benefit to include the use of a formulary, then Applicant must also provide a P&T committee member list either directly or through its pharmacy benefit manager (PBM). Applicant must attest 'yes' or 'no' that it is using its PBM's P&T committee, in order to be approved for a Part D contract. Attest 'yes' or 'no' by clicking the appropriate response in HPMS:	**Yes**	**No**	**Requesting Waiver?** ***Yes or No***
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 *Applicant Submission of P&T Committee Member List and Certification Statement*.			
3. Applicant will develop and use a P&T committee to develop and review the formulary and to ensure that the formulary is appropriately revised to adapt to both the number and types of drugs on the market. *Note: While the P&T committee may be involved in providing recommendations regarding the placement of a particular Part D drug on a formulary cost-sharing tier, the ultimate decision maker on such formulary design issues is the Part D plan sponsor, and that decision weighs both clinical and non-clinical factors.*			
4. Applicant's P&T committee will first look at medications that are clinically effective. When two or more drugs have the same therapeutic advantages in terms of safety and efficacy, the committee may review economic factors that achieve appropriate, safe, and cost-effective drug therapy.			
5. Applicant will assure that the P&T committee uses appropriate scientific and economic considerations to consider utilization management activities that affect			

access to drugs, such as access to non-formulary drugs, prior authorization, step therapy, generic substitution, and therapeutic interchange protocols.			
6. Applicant will adhere to P&T guidelines that will, from time to time, be promulgated with regard to such subject areas as membership, conflict of interest, meeting schedule, meeting minutes, therapeutic classes, drug review and inclusion, formulary management, utilization management and review, formulary exceptions, and educational programs for providers.			
7. Applicant's P&T committee will make a reasonable effort to review 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.			
8. Applicant's P&T committee will approve inclusion or exclusion of the therapeutic classes in the formulary on an annual basis.			
9. The majority of the membership of the Applicant's P&T committee shall be practicing physicians and/or practicing pharmacists.			
10. The membership of the Applicant's P&T committee will include at least one practicing physician and at least one practicing pharmacist who are both free of conflict with respect to the Applicant organization and pharmaceutical manufacturers.			
11. The membership of the Applicant's P&T committee will include at least one practicing physician and at least one practicing pharmacist who are experts in the care of the elderly or disabled persons.			
12. Applicant's P&T committee will recommend protocols and procedures for the timely use of and access to both formulary and non-formulary drug products.			
13. Applicant will verify that their P&T Committee members (listed in 3.2.1 C) do not appear on the HHS Office of Inspector General's Exclusion List. This list can be found at http://exclusions.oig.hhs.gov/search.html			

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

D. In HPMS complete the table below:

Applicant must attest 'yes' to each of the following qualifications to be approved for a Part D contract. Attest 'yes' or 'no' to each of the following qualifications by clicking on the appropriate response in HPMS:	**Yes**	**No**	**Requesting Waiver? Yes or No**
1. Applicant's formulary will include at least two Part D drugs that are not therapeutically equivalent and bioequivalent in each therapeutic category and class of covered Part D drugs – except where a particular category or class includes only one Part D drugs – as provided at 42 CFR §423.120(b)(2)(i).			
2. Applicant seeks to obtain a waiver of the requirement at 42 CFR §423.120(b)(2)(i) for applicable formulary categories and classes when Part D home infusion drugs are provided as part of a bundled service as a supplemental benefit under Part C.			
3. If Applicant attests YES to 3.2.1D2, it will always cover a particular home infusion drug as part of a bundled service under Part C or will always cover a particular home infusion drug under Part D.			
4. If Applicant attests YES to 3.2.1D2, it will ensure that the bundled service is available to all enrollees of any MA-PD plan in which it chooses to provide Part D home infusion drugs as part of a supplemental benefit under Part C.			
5. If Applicant attests YES to 3.2.1D2, it will appropriately apportion costs between Part D and Part C components of its bid to account for these drugs, as well as provide, in a supplemental formulary file submission, the home infused covered Part D drugs that will be offered as part of a supplemental benefit under Part C.			

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

If the Applicant is an MA Private Fee for Service (MA-PFFS) organization, as described in 42 CFR §422.4 (a)(3), the utilization management requirements used as the basis for this subsection of the application do not apply. (See 42 CFR §423.153(e).) The MA-PFFS Applicants should proceed to subsection 3.2.3 "Quality Assurance and Patient Safety" of the application.

A. In HPMS, complete the table below:

Applicant must attest 'yes' to each of the following qualifications to be approved for a Part D contract. Attest 'yes' or 'no' to each of the following qualifications by clicking on the appropriate response in HPMS:	**Yes**	**No**	**Requesting Waiver? Yes or No**
1. Applicant maintains policies and procedures to prevent over-utilization and under-utilization of prescribed medications, including but not limited to the following elements: • Programs designed to improve adherence/compliance with appropriate medication regimens • Monitoring procedures to discourage over-utilization through multiple prescribers or multiple pharmacies • Quantity versus time edits • Early refill edits			
2. Applicant maintains methods to ensure cost-effective drug utilization management. Examples of these tools include, but are not limited to: • Step therapy • Prior authorization • Tiered cost-sharing			
3. Applicant makes enrollees aware of utilization management (UM) program requirements through information and outreach materials.			
4. Applicant develops incentives to reduce costs when medically appropriate such as, but not limited to encouragement of generic utilization.			

5. Applicant 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 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**	**Requesting Waiver?** ***Yes or No***
1. Applicant establishes a concurrent drug utilization review program that includes but not limited to, the following checks each time a prescription is dispensed: • Screening for potential drug therapy problems due to therapeutic duplication; • Age/gender-related contraindications; • Over-utilization and under utilization; • Drug-drug interactions; • Incorrect drug dosage or duration of drug therapy; • Drug-allergy contraindications; and • Clinical abuse/misuse.			
2. Applicant performs retrospective drug utilization review.			
3. Applicant develops and implements internal medication error identification and reduction systems.			

3.2.4. Medication Therapy Management 42 CFR §423.153(d); Prescription Drug Benefit Manual, Chapter 7; 2010 Call Letter; CMS issued guidance 04/10/2009

If the Applicant is an MA Private Fee for Service (MA-PFFS) organization, as described in 42 CFR §422.4(a)(3), the medication management standards used as the basis for this sub-section of the application do not apply (See 42 CFR §423.153(e)). The MA-PFFS Applicants should proceed to sub-section 3.2.5 "Electronic Prescription Program" of the application.

A. In HPMS, complete the table below:

Applicant must attest 'yes' to each of the following qualifications to be approved for a Part D contract. Attest 'yes' or 'no' to each of the following qualifications by clicking on the appropriate response in HPMS:	**Yes**	**No**	**Requesting Waiver?** ***Yes or No***
1. Applicant will develop and implement a Medication Therapy Management (MTM) Program designed to : • Ensure optimum therapeutic outcomes for targeted beneficiaries through improved medication use • For targeted beneficiaries, reduce the risk of adverse events, including adverse drug interactions			
2. Applicant will develop the MTM program in cooperation with licensed and practicing pharmacists and physicians.			
3. Applicant will target beneficiaries for enrollment in the MTM program based on all three of the following criteria: • Beneficiary must have multiple chronic diseases (list to be determined by organization). In defining multiple chronic diseases, organizations must meet requirements for the minimum number and types of diseases for targeting as determined by CMS; • Beneficiary must be taking multiple covered Part D drugs (specifics to be determined by organization). In defining multiple Part D drugs, organizations must meet requirements for the minimum number of Part D drugs for targeting as determined by CMS; and • Beneficiary must be identified as likely to incur annual costs for covered Part D drugs that exceed a predetermined level specified by the Secretary through CMS guidance.			
4. Applicant will establish an appropriate MTM enrollment policy which enrolls targeted beneficiaries using an opt-out method of enrollment only.			
5. Applicant will establish an appropriate MTM enrollment policy which targets beneficiaries for enrollment at least quarterly during each year.			
6. Applicant will establish appropriate policies and procedures for offering a minimum level of MTM services including interventions for both beneficiaries and			

prescribers, an annual comprehensive medication review for the beneficiary, which includes a review of medications, interactive, person-to-person consultation, and an individualized, written summary of interactive consultation, and quarterly targeted medication reviews.			
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: 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.			
8. Applicant will establish 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.			
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.			
10. Applicant will establish 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: • 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. • 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.) • 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. • 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. • Applicant will put into place safeguards against discrimination based on the nature of their MTM interventions (i.e., TTY if phone based, Braille if mail based, etc.) • 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. • Applicant will have procedures in place to drive participation and follow-up with beneficiaries that do not respond to initial offers for MTM services. • Applicant will consider using more than one approach when possible to reach all eligible patients who may wish to receive MTM services. • Applicant will analyze and evaluate their MTMP and make changes to continuously improve their programs.			

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:

Applicant must attest 'yes' to each of the following qualifications to be approved for a Part D contract. Attest 'yes' or 'no' to each of the following qualifications by clicking on the appropriate response in HPMS:	**Yes**	**No**	**Requesting Waiver? Yes or No**
1. Applicant agrees to support and comply with electronic prescription standards relating to covered Part D drugs for			

Part D enrollees.			
2. Applicant agrees to establish and maintain an electronic prescription drug program that complies with final part D standards when 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 agrees to obtain the Prescription Origin Code on original prescriptions submitted via the NCPDP 5.1 option field 419 DJ and report 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 will 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.			

3.3. Service Area/Regions 42 CFR §423.112; Prescription Drug Benefit Manual, Chapter 5

If Applicant is offering a local MA-PD plan (as defined under 42 CFR §422.2) then the plan service area does not have to meet a regional definition.

A. Only Applicants that intent to offer a Regional PPO plan must complete the table below in HPMS:

Applicant must attest 'yes' to each of the following qualifications to be approved for a Part D contract. Attest 'yes' or 'no' to each of the following qualifications by clicking on the appropriate response in HPMS:	**Yes**	**No**	**Requesting Waiver?** ***Yes or No***
1. Applicant will offer Part D coverage for the entire MA region(s) to be operated under the Regional PPO plan.			

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. Information on MA regions may be found on the www.cms.hhs.gov/ website. Be sure to list both the MA region name and associated number. Note: CMS bases its pharmacy network analyses on the service area your organization inputs into HPMS. Please make sure that the service area information you input into HPMS

corresponds to the pharmacy lists and geo-access reports that are provided under the Pharmacy Access section of the application.

3.4. Private Fee-For-Service Pharmacy Access 42 CFR §423.120(a)(7); Prescription Drug Benefit Manual, Chapter 5

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

Applicant must attest 'yes' to each of the following qualifications to be approved for a Part D contract. Attest 'yes' or 'no' to each of the following qualifications by clicking on the appropriate response in HPMS:	**Yes**	**No**	**Requesting Waiver?** ***Yes or No***
1. Applicant intends to use a contracted network of pharmacies and therefore will meet the retail pharmacy convenient access standards; LTC and I/T/U pharmacy convenient access standards; and home infusion pharmacy adequate access standards. Note: If answer Yes, Applicant must complete all of Section 3.5.			
2. If Applicant attests 'NO' to 3.4A1, Applicant agrees to provide coverage for drugs purchased from all pharmacies, regardless of whether they are network pharmacies.			
3. If Applicant attests 'NO' to 3.4A1, Applicant agrees not to charge additional cost-sharing to beneficiaries for obtaining their drugs at a non-network pharmacy.			
4. If Applicant attests 'NO' to 3.4A1, Applicant agrees that providing access at non-network pharmacies is provided by reimbursing the pharmacy its Usual and Customary price (defined as the price an out of network pharmacy charges a customer who does not have any form of prescription drug coverage for a covered Part D drug) minus any applicable beneficiary cost sharing.			
5. If Applicant attests 'NO' to 3.4A1, Applicant agrees it will not routinely rely on billing practices that require enrollee to pay the usual and customary price upfront and then submit a paper claim to the applicant for reimbursement.			
6. If Applicant attests 'NO' to 3.4A1, Applicant agrees to establish policies and procedures appropriately restricting the use of paper claims only to the situations in which online claims processing is not available at the point of			

sale in order to promote accurate TrOOP accounting, as well as to minimize administrative costs to the Part D plans and the Medicare program and opportunities for fraudulent duplicate claims reimbursement.			
7. If Applicant attests 'NO' to 3.4A1, Applicant agrees to arrange for automated, online billing at non-network pharmacies (similar to the way in which our point-of-sale contractor has allowed for online billing by non-contracted pharmacies).			

Note: Only if Applicant attests No to 3.4.1, and Yes to 3.4A2-4, Applicant may move directly to Section 3.6 and will be granted a waiver of convenient access.

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

A. In HPMS, complete the table below:

Applicant must attest 'yes' to each of the following qualifications to be approved for a Part D contract. Attest 'yes' or 'no' to each of the following qualifications by clicking on the appropriate response in HPMS:	**Yes**	**No**	**Requesting Waiver?** ***Yes or No***
1. Applicant agrees to permit in its plan networks any pharmacy that is willing to accept and meets the plans' standard terms and conditions. However, terms and conditions may vary, particularly with respect to payment terms to accommodate geographical areas (e.g. rural pharmacies) or different types of pharmacies (e.g. mail order and retail), provided that all similarly-situated pharmacies are offered the same standard terms and conditions.			
2. Applicant agrees not to require a pharmacy to accept insurance risk as a condition of participation in the MA-PD sponsor's network.			
3. Where applicable, Applicant's network pharmacy contracts contain provisions governing the submission of claims to a real-time adjudication system, except in the limited case of pharmacies for which only batch processing is feasible (e.g. some I/T/U pharmacies and certain pharmacies that are allowed to submit claims in the X12 format).			

4. Applicant's network pharmacy contracts contain provisions governing providing Part D enrollees access to negotiated prices as defined in 42 CFR §423.100.			
5. Applicant's network pharmacy contracts contain provisions regarding charging/applying the correct cost-sharing amount, including that which applies to individuals qualifying for the low-income subsidy.			
6. Where applicable, Applicant's network pharmacy contracts contain provisions governing informing the Part D enrollee at the point of sale (or at the point of delivery for mail order drugs) of the lowest-priced, generically equivalent drug, if one exists for the beneficiary's prescription, as well as any associated differential in price.			
7. Applicant agrees that each of the contract provisions referenced in the Appendices entitled, • Crosswalk for Retail Pharmacy Access Contracts • Crosswalk for Mail Order Pharmacy Access Contracts • Crosswalk for Home Infusion Pharmacy Access Contracts • Crosswalk for Long-Term Care Pharmacy Access Contracts • Crosswalk for I/T/U Pharmacy Access Contracts will be included in the respective downstream pharmacy network contracts.			
8. Applicant agrees to notify CMS when the Applicant changes its pharmacy benefit manager.			
9. 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.

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

A. In HPMS, complete the table below:

Applicant must attest 'yes' to each of the following qualifications to be approved for a Part D contract. Attest 'yes' or 'no' to each of the following qualifications by clicking on the appropriate response in HPMS:	**Yes**	**No**	**Requesting Waiver?** ***Yes or No***
1. Applicant agrees to meet the CMS Standards for Convenient Access [42 CFR §423.120 (a) (1) and (2)] no later than the application submission date (See the Appendix entitled *Retail Pharmacy Network Access Instructions)*.			
2. Applicant agrees that when Applicant is offering extended supplies via mail order, it also has to contract with a sufficient number of network retail pharmacies so as to ensure that enrollees have reasonable access to the same			

extended day supply benefits at retail that are available at mail-order.			
3. Applicant agrees to use the CMS beneficiary counts in the data file entitled “Beneficiary Count Data” to prepare the retail network analyses.			
4. Applicant seeks to obtain a waiver of retail pharmacy convenient access standards. If YES, complete table G below in HPMS.			
5. Applicant seeks to obtain a waiver of any willing pharmacy requirements. If YES, complete table H below in HPMS.			

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

C. Upload in HPMS the Retail Pharmacy List:

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

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

CMS will consider supporting discussion provided by an Applicant in evaluating the applicant’s 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 as defined in Appendix entitled Retail Pharmacy Network Access Instructions.
2. Explain why these standards cannot be met. Include in the discussion relevant information such as geographic barriers, pharmacy infrastructure barriers, and/or market barriers.
3. Describe how the pharmacies in the Applicant’s retail contracted network will provide access to all eligible Part D individuals enrolled in the Applicant’s plan(s) in each of the geographic areas defined in item 1 above.

E. In HPMS, 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.

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

F. Complete the following if you marked YES to requesting a waiver of convenient access standards for any of the territories in 3.5.1E. In HPMS, in .pdf format, provide the following information:

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

G. In HPMS complete the table below:

Waiver of Retail Convenient Access Standards for MA-PDs	
Provide the number of prescriptions provided in 2009 by retail pharmacies owned and operated by Applicant.	
Provide the number of prescriptions provided in 2009 at all retail pharmacies contracted by Applicant.	

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

H. In HPMS complete the table below:

Waiver of Any Willing Pharmacy Requirements for MA-PDs	
Provide the number of prescriptions provided in 2009 by all pharmacies owned and operated by Applicant.	

Provide the number of prescriptions provided in 2009 at all pharmacies contracted by Applicant.	

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

3.5.2. 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**	**Requesting Waiver?** ***Yes or No***
1. Applicant agrees to ensure that enrollees have adequate access to covered Part D drugs dispensed at out-of-network pharmacies when an enrollee cannot reasonably be expected to obtain such drugs at a network pharmacy and provided such enrollees do not access Part D drugs at an out-of-network pharmacy on a routine basis. The coverage rules applicable to covered Part D drugs dispensed at out-of-network pharmacies may generally mirror those applicable to covered Part D drugs dispensed at network pharmacies (to the extent that the out-of-network pharmacy has the ability to effectuate those coverage rules). However, Applicant agrees to develop policies and procedures governing reasonable rules for appropriately limiting out-of-network access (for example, quantity limits, purchase of maintenance medications via mail-order for extended out-of-area travel, or plan notification or authorization processes).			
2. Applicant agrees to ensure that enrollees have adequate access to covered Part D drugs dispensed at physician offices for covered Part D drugs that are appropriately dispensed and administered in physician offices (e.g. Part D-covered vaccines).			
3. Applicant agrees to abide by 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 MA-PD sponsor plan allowance, consistent with the requirements of 42 CFR §§ 423.104(d)(2)(i)(B) and 423.104(e).			
4. Applicant agrees to ensure that it will 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.			

3.5.3. 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**	**Requesting Waiver?** ***Yes or No***
1. Applicant will offer mail order pharmacy as part of its Part D plan(s).			
2. If Applicant attests 'Yes' to 3.5.3A1, will Applicant's mail order contract include an extended (e.g., 90) day supply?			
3. If Applicant attests 'YES' to 3.5.3A2, then Applicant will include in its contracts with at least some retail pharmacies a provision that will allow a retail pharmacy to offer an extended supply of drugs to any Plan beneficiary at the same price, reimbursement rate and cost sharing as the Plan's mail order pharmacy or pharmacies—the network mail order pharmacy rate; or an Applicant may use an alternative retail/mail order pharmacy rate with a higher contracted reimbursement rate provided that any differential in charge between the Network Mail Order Pharmacy rate and the higher contract reimbursement rate would be reflected in higher cost sharing paid by the beneficiary. 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 template from HPMS that is located on the Pharmacy Upload page, complete the worksheet and upload the finished document back into HPMS.

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

A. In HPMS, complete the table below:

Applicant must attest 'yes' to each of the following qualifications to be approved for a Part D contract. Attest 'yes' or 'no' to each of the following qualifications by clicking on the appropriate response in HPMS:	**Yes**	**No**	**Requesting Waiver?** ***Yes or No***
1. Applicant agrees to provide adequate access to home infusion pharmacies. Applicant should use the reference file entitled "Adequate Access to Home Infusion Pharmacies" located on the www.cms.hhs.gov website.			
2. Applicant agrees that its network contracts will address Part D drugs delivered and administered in the home setting.			
3. Applicant agrees that its contracted home infusion pharmacies will deliver home infused drugs in a form that can be administered in a clinically appropriate fashion in the beneficiary's place of residence.			
4. Applicant agrees that its home infusion pharmacy network in the aggregate has a sufficient number of contracted pharmacies capable of providing infusible Part D drugs for both short term acute care (e.g. IV antibiotics) and long term chronic care (e.g. alpha protease inhibitor) therapies.			
5. Applicant agrees that its contracted network pharmacies that deliver home infusion drugs ensure that the professional services and ancillary supplies necessary for home infusion are in place before dispensing home infusion drugs to the beneficiary in his/her place of residence.			
6. Applicant agrees that its contracted network pharmacies that deliver home infusion drugs provide home infusion			

drugs within 24 hours of discharge from an acute setting, unless the next required dose, as prescribed, is required to be administered later than 24 hours after discharge.			

B. Home Infusion Pharmacy List

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

3.5.5. 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:

Applicant must attest 'yes' to each of the following qualifications to be approved for a Part D contract. Attest 'yes' or 'no' to each of the following qualifications by clicking on the appropriate response in HPMS:	**Yes**	**No**	**Requesting Waiver?** ***Yes or No***
1. Applicant agrees to offer standard contracting terms and conditions to all long-term care pharmacies in its service area. These terms and conditions must include all the performance and service criteria for long-term care pharmacies that are cited in section 50.5.2 of Chapter 5 of the Prescription Drug Benefit Manual.			
2. Applicant agrees that all of the Part D contracted pharmacies in Applicant's LTC network have signed directly or through a power of attorney a contract that meets the LTC performance and service criteria established by CMS.			
3. Applicant agrees to recognize the CMS special election period (SEP) or open enrollment period for institutionalized individuals for Part D drug plan enrollment and disenrollment for beneficiaries entering, living in, or leaving a long-term care facility.			
4. Applicant agrees that it will ensure convenient access to network LTC pharmacies for all of its enrollees residing in an IMD or ICF-MR designated by the State as an institution and in which any institutionalized individuals reside.			
5. Applicant agrees to provide convenient access to network LTC pharmacies for all of its 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 agrees that it will contract 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 agrees that it will not rely upon beneficiary SEPs or on out-of-network access in lieu of contracting with a sufficient number of pharmacies to ensure that an enrollee can remain in his/her current plan for as long as he/she reside in a LTC facility in Applicant's service area.			
8. Applicant ensures that LTC pharmacy contracting 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 agrees that it is prepared to readily negotiate 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 agrees to utilize CMS data on beneficiary residence in LTC facilities to facilitate its LTC contracting efforts.			
12. Applicant will ensure that, in contracting with LTC			

pharmacies, it does not agree to particular contracting terms and conditions containing provisions that have the net result of creating a non-uniform benefit for plan enrollees served by those LTC pharmacies relative to those residing in LTC facilities serviced by 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.

3.5.6. 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:

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:	**Yes**	**No**	**N/A**	**Requesting Waiver? *Yes or No***
1. Using the list of I/T/U pharmacies provided at the www.cms.hhs.gov/PrescriptionDrugCovContra/ indicate whether your service area includes at least one state in which an I/T/U pharmacy resides.				
Not all Part D regions have I/T/U pharmacies. If the Applicant's service area covers <u>any</u> region that includes I/T/U pharmacies, then the Applicant must attest 'yes' to each of the following qualifications to be approved for a Part D contract. If <u>all</u> of the Applicant's service area <u>does not</u> include I/T/U pharmacies, then the Applicant may answer 'no' or n/a and still be approved for a Part D contract since these requirements do not apply. Attest 'yes,' 'no' or n/a to each of the following qualifications by clicking on the appropriate response in HPMS.	**Yes**	**No**	**N/A**	**Requesting Waiver? *Yes or No***
2. Applicant agrees to offer standard terms and conditions that conform to the model contract addendum provided by CMS to all I/T/U pharmacies in its service area by sending a conforming contract offer to all such pharmacies. The model contract				

addendum is posted on the www.cms.hhs.gov/PrescriptionDrugCovContra/ website. The model contract addendum account for differences in the operations of I/T/U pharmacies and retail pharmacies.				
3. Applicant agrees to submit documentation upon CMS' request to demonstrate offering all I/T/U pharmacies in its service area a conforming contract. Such documentation may be proof of fax or U.S. postage 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 counties 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.

3.5.7. 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 following qualifications by clicking on the appropriate response in HPMS:	**Yes**	**No**	**Requesting Waiver?** ***Yes or No***
1. Applicant agrees not to restrict access to Part D drugs by limiting distribution through a subset of network pharmacies, except when necessary to meet FDA limited distribution requirements or to ensure the appropriate dispensing of Part D drugs that require extraordinary special handling, provider coordination, or patient education when such extraordinary requirements cannot be met by a network pharmacy. Applicant agrees that additional education or counseling alone does not qualify a drug for limited distribution within the overall pharmacy network.			
2. Applicant agrees not to restrict access solely on the placement of a Part D drug in a "specialty/high cost" tier			

because this tier placement alone is not indicative of any special requirements associated with such drug. Applicant further agrees that 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 agrees not to 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.			

3.6. Enrollment and Eligibility 42 CFR §423.30 and 42 CFR §423.44 ; Prescription Drug Benefit Manual, Chapters 3, 4, and 13; Plan Communications User Guide Version; CMS issued guidance 07/21/09

A. In HPMS, complete the table below:

Applicant must attest 'yes' to each of the following qualifications to be approved for a Part D contract. Attest 'yes' or 'no' to each of the following qualifications by clicking on the appropriate response in HPMS:	**Yes**	**No**	**Requesting Waiver? Yes or No?**
1. Applicant agrees to comply with the CMS MA Eligibility and Enrollment and Disenrollment Guidance documents that are provided on the www.cms.hhs.gov/ website.			
2. Applicant will identify full dual and other LIS eligible individuals enrolled in MA-only plans and agrees to conduct auto- and facilitated enrollment of these individuals in accordance with the guidance provided by CMS.			
3. Applicant agrees to comply with CMS operational guidance on Creditable Coverage and the Late Enrollment Penalty.			
4. Applicant agrees to establish business processes for quickly resolving urgent issues affecting beneficiaries, such as late changes in enrollment or copay status, in collaboration with CMS caseworkers.			
5. Applicant will query the Batch Eligibility Query (BEQ) or the User Interface (UI) for every new enrollment request to			

receive: • Verification of Medicare Entitlement and Part D Eligibility, • Periods of enrollment in a Medicare plan that provides prescription drug coverage, • Periods of enrollment in a retiree prescription drug plan whose sponsor receives a retiree drug subsidy from Medicare, and • Information regarding the Low Income Subsidy applicable to each new enrollee.			
6. Applicant will collect, review and transmit creditable coverage information in accordance with CMS guidance and policies.			
7. Applicant agrees to use 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.			
8. Applicant agrees 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, 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.			
9. Applicant agrees to ensure a process is 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.			
10. Applicant agrees not to disenroll members for failure to pay premiums (or notify them of impending disenrollment) in cases where the member has requested that premiums be withheld from his/her Social Security benefit check in accordance with CMS Enrollment and Disenrollment Guidance and Premium Payment policies.			
11. Applicant agrees that it may 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.			
12. Applicant agrees to receive via a daily download and process all enrollment elections made via the on-line enrollment center (OEC) hosted by CMS.			
13. Applicant agrees to transmit enrollment and disenrollment and change transactions within the timeframes provided in CMS Enrollment and Disenrollment guidance and in accordance with the published MARx Monthly Processing calendar..			
14. Applicant agrees to review all systems responses, files and reports received from CMS and compare these to its internal data to identify discrepancies and reconcile.			
15. Applicant agrees to complete the reconciliation of all enrollment, membership, and payment data in compliance with the 45-day schedule to submit the monthly CEO certification of enrollment data for payment.			
16. Applicant will establish 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, www.cms.hhs.gov/mapdhelpdesk, in the Plan Reference Guide for CMS Part C/D system link.			
17. Applicant will obtain CMS User ID and Password.			

3.7. 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:

Applicant must attest 'yes' to each of the following qualifications to be approved for a Part D contract. Attest 'yes' or 'no' to each of the following qualifications by clicking on the appropriate response in HPMS:	**Yes**	**No**	**Requesting Waiver?** ***Yes or No***
1. Applicant will resolve 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 will continue to monitor and document 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 will maintain 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.			

3.8. Medicare Prescription Drug Plan Finder Prescription Drug Benefit Manual, Chapter 7; CMS issued guidance 07/17/06, 11/20/07, and 08/21/08

A. In HPMS, complete the table below:

Applicant must attest 'yes' to each of the following qualifications to be approved for a Part D contract. Attest 'yes' or 'no' to each of the following qualifications by clicking on the appropriate response in HPMS.	**Yes**	**No**	**Requesting Waiver?** ***Yes or No***
1. Applicant agrees to provide its current and accurate calendar year drug pricing and pharmacy network data for publishing on the "Medicare Prescription Drug Plan Finder (MPDPF)" in the format and on a schedule required by CMS.			
2. Applicant agrees to perform quality checks for data submitted to CMS for display on the MPDPF and agrees that failure to conduct quality checks may result in suppression of the Applicant's pricing data from the website.			
3. Applicant agrees that errors or omissions identified by CMS during analyses of the data will also result in the suppression of the Applicant's pricing data from the			

website.			
4. Applicant agrees to respond to CMS' MPDPF 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.			

3.9. 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**	**Requesting Waiver?** ***Yes or No***
1. Applicant will process beneficiary grievances consistent with 42 CFR §423 subpart M.			
2. Applicant agrees to abide by Chapter 18 of the Prescription Drug Benefit Manual.			
3. Applicant will, consistent with 42 CFR §423.564 : • Track and address enrollees' grievances, • Process enrollees' grievances within the appropriate timeframes, • Work with the QIO to resolve quality of care grievances when appropriate, • Provide appropriate and timely notification enrollees of grievance dispositions, and • Train relevant staff and first tier, downstream and related entities on all regulatory requirements.			
4. Applicant will inform enrollees about the grievance process through information and outreach materials.			
5. Applicant will accept grievances from enrollees at least by telephone and in writing (including facsimile).			
6. Applicant will maintain, and provide to CMS upon request, records on all grievances received both orally and in writing. At a minimum, such records must track the:			

• Date of receipt of the grievance • Mode of receipt of grievance (i.e. fax, telephone, letter, etc.) • Person who filed the grievance • Subject of the grievance • Final disposition of the grievance • Date the enrollee was notified of the disposition			

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

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

3.10. Coverage Determinations (including Exceptions) and Appeals 42 CFR Part 423 Subpart M; Prescription Drug Benefit Manual, Chapter 18; 2010 Call Letter

A. In HPMS, complete the table below:

Applicant must attest 'yes' to each of the following qualifications to be approved for a Part D contract. Attest 'yes' or 'no' to each of the following qualifications by clicking on the appropriate response in HPMS:	**Yes**	**No**	**Requesting Waivers? *Yes or No***
1. Applicant will process coverage determinations (including exceptions) and appeals consistent with 42 CFR §423 subpart M.			
2. Applicant agrees to abide 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.			
3. Applicant will make arrangements with its network pharmacies for the standardized pharmacy notice ("Medicare Prescription Drug Coverage and Your Rights") to be posted or distributed to enrollees in accordance with the requirements set out in 42 CFR §423.562 (a)(3).			

4. Applicant will, in accordance with 42 CFR §423 subpart M: • Track coverage determination (including exceptions) and redetermination requests received both orally and in writing, • Process coverage determinations (including exceptions) and redeterminations within the appropriate timeframes, • Provide appropriate and timely notification to enrollees (and prescribing physicians or other prescribers, when appropriate) of coverage determination (including exceptions) and redetermination decisions, and • Train relevant staff and first tier, downstream and related entities on all regulatory requirements.			
5. At a minimum, Applicant must track the: • Date of receipt of a coverage determination request (including an exception request) or redetermination request, • Mode of receipt (i.e. fax, telephone, letter, etc.), • Person who filed the request, • Type of request made (i.e., standard or expedited), • Date of receipt of a physician's or other prescriber's supporting statement (for an exception request), • Disposition of request, and • Date of disposition.			
6. Applicant will notify the enrollee (and the prescribing physician or other prescriber involved as appropriate) of an expedited coverage determination as expeditiously as the enrollee's health condition requires, but no later than 24 hours after receipt of the request.			
7. Applicant will ensure that an enrollee is notified of standard coverage determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receipt of the request.			
8. Applicant will ensure 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.			

9. Applicant will ensure that an enrollee is notified of a decision on an exception request in accordance with regulatory timelines applicable to coverage determinations. For exception requests, the processing timeframe begins upon receipt of the physician's or other prescriber's supporting statement.			
10. Applicant will notify 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.			
11. Applicant will ensure that an enrollee is notified of standard redetermination as expeditiously as the enrollee's health condition requires, but no later than 7 calendar days after receipt of the request.			
12. Applicant must automatically forward coverage determination (including exception) and redetermination requests to the Independent Review Entity (IRE) when the notification timeframes are not met.			
13. Applicant will maintain 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.			
14. Applicant will ensure that it will comply with 42 CFR §423.578(a) (b) which require a Part D sponsor to: • Grant a tiering or non-formulary exception (including an exception to a utilization management tool) when it is medically appropriate to do so, and • Provide the criteria for evaluating whether approval is appropriate. These requirements also apply to exceptions requests by Medicare eligible children for off-formulary Part D pediatric drugs and doses that are medically appropriate.			
15. Applicant agrees that the exceptions process will not be overly burdensome or onerous. For example, a Part D			

Sponsor may not require that ALL exception requests be accompanied by laboratory evidence.			
16. Applicant agrees that approved non-formulary drugs must be 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 create a tier specifically designed for non-formulary exceptions.			
17. Applicant agrees it may not restrict the number of exception requests submitted by an enrollee.			
18. Applicant agrees to : • Timely effectuate favorable decisions issued by the IRE, an Administrative Law Judge, the Medicare Appeals Council, or a federal court, and • Timely notify the IRE when a favorable decision has been effectuated.			
19. Applicant agrees to timely forward case files to the IRE (upon request by the IRE) when an enrollee requests a reconsideration by the IRE.			
20. Applicant will inform its enrollees about the coverage determination (including exceptions) and appeals process through information provided in the Evidence of Coverage and outreach materials.			
21. Applicant will make available to CMS upon CMS request, coverage determination (including exceptions) and appeals records.			

3.11. Coordination of Benefits 42 CFR Part 423 Subpart J; Prescription Drug Benefit Manual, Chapter 14; 2010 Call Letter

A. In HPMS, complete the table below:

Applicant must attest 'yes' to each of the following qualifications to be approved for a Part D contract. Attest 'yes' or 'no' to each of the following qualifications by clicking on the appropriate response in HPMS:	**Yes**	**No**	**Requesting Waiver?** ***Yes or No***

1. Applicant agrees to comply with Chapter 14 of the Prescription Drug Benefit Manual.			
2. Applicant develops and operates a system for requesting and collecting updated information from enrollees about enrollees' other health insurance, including whether such insurance covers outpatient prescription drugs.			
3. Applicant permits SPAPs 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 agrees to pay user fees as required under 42 CFR §423.6 and as may be required under 42 CFR §423.464 (c).			
5. Applicant agrees not to impose fees on SPAPs or other third-party insurers that are unreasonable and/or unrelated to the cost of coordination of benefits.			
6. Applicant agrees to send updated information captured in the beneficiary COB notification process about its enrollees' other sources of prescription drug coverage by sending 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.			
8. When a supplemental payer wishes to pay premiums on behalf of plan enrollees, Applicant will: • As may be required by a supplemental payer, enter into agreements with, and accept premium payments made by these supplemental payers; • Suppress premium billing to the beneficiaries for whom it accepts premium payments from supplemental payers; • Inform enrollees not to use the SSA withhold when another payer is paying their premium (in whole or in part); and • Ensure that, the overall premium payment made by or on behalf of a beneficiary does not vary among plan enrollees (e.g., Sponsor cannot charge a different premium to			

SPAPs for their members versus all 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 will: • Enter into an agreement to receive such subsidies; • Apply such subsidies to the first dollar of beneficiary cost sharing under the Applicant's Part D plan; and • Submit claims information to the State to support reconciliation.			
11. Applicant will provide clear and prominently displayed information identifying the SPAP as a co-sponsor of benefits when the Applicant participates in a risk- or non-risk lump sum per capita contract with an SPAP to provide wrap-around benefits to Part D enrollees.			
12. Applicant agrees to receive and process plan to plan reconciliation reports on a monthly basis.			
13. Applicant agrees to coordinate the reconciliation of claims when a Part D sponsor other than the Part D sponsor on 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.			

3.12. Tracking Out-of Pocket Costs (TrOOP) 42 CFR 423 Subpart J; Prescription Drug Benefit Manual, Chapters 13 and Chapter 14; 2010 Call Letter

A. In HPMS, complete the table below:

Applicant must attest 'yes' to each of the following qualifications to be approved for a Part D contract. Attest 'yes' or 'no' to each of the following qualifications by clicking on the appropriate response in HPMS.	**Yes**	**No**	**Requesting Waiver?** ***Yes or No***

1. Applicant will track each enrollee's true out of pocket (TrOOP) costs reflecting the amount the enrollee has spent out of pocket during a program year on covered Part D drugs.			
2. Applicant will accept data concerning third party payers in a format to be specified by CMS and use these data in the Applicant's TrOOP calculation process.			
3. Applicant will process claims and track TrOOP in real time using the current HIPAA-approved NCPDP standard.			
4. Applicant will provide enrollees with a report on their TrOOP status at least monthly if the enrollee's TrOOP status has changed.			
5. Applicant will provide enrollees daily access to their current TrOOP status through the organization's toll-free customer service phone number.			
6. In the event of disenrollment, Applicant agrees to provide 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 will retroactively adjust 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 will retroactively adjust claims and recalculate TrOOP balances based on receipts received from its Medicare enrollees that reflect amounts the enrollee paid on other than real-time TrOOP-eligible claims.			
9. Applicant agrees that when it receives an 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 agrees to retroactively adjust claims, recalculate 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 will count other payer paid amounts as satisfying the Part D deductible whether or not the entire amount counts toward TrOOP.			
12. Applicant will establish and identify in the Health Plan Management System (HPMS) a COB contact who can be contacted by CMS, the States and other payers to resolve COB issues.			
13. Applicant will establish an Automated TrOOP Balance Transfer (ATBT) contact who can be contacted by CMS or the TrOOP Facilitation Contractor to resolve ATBT issues.			
14. Applicant agrees to develop 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.			
15. Applicant agrees that, when an exception to the ATBT process is required, the Applicant will send TrOOP-related data manually for disenrolling Part D beneficiaries as well as receive these data for newly enrolling Part D beneficiaries transferring mid-year from another plan.			
16. Applicant agrees to develop 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.			

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

3.13. Medicare Secondary Payer 42 CFR §423.462; Prescription Drug Benefit Manual, Chapter 14; 2010 Call Letter

A. In HPMS, complete the table below:

Applicant must attest 'yes' to each of the following qualifications to be approved for a Part D contract. Attest 'yes' or 'no' to each of the following qualifications by clicking on the appropriate response in HPMS.	**Yes**	**No**	**Requesting Waiver?** ***Yes or No***

1. Applicant is familiar with rules that determine when other payers are primary or secondary to Medicare as referenced in 42 CFR §423.462.			
2. Applicant will adhere to MSP laws and any other Federal and State laws in establishing payers of last resort.			
3. Applicant will follow the Rules for Coordination of Benefits adopted in the most current National Association of Insurance Commissioner Coordination of Benefits Model Regulation.			
4. Applicant will process claims in real time to support the TrOOP facilitation process when it is a secondary payer in accordance with the application of MSP rules.			
5. Applicant will collect mistaken primary payment from insurers, group health plans, employer sponsors, enrollees and other entities.			
6. Applicant agrees that in situations involving workers' compensation, 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.			
7. Applicant agrees that in situations involving workers' compensation Medicare set-asides including prescription drugs, the Applicant will establish point-of-sale edits to deny payment and reject claims for the included drugs.			

3.14. Marketing/Beneficiary Communications 42 CFR §423.50 and 42 CFR §423.128; Prescription Drug Benefit Manual, Chapter 2; 2010 Call Letter

A. In HPMS, complete the table below:

Applicant must attest 'yes' to each of the following qualifications to be approved for a Part D contract. Attest 'yes' or 'no' to each of the following qualifications by clicking on the appropriate response in HPMS.	**Yes**	**No**	**Requesting Waiver?** ***Yes or No***
1. Applicant will comply with marketing guidelines and			

approval procedures that are contained with Chapter 2 of the Prescription Drug Benefit Manual and posted on the www.cms.hhs.gov/ website.			
2. Applicant will make available to beneficiaries only those marketing materials that comply with CMS' marketing guidelines.			
3. Annually and at the time of enrollment, the Applicant agrees to provide enrollees information about the following Part D features, as described in the marketing guidelines: • Enrollment and Disenrollment Procedures • Beneficiary Procedural Rights • Potential for Contract Termination • Benefits • Types of Pharmacies in the Pharmacy Network • Out-of-network Pharmacy Access • Formulary • Premiums and cost-sharing • Service Area			
4. Applicant agrees to provide 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 agrees to make marketing materials available in any language that is the primary language of more than 10% of an Applicant's plan's geographic service area.			
6. Applicant will maintain a toll-free customer service call center that provides customer telephone service in compliance with CMS standards. This means that the Applicant must comply with at least the following: • Call center operates during normal business hours, seven days a week from 8:00 AM to 8:00 PM for all time zones in which the Applicant offers a Part D plan. • A customer service representative will be available to answer beneficiary calls directly during the annual enrollment period and 60 days after the annual enrollment period.			

• On Saturdays, Sundays and holidays, from March 2nd until the following annual enrollment period, a customer service representative or an automated phone system may answer beneficiary calls. • If a beneficiary is required to leave a message in voice mail box due to the utilization of an automated phone system, the applicant must ensure 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. • The average hold time for a beneficiary to reach a customer service representative must be two minutes or less. • The disconnect rate of all incoming customer calls does not exceed 5 percent. • Call center provides thorough information about the Part D benefit plan, including co-payments, deductibles, and network pharmacies. • Call center features an explicit process for handling customer complaints. • Call center shall provide service to non-English speaking, limited English proficient (LEP), and hearing impaired beneficiaries.			
7. Applicant will operate an Internet Web site that includes all items identified in Chapter 2 of the Prescription Drug Benefit Manual, including but not limited to: a) describes the Applicant's Part D current, approved formularies, b) describes prior authorization criteria, step therapy requirements, and quantity limits, and c) provides 60-days' notice to potential and current plan enrollees regarding negative changes including the removal or change in the tier placement of any drug on the plan's formulary.			
8. Applicant agrees to ensure that the marketed and adjudicated formularies are consistent with the HPMS approved formulary file.			
9. Applicant will provide its plan enrollees, in a form understandable to enrollees and on at least a monthly basis for those months in which the enrollees use their Part D benefits, an explanation of benefits that states a) the item or service for which payment was made; b) notice of the enrollee's right to an itemized statement; c) a year-			

to-date statement of the total Part D benefits provided in relation to deductibles, coverage limits, and annual out-of-pocket thresholds; d) cumulative year-to-date total of incurred costs; and e) applicable formulary changes.			
10. Applicant agrees not to include co-branding names and/or logos of contracted providers or names and/or logos that are substantially similar to a contracted provider's name and/or logo on member identification cards.			
11. Applicant agrees that the subsequent CY Annual Notice of Change (ANOC) / Summary of Benefits (SB) / Formulary must be received by members (if applicable) by October 31st of the current benefit year.			
12. Applicant will notify 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.			

3.15. Provider Communications 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**	**Requesting Waiver?** ***Yes or No***
1. Applicant will operate toll-free call center to respond to inquiries from pharmacies and providers regarding the Applicant's Medicare prescription drug benefit. Inquiries will concern such operational areas as claims processing, benefit coverage, claims submission, and claims payment. This means that the Applicant must comply with at least the following: • Be available 24 hours a day when the pharmacy network includes pharmacies that are open 24 hours a day; • The average hold time for a pharmacist to reach a customer service representative must be two minutes or less. • The disconnect rate of all incoming calls does not exceed 5 percent.			

2. Applicant agrees that it will have 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.			
3. Applicant will operate a toll-free call center to respond to physicians and other prescribers for information related to prior authorizations, coverage determinations (including exceptions), and appeals requests. The call center must operate during normal business hours and never less than 8:00 a.m. to 6:00 p.m., Monday through Friday according to the time zones for the regions in which their plans operate. Applicant may use voicemail provided the message: • Indicates that the mailbox is secure. • Lists the information that must be provided so the case can be worked (e.g., provider identification, beneficiary identification, type of request (coverage determination, exception, or appeal) and whether the request is an expedited or standard request). . • 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. • For appeals requests: articulates and follows a process for resolution within 72 hours for expedited appeals, and 7 calendar days for standard appeals. • Provides and follows a process for immediate access in situations where an enrollee’s life or health is in serious jeopardy.			

3.16. Compliance Plan 42 CFR §423.504(b)(4)(vi); Prescription Drug Benefit Manual, Chapter 9

A. In HPMS, complete the table below:

Applicant must attest ‘yes’ to each of the following qualifications to be approved for a Part D contract. Attest ‘yes’ or ‘no’ to each of the following qualifications by clicking on the appropriate response in HPMS.	**Yes**	**No**	**Requesting Waiver? Yes or No**

1. Applicant's Part D compliance plan is accordance with all Federal and State regulations and guidelines, including Chapter 9—Part D Program to Control Fraud, Waste and Abuse of the Prescription Drug Benefit Manual by time of CMS contract with the Part D Applicant. The compliance plan must clearly establish that it will address Part D.			
2. Applicant's Part D compliance plan consists of written policies, procedures, and standards of conduct addressing Part D issues and articulating your organization's commitment to abide by all applicable Federal and State standards.			
3. Applicant's Part D compliance plan designates an employee as the compliance officer and compliance committee accountable to senior management. (Note: This requirement cannot be delegated to a first tier, downstream, or related entity.)			
4. Applicant's Part D compliance plan includes effective training and education between the compliance officer and the Part D Applicant's employees, managers and directors and the Part D Applicant's first tier, downstream and related entities. Note: To the extent that aspects of the compliance plan are delegated, it is important to remember that the Applicant's compliance officer must maintain appropriate oversight of the delegated activities.			
5. Applicant's Part D compliance plan includes effective lines of communication between the compliance officer, members of the compliance committee, the Part D Applicant's employees, managers and directors and the Part D Applicant's first tier, downstream and related entities.			
6. Applicant's Part D compliance plan includes disciplinary standards that are well-publicized within the organization.			
7. Applicant's Part D compliance plan includes procedures for internal monitoring and auditing (including first tier, downstream, and related entities) of operations as they relate to Part D administration.			
8. Applicant's Part D compliance plan includes procedures for ensuring prompt response to detected Part D offenses and development of corrective action initiatives, relating to the Applicant's contract as a Part D sponsor. This			

compliance plan should include procedures to voluntarily self report potential fraud or misconduct related to the Part D program to CMS or its designee.			

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

The Part D compliance plan must be in accordance with 42 CFR §423.504(b)(4)(vi). In addition, the Part D compliance plan must demonstrate that all 7 elements in the regulation and in Chapter 9 are being implemented and are specific to the issues and challenges presented by the Part D program. A general compliance plan applicable to healthcare operations is not acceptable.

Note: Please be advised that the Part D Applicant is ultimately responsible for the implementation and monitoring of the day-to-day operations of its Part D compliance program. 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 the Medicare Compliance Officer identified in HPMS Contacts (see section entitled HPMS Part D Contacts) must be an employee of the Applicant. A compliance plan adopted and operated by a Part D Applicant's (first tier, downstream and related entities) is not sufficient to demonstrate that the Part D Applicant meets the compliance program requirement.

C. In HPMS, complete and upload the table below. Applicant must clearly identify where each requirement can be found in the uploaded documents.

Crosswalk for Part D Compliance Plan	**Document Page Number**
Written policies, procedures, and standards of conduct addressing Part D issues and articulating your organization's commitment to abide by all applicable Federal and State standards.	
Designation of an employee as the compliance officer and compliance committee accountable to senior management. (Note: This requirement cannot be delegated to a first tier, downstream, or related entity).	
Effective training and education between the compliance officer and organization employees, contractors, agents, directors, first tier, downstream, and related entities.	
Effective lines of communication between the compliance officer and organization employees, contractors, agents and directors and members of the compliance committee.	
Enforcement of standards through disciplinary guidelines that are well-	

publicized in the organization.	
Procedures for internal monitoring and auditing of operations as they relate to Part D administration.	
Procedures for ensuring prompt response to detected Part D offenses and development of corrective action initiatives, relating to the Applicant's contract as a Part D sponsor.	

3.17. Reporting Requirements 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**	**Requesting Waiver?** ***Yes or No***
Reporting Requirements Guidance			
1. Applicant agrees to comply with the Reporting Requirements Guidance that is posted on the www.cms.hhs.gov/ website.			
2. Applicant agrees that an individual with authority to sign on behalf of your organization will attest that the reporting requirements data has been audited internally for accuracy.			
Claims Data			
3. 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 will encompass quantity, type, and costs of pharmaceutical prescriptions filled for enrollees. The plan must link this information to Medicare beneficiary identification numbers (HIC#s).			
4. 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 prescription drug event records for Medicare enrollees for every Part D drug prescription in the format required by CMS, using batch submission			

processes. Data to be submitted will encompass quantity, type and costs of pharmaceutical prescriptions filled for enrollees. The plan must link this information to Medicare beneficiary identification numbers (HIC#s).			
5. 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).			
6. 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.			
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 correcting all data errors identified by CMS.			
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 collecting data for dates of service within the coverage year with a 3-month closeout window for the submission of remaining unreported claims data.			
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 providing additional information for the purposes of reconciliation of risk factors, low income subsidy payments, reinsurance payments, and risk corridor as required by CMS.			
Rebate Data			
10. The Applicant will report 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 will maintain records and documentation to verify the DIR data reported to CMS.			

Other Data			
11. Applicant will report at a frequency determined by CMS specified data (pursuant to 42 CFR §423.514(a)) on a variety of measures to support payment, program integrity, program management, and quality improvement activities in a manner prescribed by CMS. Such data submissions will be accurate and timely.			
12. The Applicant will provide CMS with routine administrative reports (pursuant to 42 CFR §423.514 (a)) on a variety of measures that concern the Applicant's performance in the administration of the Part D benefit. Such reports shall be submitted according to instructions issued with timely notice by CMS.			
Supporting www.medicare.gov			
13. The Applicant will submit pricing and pharmacy network information to be publicly reported on www.medicare.gov in order to provide Medicare beneficiaries with necessary information regarding prescription drug costs under the respective plans. Details regarding this data requirement will be posted on www.cms.hhs.gov by April of the prior year.			
Conflict of Interest			
14. The Applicant will provide financial and organizational conflict of interest reports to CMS.			

3.18. 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**	**Requesting Waiver?** ***Yes or No***
HPMS			
1. Applicant will use HPMS to communicate with CMS in support of the application process, formulary submission process, bid submission process, ongoing operations of the Part D program, and reporting and oversight activities.			

Part D sponsors are required to secure access to HPMS in order to carry out these functions.			
Enrollment & Payment			
2. Applicant will reconcile Part D data to CMS enrollment/payment reports within 45 days of availability.			
3. Applicant will submit enrollment/payment attestation forms within 45 days of CMS report availability.			
4. Applicant will participate in connectivity testing and other system testing measures as provided to the Applicants prior to contract execution to validate system setup.			
5. Applicant will establish system(s) to process enrollment and payment transactions as exchanged with CMS in accordance with system development lifecycle standards.			
6. Applicant will ensure appropriate security safeguards and protocols are in place to protect the protected health information in the system(s).			
7. Applicant will maintain all pertinent system security and disaster recovery plans and procedures.			
8. In accordance with 42 CFR §423.322, the Applicant agrees to provide 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.			

3.19. Health Insurance Portability and Accountability Act of 1996 (HIPAA) and Related CMS Requirements 45 CFR Parts 160, 162, and 164; CMS issued guidance 08/15/2006 and 08/26/08; 2008 Call Letter; and P.L. 111-5 (2009)

A. In HPMS, complete the table below:

Applicant must attest 'yes' to each of the following qualifications to be approved for a Part D contract. Attest 'yes' or 'no' to each of the following qualifications by clicking on the appropriate response in HPMS.	**Yes**	**No**	**Requesting Waiver?** ***Yes or No***

1. Applicant will comply with all applicable standards, implementation specifications, and requirements in the Standards for Privacy of Individually Identifiable Health Information under 45 CFR Parts 160 and 164, Subparts A and E.			
2. Applicant will comply with all applicable standards, implementation specifications, and requirements in the Security Standards under 45 CFR Parts 160 and 164, Subparts A and C.			
3. Applicant agrees to encrypt all hard drives or other storage media within the device as well as all removable media.			
4. Applicant agrees to develop and implement policies addressing the secure handling of portable media that is accessed or used by the organization.			
5. Applicant will comply 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.			
6. Applicant agrees that when its organization receives a National Provider Identifier (NPI) in prescription drug event data, that the organization must report an NPI.			
7. Applicant agrees to implement a contingency plan related to compliance with the NPI provisions.			
8. Applicant will comply with all applicable standards, implementation specifications, and requirements in the Standards for Electronic Transactions under 45 CFR Parts 160 and 162.			
9. Applicant agrees to transmit payment and remittance advice consistent with the HIPAA-adopted ACS X12N 835, Version 4010/4010A1: Health Care Claim Payment and Remittance Advice Implementation Guide (“835”).			
10. Applicant agrees to submit 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.			
11. Applicant agrees to comply with privacy and security provisions found in sections 13401, 13402, and 13404 of the American Recovery and Reinvestment Act of 2009, P.L. 111-5.			

3.20. 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**	**Requesting Waiver?** ***Yes or No***
1. Applicant agrees not to use an enrollee's Social Security Number (SSN) or Medicare ID Number on the enrollee's identification card.			

3.21. Record Retention 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**	**Requesting Waiver?** ***Yes or No***
1. The Applicant will maintain books, records, documents, and other evidence of accounting procedures and practices consistent with 42 CFR §423.505(d).			
2. Applicant agrees to have pharmacies, contracted for the Part D benefit, maintain prescription records in their original format for the greater of 3 years or the period required by State law and allow those records to be transferred to an electronic format that replicates the original prescription for the remaining 7 years of the 10 year record retention requirement.			
3. Applicant agrees to keep all other records—except			

prescription records—that must be retained for Medicare under Part C and Part D in the format(s) required by State law or at the Applicant's discretion.			

3.22. Prescription Drug Event (PDE) Records; 42 CFR Part 423 Subpart G; CMS issued guidance 04/27/2006

Applicant must attest 'yes' to each of the following qualifications to be approved for a Part D contract. Attest 'yes' or 'no' to each of the following qualifications by clicking on the appropriate response in HPMS:	**Yes**	**No**	**Requesting Waiver?** ***Yes or No***
1. Applicant agrees to abide by CMS guidance related to PDE data. Such guidance includes the 2008 Regional Prescription Drug Event Data Technical Assistance Resource Guide which can be found at www.csscoperations.com/new/pdic/pdd-training/pdd-training.html.			
2. Applicant agrees to submit data and information necessary for CMS to carry out payment provisions.			
3. Applicant agrees to submit PDE data at least monthly.			
4. Applicant agrees to submit 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 agrees to provide diagnosis data for risk adjustment as required by CMS.			
6. Applicant agrees to meet all data submission deadlines.			

3.23. Claims Processing; CMS issued guidance 04/26/2006

A. In HPMS, complete the table below:

Applicant must attest 'yes' to each of the following qualifications to be approved for a Part D contract. Attest 'yes' or 'no' to each of the following qualifications by clicking on the appropriate response in HPMS.	**Yes**	**No**	**Requesting Waiver?** ***Yes or No***

1. Applicant develops and operates an on-line claims processing system that operates in real time to ensure accurate and timely payment of all claims submitted by network pharmacies on behalf of Part D plan enrollees. System operates according to the following standards: • 98% response within 4 seconds; • 99% of all claims paid with no errors; • 99% system availability.			
2. Applicant develops and operates a system designed to : • Pay non-electronic claims submissions from network pharmacies in accordance with 42 CFR §423.520; and • Pay requests for reimbursement from beneficiaries in accordance with 42 CFR §423.568(b).			
3. Applicant will develop and have available for CMS inspection a complete description of your claims adjudication system including: • Hardware and software; • Operating system; • Commercial organization from which Applicant receives pricing files, including file revision history; • Number of sites processing claims (including disaster recovery back-up system); and • System volume in covered lives, including the number of transactions the system can support per day and per hour.			
4. Applicant will develop and have available to CMS upon request policies and procedures that include a complete description and flow chart detailing the claims adjudication process for each: • Contracted network pharmacies; • Paper claims; • Out-of-network pharmacy claims submitted by beneficiaries;			

• Non-electronic claims submitted by network pharmacies, and other payers seeking to coordinate benefits; • Batch-processed claims; and • Manual claim entry (e.g. for processing direct member reimbursement).			
5. Applicant will develop and will make available to CMS upon request policies and procedures that include a complete description of claim detail management, including: • The length of time that detailed claim information is maintained online (not less than 12 months) • The data storage process after it is no longer online • The length of time that detailed claim information is stored when it is no longer online (not less than 10 years)			
6. Applicant will develop and have available to CMS upon request policies and procedures that include a complete description of the accessibility of this information for data capture purposes and flow chart of the claims data retrieval process for each: • Entire claims history file; • File claims adjustments including records of reimbursements and recoveries due to network pharmacies and beneficiaries; and • Deductible files/TrOOP/ and gross covered prescription drug cost accumulator.			
7. Applicant will have a robust testing process that will identify and correct any plan configuration errors prior to implementation.			
8. Applicant will use HIPAA compliant transactions where applicable.			
9. Applicant can and will document the manner and extent to which it has tested benefit designs such as drug exclusions or quantity limitations and plan parameters such as co-payments and benefit intervals (phases).			

10. Applicant agrees to rapidly adopt any new messaging approved by the NCPDP Workgroup to adjudicate a Part D claim and appropriately coordinate benefits in real time.			
11. Applicant agrees to regularly update their systems with the most current information on sanctioned providers and have 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.			

3.24. 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**	**Requesting Waiver?** ***Yes or No***
1. Applicant agrees it will take 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 agrees it will promptly reimburse members for overpayments.			
3. Applicant agrees it will 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 will resolve the matter with CMS not with the member.			

3.25. Consumer Assessment Health Providers Survey (CAHPS) Administration 2010 Call Letter

A. In HPMS, complete the table below:

Applicant must attest 'yes' to each of the following qualifications to be approved for a Part D contract. Attest 'yes' or 'no' to each of the following qualifications by clicking on the appropriate response in HPMS.	**Yes**	**No**	**Requesting Waiver?** ***Yes or No***
1. Applicant 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.

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

5. Appendices

APPENDIX I – Summary of Medicare Part D Regulatory Requirements Fulfilled under Part C for Medicare Advantage Prescription Drug (MA-PD) Applicants

Part D Regulation	Regulatory Requirement(s) Description	Basis for Waiver
42 CFR 423Subpart I, excepting 42 CFR §423.440 (which concerns Federal preemption of State law and prohibition of State premium taxes)	Licensure and Solvency – Applicant must be licensed to bear risk in the State in which it intends to operate or apply for a licensure waiver and meet CMS solvency standards.	Duplicative of MA Organization requirements for licensure and solvency under 42 CFR §422.6 (i); 42 CFR §422.400; and 42 CFR §422.501).
42 CFR §423.153(b) ***Waiver applies to MA-PFFS only***	Utilization Management - Applicant must have a cost effective utilization management system.	Waiver stated in regulations at 42 CFR §423.153 (e) excuses MA PFFS organizations from meeting the utilization management requirements specified in 42 CFR §423.153 (b).
42 CFR §423.153(d) ***Waiver applies to MA-PFFS only***	Medication Therapy Management Program – Applicant must have a program to manage medication therapy to optimize outcomes, reduce adverse drug interactions.	Waiver stated in regulations at 42 CFR §423.153 (e) excuses MA PFFS organizations from meeting Medication Therapy Management Program requirements specified in 42 CFR §423.153(d).
42 CFR §423.112 (a)	Service Area – Applicant must offer a Part D plan that serves at least an entire PDP region.	Conflicts with MA regulations (42 CFR§ 422.2) that allow MA organizations to offer local MA plans (i.e., plans that serve less than an entire state).
42 CFR	Pharmacy Network – Applicant must offer its Part D plan benefit through a contracted retail	Waiver stated in regulations at 42 CFR§ 423.120(a)(7) (i) excuses from the CMS convenient access

Part D Regulation	Regulatory Requirement(s) Description	Basis for Waiver
§423.120 (a)(7)(i) ***Waiver applies only to MA-PDs that operate their own pharmacies***	pharmacy network that meets CMS convenient access standards.	standards those MA organizations that administer their Part D benefit through pharmacies owned and operated by the MA organization if that organization's pharmacy network access meets the CMS convenient access standards .
42 CFR §423.120(a)(7)(ii) ***Waiver applies to MA-PFFS plan that provides access through all pharmacies.***	Pharmacy Network – Applicant must offer its Part D plan benefit through a contracted retail pharmacy network that meets CMS convenient access standards	Waiver stated in regulations at 42 CFR §423.120 (a) (7) (ii). excuses from the CMS convenient access standards those MA-PFFS organizations that offer a qualified prescription drug coverage, and provide plan enrollees with access to covered Part D drugs dispensed at all pharmacies, without regard to whether they are contracted network pharmacies and without charging cost-sharing in excess of the requirements for qualified prescription drug coverage.
42 CFR §423.120(a)(8)(i) **Waiver applies only to MA-PDs that operate their own pharmacies**	Pharmacy Network – Applicant must offer its Part D benefit through any willing pharmacy that agrees to meet reasonable and relevant standard network terms and conditions.	Waiver promotes the coordination of Parts C and D benefits. Excuses from CMS any willing pharmacy requirement those MA organizations that administer their Part D benefit through pharmacies owned and operated by the MA organization and dispense at least 98% of all prescriptions through pharmacies owned and operated by Applicant.
42 CFR §423.34 42 CFR §423.36 42 CFR §423.38 42 CFR §423.40 42 CFR §423.44	Enrollment and Eligibility – Applicant agrees to accept Part D plan enrollments and determine Part D plan eligibility consistent with Part D program requirements.	Duplicative of MA requirements under 42 CFR §422 Subpart B - Eligibility, Election, and Enrollment. MA organizations will conduct enrollment and determine eligibility consistent with MA program requirements. These requirements mirror those stated in the Part D regulation.
42 CFR	Reporting Requirements – Applicant must report information	Duplicative of MA requirements for reporting significant transactions

Part D Regulation	Regulatory Requirement(s) Description	Basis for Waiver
§423.514(b) and (c)	concerning significant business transactions.	under 42 CFR §422.500 and 42 CFR §422.516(b) and (c) and requirements for providing annual financial statements.
42 CFR §423.514(e)	Reporting Requirements – Applicant must notify CMS of any loans or any other special arrangements it makes with contractors, subcontractors, and related entities.	Duplicative of MA requirement for reporting loans or special arrangements under 42 CFR §422.516(e).
42 CFR §423.512	Experience and Capabilities – Applicant must reach the minimum enrollment standard within the first year it offers a Part D benefit.	Conflicts with MA regulation at 42 CFR §422.514 that permits three years to achieve the minimum enrollment level.

APPENDIX II – Direct Contract MA-PFFS Attestations

1. EGWP 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 MA-PFFS Sponsors. Direct Contract MA-PFFS Sponsors can extend coverage to all of their retirees, regardless of whether they reside in one or more MA regions in the nation. In order to provide coverage to retirees wherever they reside, Direct Contract MA-PFFS Sponsors must set their service areas to include all areas where retirees may reside during the plan year. Applicants 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 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 Direct Contract MA-PFFS. 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 this underlying Solicitation apply to all plan benefit packages offered by the Direct Contract MA-PFFS 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 *2011 Solicitation for Applications for New Medicare Advantage Prescription Drug Plan (MA-PD) Sponsors* that have been waived or modified for new Direct Contract MA-PFFS Applicants are noted in parentheses).

I, the undersigned, certify to the following:

1) Applicant is applying to offer new employer/union-only Direct Contract Medicare Advantage Prescription Drug Plans and agrees to be subject to and comply with all CMS employer/union-only group waiver guidance.

2) Applicant understands and agrees that it must complete and submit the *2011 Medicare Advantage Application, 2011 Initial Application For Employer/Union Direct Contract Private Fee-For-Service (PFFS) Medicare Advantage Organization,* and *the underlying 2011 Solicitation for Applications for New Medicare Advantage Prescription Drug Plan (MA-PD) Sponsors* in addition to the Appendix entitled "Part D Financial Solvency & Capital Adequacy Documentation for Direct Contract MA-PFFS Applicants". All these documents comprise new Direct Contract MA-PFFS Applicant's entire Direct Contract MA-PFFS application.

3) Applicant agrees to restrict enrollment in its Direct Contract MA-PFFS plans to those Medicare eligible individuals eligible for the employer's/union's employment-based group coverage.

4) Applicant understands and agrees that it is not required to submit a 2011 Part D bid (i.e., bid pricing tool) to offer its Direct Contract MA-PFFS. (Section 2.7*)*

5) 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 MA-PFFS'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 3.5.1A1)

6) Applicant understands and agrees that as part of its completion of the underlying application, it will submit retail pharmacy access reports (See Appendix entitled "Retail Pharmacy Network Access Instructions" and other pharmacy access submissions (mail order, home infusion, long-term care, I/T/U) required at the time of application for its entire designated service area. (Section 3.5)

7) Applicant understands that its Direct Contract MA-PFFS plans will not be included in the processes for auto-enrollment (for full-dual eligible beneficiaries) or facilitated enrollment (for other low income subsidy eligible beneficiaries). (Section 3.6.A2*)*

8) Applicant understands that CMS has waived the requirement that the Direct Contract MA-PFFS must provide beneficiaries the option to pay their premium through Social Security withholding. Thus, the premium withhold option will not be available for enrollees in Applicant's Direct Contract MA-PFFS. (Sections 3.6.A10 and 3.24.A2-A4*)*

9) Applicant understands that dissemination materials for its Direct Contract MA-PFFS plans are not subject to the requirements contained in 42 CFR §423.50 to be submitted for review and approval by CMS prior to use. However, Applicant agrees that it will submit these materials to CMS at the time of use in accordance with the procedures outlined in Chapter 9 of the Medicare Managed Care Manual (MMCM). 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 3.14A1)

10) Applicant understands that its Direct Contract MA-PFFS will not be 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 3.14A11)

11) Applicant understands that the dissemination/disclosure requirements set forth in 42 CFR §423.128 will not apply to its Direct Contract MA-PFFS plans 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 agrees to comply with the requirements for this waiver contained in employer/union-only group waiver guidance, including those requirements contained in Chapter 9 of the MMCM. (Section 3.14.A1-A2, A9)

12) Applicant understands that its Direct Contract MA-PFFS plans will not be 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 (Medicare Prescription Drug Plan Finder). (Sections 3.8A and 3.17A14)

13) Applicant understands that its Direct Contract MA-PFFS plans will not be subject to the Part D beneficiary customer service call center hours and call center performance requirements. Applicant attests that it will ensure that a sufficient mechanism is available to respond to beneficiary inquiries and will provide 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 3.14A6)

14) 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 will modify these reporting requirements for Direct MA-PFFSs 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 3.17A12-A13)

15) 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.

16) 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.

17) 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.

18) 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.

19) 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 to offer employer/union-only group waiver plans in association with the organization's MA-PFFS Contract with CMS.

☐ 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 Direct Contract plans in association with my organization's MA-PFFS Contract with CMS. I have read and agree to comply with the above certifications.

{Entity MUST check box for a complete application.}

APPENDIX III -- 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.

Section	Requirement	Location in Subcontract by Page number and Section
3.1.1D1	The parties to the contract	
3.1.1D2	The functions to be performed by the first tier, downstream, or related entity. 42 CFR §423.505(i)(4)(i)	
3.1.1D3	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)	
3.1.1D4	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).	
3.1.1D5	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)	
3.1.1D6	The payment the first tier, downstream, or related entity will receive for performance under the contract, if applicable.	
3.1.1D7	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 November 15 extending through the full contract year ending on December 31 of the next year).	
3.1.1D8	Are signed by a representative of each party with legal authority to bind the entity.	
3.1.1D9	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)	
3.1.1D10	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.	
3.1.1D11	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	
3.1.1D12	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)	
3.1.1D13	Language indicating that any books, contracts, records, including medical records and documentation relating to the Part D program will be provided to either the sponsor to provide to CMS or its designees or will be provided	

	directly to CMS or its designees. 42 CFR §423.505(i)(3)(iv)	
3.1.1D14	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)	
3.1.1D15	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	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)	
3.1.1D17	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)	
3.1.1D18	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 if a prescription drug pricing standard is used for	

	reimbursement, identify the source used by the Part D sponsor for the prescription drug pricing standard of reimbursement. 42 CFR §423.505(i)(3)(viii)(B)	
3.1.1D19	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 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(i)(3)(viii)(A)	

APPENDIX IV -- Crosswalk for Retail Pharmacy Access Contracts

INSTRUCTIONS: 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 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 to 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. 42 CFR §423.505(i)(4)(i)	
3.1.1D3	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 indicating that any books, contracts, records, including medical records and documentation relating to the Part D program will be provided to either the sponsor to provide to CMS or its designees or will be provided directly to CMS or its designees. 42 CFR §423.505(i)(3)(iv)	
3.1.1D13	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)	
3.1.1D14	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)	
3.1.1D17	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)	
3.1.1D18	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)	
3.1.1D19	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)	
3.4A3	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 V -- Crosswalk for Mail Order 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 Mail Order 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. 42 CFR §423.505(i)(4)(i)	
3.1.1D3	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 indicating that any books, contracts, records, including medical records and documentation relating to the Part D program will be provided to either the sponsor to provide to CMS or its designees or will be provided directly to CMS or its designees. 42 CFR §423.505(i)(3)(iv)	
3.1.1D13	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)	
3.1.1D14	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)	
3.1.1D18	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)	
3.1.1D19	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)	
3.4A3	Provisions governing submitting claims to a real-time claims adjudication system. 42 CFR §423.505(j) and §423.505(b)(17)	
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	
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 VI -- Crosswalk for Home Infusion 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 Home Infusion 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. 42 CFR §423.505(i)(4)(i)	
3.1.1D3	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 indicating that any books, contracts, records, including medical records and documentation relating to the Part D program will be provided to either the sponsor to provide to CMS or its designees or will be provided directly to CMS or its designees. 42 CFR §423.505(i)(3)(iv)	
3.1.1D13	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)	
3.1.1D14	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)	
3.1.1D17	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)	
3.1.1D18	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)	
3.1.1D19	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)	
3.4A3	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. 42 CFR §423.120(a)(4)(iii)	
3.4.4A6	Provisions ensuring that 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. 42 CFR §423.120(a)(4)(iv)	

APPENDIX VII -- Crosswalk for Long-Term Care 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 Long-Term Care pharmacy contract template submitted under Section 3.4. Applicants must 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. 42 CFR §423.505(i)(4)(i)	
3.1.1D3	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.	
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 indicating that any books, contracts, records, including medical records and documentation relating to the Part D program will be provided to either the sponsor to provide to CMS or its designees or will be provided directly to CMS or its designees. 42 CFR §423.505(i)(3)(iv)	
3.1.1D13	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)	
3.1.1D14	Language specifying that the Applicant, upon becoming a Part D sponsor, will monitor the performance of the subcontractor (first tier, downstream and related entities) on an ongoing basis. 42 CFR §423.505(i)(4)(iii)	
3.1.1D18	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)	
3.1.1D19	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)	
3.4A3	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(g)	

Elements Specific to Long-Term Care Contracts

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 should, at a minimum, incorporate these criteria in ALL LTC pharmacy network contracts. Applicant must list the criteria below, and then identify where the elements reside in the contract template(s) submitted.

Performance and Service Criteria	**Citation**
Comprehensive Inventory and Inventory Capacity – Network Long Term Care Pharmacies [NLTCPs] must provide a comprehensive inventory of Plan formulary drugs commonly used in the long term care setting. In addition, NLTCPs must provide a secured area for physical storage of drugs, with necessary added security as required by federal and state law for controlled substances. This is not to be interpreted that the pharmacy will have inventory or security measures outside of the normal business	

setting.	
Pharmacy Operations and Prescription Orders -- NLTCPs must provide services of a dispensing pharmacist to meet the requirements of pharmacy practice for dispensing prescription drugs to LTC residents, including but not limited to the performance of drug utilization review (DUR). In addition, the NLTCP pharmacist must conduct DUR to routinely screen for allergies and drug interactions, to identify potential adverse drug reactions, to identify inappropriate drug usage in the LTC population, and to promote cost effective therapy in the LTC setting. The NLTCP must also be equipped with pharmacy software and systems sufficient to meet the needs of prescription drug ordering and distribution to an LTC facility. Further, the NLTCP must provide written copies of the NLTCP's pharmacy procedures manual and said manual must be available at each LTC facility nurses' unit. NLTCPs are also required to provide ongoing in-service training to assure that LTC facility staff are proficient in the NLTCP's processes for ordering and receiving of medications. NLTCP must be responsible for return and/or disposal of unused medications following discontinuance, transfer, discharge, or death as permitted by State Boards of Pharmacy. Controlled substances and out of date substances must be disposed of within State and Federal guidelines.	
Special Packaging -- NLTCPs must have the capacity to provide specific drugs in Unit of Use Packaging, Bingo Cards, Cassettes, Unit Dose or other special packaging commonly required by LTC facilities. NLTCPs must have access to, or arrangements with, a vendor to furnish supplies and equipment including but not limited to labels, auxiliary labels, and packing machines for furnishing drugs in such special packaging required by the LTC setting.	
IV Medications -- NLTCPs must have the capacity to provide IV medications to the LTC resident as ordered by a qualified medical professional. NLTCPs must have access to specialized facilities for the preparation of IV prescriptions (clean room). Additionally, NLTCPs must have access to or arrangements with a vendor to furnish special equipment and supplies as well as IV trained pharmacists and technicians as required to safely provide IV medications.	
Compounding /Alternative Forms of Drug Composition -- NLTCPs must be capable of providing specialized drug delivery formulations as required for some LTC residents. Specifically, residents unable to swallow or ingest	

medications through normal routes may require tablets split or crushed or provided in suspensions or gel forms, to facilitate effective drug delivery.	
Pharmacist On-call Service -- NLTCP must provide on-call, 24 hours a day, 7 days a week service with a qualified pharmacist available for handling calls after hours and to provide medication dispensing available for emergencies, holidays and after hours of normal operations.	
Delivery Service -- NLTCP must provide for delivery of medications to the LTC facility up to seven days each week (up to three times per day) and in-between regularly scheduled visits. Emergency delivery service must be available 24 hours a day, 7 days a week. Specific delivery arrangements will be determined through an agreement between the NLTCP and the LTC facility. NLTCPs must provide safe and secure exchange systems for delivery of medication to the LTC facility. In addition, NLTCP must provide medication cassettes, or other standard delivery systems, that may be exchanged on a routine basis for automatic restocking. The NLTCP delivery of medication to carts is a part of routine "dispensing".	
Emergency Boxes -- NLTCPs must provide "emergency" supply of medications as required by the facility in compliance with State requirements.	
Emergency Log Books -- NLTCP must provide a system for logging and charging medication used from emergency/first dose stock. Further, the pharmacy must maintain a comprehensive record of a resident's medication order and drug administration.	
Miscellaneous Reports, Forms and Prescription Ordering Supplies -- NLTCP must provide reports, forms and prescription ordering supplies necessary for the delivery of quality pharmacy care in the LTC setting. Such reports, forms and prescription ordering supplies may include, but will not necessarily be limited to, provider order forms, monthly management reports to assist the LTC facility in managing orders, medication administration records, treatment administration records, interim order forms for new prescription orders, and boxes/folders for order storage and reconciliation in the facility.	

APPENDIX VIII -- 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. 42 CFR §423.505(i)(4)(i)	
3.1.1D3	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 indicating that any books, contracts, records, including medical records and documentation relating to the Part D program will be provided to either the sponsor to provide to CMS or its designees or will be provided directly to CMS or its designees. 42 CFR §423.505(i)(3)(iv)	
3.1.1D13	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)	
3.1.1D14	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)	
3.1.1D17	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)	
3.1.1D18	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)	
3.1.1D19	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)	
3.4A3	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	
Elements Specific to Indian Tribe and Tribal Organization, and Urban Indian Organization (I/T/U) Pharmacy Contracts **Note: Provisions listed below are in the model I/T/U Addendum, located in Appendix XI or at** www.cms.hhs.gov/10_RxContracting_SpecialGuidance.asp#TopOfPage **and all** I/T/U Contracts must contain language consistent with the model addendum that addresses the following.		
Item 1	Supersession of the addendum from underlying agreement.	

Item 3	The description of the provider.	
Item 4	Counting of costs paid for by provider toward any deductibles.	
Item 5	Persons eligible for services of the provider.	
Item 6	The applicability of certain Federal law.	
Item 7	The non-taxable status of the provider.	
Item 8	Insurance and indemnification.	
Item 9	Applicability of state licensing law to provider's employees.	
Item 10	Provider eligibility for payments	
Item 11	Dispute resolution.	
Item 12	Federal law as the governing law.	
Item 13	The contract will apply to all pharmacies and dispensaries operated by the provider.	
Item 14	The contract will not affect the provider's acquisition of pharmaceuticals.	
Item 15	The provider's point of sale processing capabilities.	
Item 16	Claims processing.	
Item 17	Reasonable and appropriate payment rates.	
Item 18	Any information, outreach or enrollment materials prepared by the Applicant will be supplied at no cost to the provider.	
Item 19	The provider determines the hours of service for the pharmacies or dispensaries of the provider.	
Item 20	Endorsement	

Item 21	Sovereign Immunity	

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

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

P&T Committee Member Disclosure to CMS

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

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

Instructions to Plans and PBMs

A. If the Part D Applicant sub-contracts with a PBM for its P&T Committee and operates under a Confidentiality Agreement (such that its members are not disclosed to the Part D Applicant) then the Applicant must (1) complete the attached Certification 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 25,

2010. The PBM should email the P&T Committee Member Disclosure form to the following email box: 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 confidential 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.

PHARMACY AND THERAPEUTICS COMMITTEE MEMBER DISCLOSURE

PBM must email the following form to drugbenefitimpl@cms.hhs.gov by February 25, 2010.

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

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

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

Applicant must upload in HPMS:

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

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

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

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

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

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

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

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

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

Part D Applicant's Contract Number: _____

_____ _____

Authorized Representative Name (printed) Title

_____ _____

Authorized Representative Signature Date (MM/DD/YYYY)

APPENDIX X -- Retail Pharmacy Network Access Instructions

Accessibility Analysis Instructions

Part D Applicants are strongly encouraged to use network access software that is compliant with Section 508 of the Rehabilitation Act of 1973, as amended by the Workforce Investment Act of 1998 to compile the reports as outlined in this appendix. As of the drafting date of these instructions, the only 508 compliant product to our knowledge is The Quest Analytics Suite™. While CMS will still accept pharmacy access reports produced using software that is not Section 508 compliant (for example, GeoNetworks), we cannot provide instructions or technical support for such software (see CMS Administrator EIT Accessibility Policy Statement, March 25, 2008 at http://www.cms.hhs.gov/InfoTechGenInfo/03_Section 508.asp).

Organizations that intend to use software other than The Quest Analytics Suite or GeoNetworks, must contact Angela Stanley at angela.stanley@cms.hhs.gov (410.786.9496) no later than January 29, 2010 to determine if analyses provided by an alternative method are acceptable. Alternative methods must produce analyses that will result in data directly comparable to the results produced by The Quest Analytics Suite™ or GeoNetworks®. Applicants that wish to use alternative methods will be required to demonstrate how their analysis is comparable to results produced by either The Quest Analytics Suite™ or GeoNetworks®.

While we provide specific instructions for formatting and compiling plan accessibility reports using The Quest Analytics Suite (the available 508 compliant product), this appendix is not intended to provide step-by-step instructions for the use of the software. Instructions and examples provided here were developed using The Quest Analytics Suite version 2007.3. It is the responsibility of Applicant to ensure that their submission provides adequate information for CMS to determine if each of their offerings meets the retail pharmacy access submission requirements. Please note that these retail pharmacy access reports will be uploaded into HPMS on the appropriate Pharmacy Access Upload page.

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

1. Defining the Medicare Beneficiary File

The Medicare Beneficiary File entitled “Beneficiary Count Data” is provided by CMS and can be accessed at the following URL: www.cms.hhs.gov\PrescriptionDrugCovContra\. The Medicare Beneficiary File referenced above contains ZIP Codes and beneficiary counts for Applicants as of September, 2009. Use of this file is required for the accessibility analysis submission.

- Download this file and create a sub-file(s) specific to their service area and/or region(s) and/or state as needed to support the level of analyses required (specified

below). Applicants may not use beneficiary counts from other sources in their accessibility analyses.

- Open the Quest Analytics Project file you downloaded and link to the data sub-file in The Quest Analytics Suite by adding an Employee Group and name it “All Beneficiaries”. Applicants may geocode by selecting the “Geocoding Tab” and select “Geocode Now” during this step, or they may defer geocoding the population file until run time.

- Verify that the beneficiary (employee) count in the population file is consistent with the total beneficiary census for the sub-file used as the basis for the analyses. CMS will check the count of beneficiaries provided in the reports against the count of beneficiaries residing in the plan’s service area.

- The most recent version of The Quest Analytics Suite™ assigns an Urban, Suburban, or Rural classification for each Medicare beneficiary record consistent with the definitions specified in 42 CFR §423.100. Select the appropriate options under project preferences.

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

- To define the subset of Urban beneficiaries, navigate to Employee Groups resource and Copy the All Beneficiaries group. Change the name to “Urban Beneficiaries” and on the zip code filter, turn off the suburban and rural check boxes.

- To define the subset of Suburban beneficiaries, navigate to Employee Groups resource and Copy the All Beneficiaries group. Change the name to “Suburban Beneficiaries” and on the zip code filter, turn off the urban and rural check boxes.

- To define the subset of Rural beneficiaries, navigate to Employee Groups resource and Copy the All Beneficiaries group. Change the name to “Rural Beneficiaries” and on the zip code filter, turn off the urban and suburban check boxes.

- Verify that the urban, suburban, and rural definitions are defined appropriately for each page of the report. CMS will compare the total of urban, suburban, and rural beneficiaries for specific counties to totals derived from the Medicare Beneficiary File.

- The Quest Analytics Suite™ default restricts beneficiaries inside your service area.

- Applicants may specify that contracted providers outside their service area (e.g., across state or county lines) be included in their accessibility analyses. The most recent release of The Quest Analytics Suite™ allows for inclusion of providers outside the specified service area under the report area options.

2. Defining the Provider File

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

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

- The Quest Analytics Suite™ will automatically geocode your provider file using an “address-based” method (if licensed). If this function is not available on your version of Quest Analytics Suite™, the default, distributive geocoding methodology, is acceptable.

- Define the Provider Group by navigating to Add Provider Groups. Select the data source on the Source Table button. On the Name enter the label of “Part D Retail Pharmacy Network”, select OK.

- Verify that the total counts for pharmacy providers in the report do not exceed the count of pharmacies in your Part D contracted retail pharmacy listing that must also be provided using the retail listing template provided in HPMS.

3. Defining Access Criteria

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

- The Urban access standard of 1 provider within 2 miles is predefined within the Quest project file that you downloaded.

- The Suburban access standard of 1 provider within 5 miles is predefined within the Quest project file that you downloaded.

- The Rural access standard of 1 provider within 15 miles is predefined within the Quest project file that you downloaded.

4. Defining the Plan Service Area

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

MA-PD Applicants

MA-PD Applicants are asked to demonstrate that they meet the accessibility standards for their entire contract service area. Reports are defined to present accessibility at the county level and provide summary level statistics for the full contract area. Please note that CMS does not wish (or require) analyses at the ZIP code level.

- Define the service area by navigating to Service Area and Add and select your service area. Applicants must include all counties and the partial counties in their Quest Analytics report.

- Verify that the service area in your report EXACTLY matches the service area you have entered in HPMS. New Applicants must include all counties in their report.

- Verify that the reports provided to CMS include subtotals for each individual state and grand total summary statistics encompassing all states in the service area.

An example analysis is provided in the file entitled “CMS Quest Analytics Example MA-PD” that is included in the reference file entitled “Geographic Access Examples and

Templates" that may be downloaded from the following URL: www.cms.hhs.gov\PrescriptionDrugCovContra\.

RPPO Applicants

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

- Define the service area by navigating to Service Area and Add and select your service area.

- Verify that the service area in your report EXACTLY matches the service area you have entered in HPMS. New Applicants must include all regional (and their component States) in their report.

- Verify that the reports provided to CMS include subtotals for each individual state and grand total summary statistics encompassing all states in the service area.

5. Generating the Accessibility Analyses Reports

A Quest Analytic report template entitled "CMS Quest Analytics Template PDPRPPO.qp" is provided for RPPO Applicants in the reference file entitled "Geographic Access Examples and Templates" that may be downloaded from the following URL: www.cms.hhs.gov\PrescriptionDrugCovContra\. This template includes all the report pages and access standards along with the applicable sorting options and may be imported to create the required Quest Analytic reports. The reports for RPPOs follow the same format as the PDP example reports provided in the Geographic Access Examples and Templates file..

6. Providing copies of the Analysis to CMS for review

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

APPENDIX XI—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. Existing Part D sponsors will be required to use this version of the I/T/U Addendum for any future re-contracting or new contracting.

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 supercede 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 IHCIA, 25 USC §1603.

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

(i) The term "Indian" has the meaning given to that term in Sec. 4 of the IHCIA, 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 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 IHCIA.

4. Deductibles.

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 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) of the IHCIA, 25 USC §1680c-(a) 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-eligible persons only under certain circumstances set forth in IHCIA section 813(b) and in emergencies under section 813(c) of the IHCIA.

(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 C.F.R. Part 423;

(2) IHCIA sections 813(a) and. 813(c), 25 USC §1680c (a) and (c);

(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).

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 C.F.R. 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 C.F.R. Parts 160 and 164.; and

(8) The IHCIA, 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 IHCIA, 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; and

(5) The HIPAA, and regulations at 45 CFR parts 160 and 164.

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

(1) The IHCIA, 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.

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. Employee license.

(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) To the extent that any directly hired employee of a tribal or 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. 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 Council for Prescription Drug Programs (NCPDP) provider number for reimbursement. To the extent a dispensary does not have a NCPDP provider number, it is required to use an NCPDP Alternate Site Enumeration Program (ASEP) number for reimbursement.

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.

_____ _____

Signature of Authorized Representative

_____ _____

Printed Name of Authorized Representative

_____ _____

Title of Authorized Representative