2013 CAPITATED FINANCIAL ALIGNMENT DEMONSTRATION APPLICATION

1. GENERAL INFORMATION

1.1. Purpose of Application

The Centers for Medicare & Medicaid Services (CMS) is seeking applications from qualified entities to enter into contracts with the CMS and applicable States to offer integrated Medicare and Medicaid services to dual eligible individuals. Please submit your application according to the process described in Section 2.0.

1.2. Background

The Patient Protection and Affordable Care Act as revised by the Health Care and Education Reconciliation Act of 2010, collectively known as the Affordable Care Act established the CMS Medicare-Medicaid Coordination Office and the Center for Medicare & Medicaid Innovation to improve both quality and care in the Medicare and Medicaid programs.

In FY 2011, the Medicare-Medicaid Coordination Office, in partnership with the Innovation Center, established a demonstration opportunity for States to align incentives between Medicare and Medicaid through the *Financial Models to Support State Efforts to Integrate Care for Medicare-Medicaid Enrollees* (Financial Alignment Initiative). Through this Initiative, CMS created two approaches for States to test models to align financing between the Medicare and Medicaid programs while preserving or enhancing the quality of care furnished to Medicare-Medicaid enrollees. The goal of the Financial Alignment Initiative is to increase access to seamless, quality programs that integrate primary, acute, behavioral, prescription drugs and long-term care supports and services for the beneficiary.

One approach is a capitated model. In this model, a State, CMS, and health plan or other qualified entity will enter into a three-way contract through which the health plan or other qualified entity will receive a prospective blended payment to provide comprehensive, coordinated care. The second approach is a managed fee-for-service model. Under this model, a State and CMS will enter into an agreement by which the State would be eligible to benefit from savings resulting from managed fee-for-service initiatives that improve quality and reduce costs for both Medicare and Medicaid. Both models are designed to achieve both State and federal health care savings by improving health care delivery and encouraging high-quality, efficient care. This application is specific to the capitated financial alignment model.

1.3. Objectives and Structure

The capitated financial alignment model seeks to fully integrate the full range of individual services- primary, acute, behavioral health, prescription drugs, and long-term supports and services to deliver care in a more coordinated and cost-effective manner. The model combines the Medicare and Medicaid authorities to test a new payment and service delivery model to achieve a more seamless care system that improves both the quality and costs of the two programs while preserving or enhancing the quality of care furnished to Medicare-Medicaid enrollees.

Plans will receive a blended capitated rate for the full continuum of benefits provided to Medicare-Medicaid enrollees across both programs. The capitated model will target aggregate savings through actuarially developed blended rates that will provide savings for both States and the Federal government. Organizations jointly selected by the respective States and the Federal government to offer the capitated financial alignment demonstration plans will be required to meet established quality thresholds.

Plans will be selected through a joint process with the States and CMS. This application incorporates the CMS Medicare criteria for prescription drug coverage, the model of care, and Medicare A and B services. This application is only for entities seeking to operate a capitated financial alignment demonstration plan.

.

1.4. Schedule

APPLICATION REVIEW PROCESS	
Date	**Milestone**
March 16, 2012	Posting of CY 2013 Part D Formulary Reference File in HPMS.
March 19, 2012 – ongoing	CY 2013 Formulary Training Webinar available.
March 19, 2012	Posting of HPMS Formulary Submission Module & Reports Technical User Manual.
March 26, 2012	Release of HPMS Part D formulary submission module for 2013.
April 2, 2012	Latest date by which Applicants can submit their Notice of Intent to Apply Form to offer demonstration plans electronically to CMS through an online Web tool at http://vovici.com/wsb.dll/s/11dc4g4ddb7.
April 4, 2012	Question and Answer Part C and D User Call on formulary training webinar. If not already registered, register at www.mscginc.com/registration. A valid CMS contract number is required.
April 6, 2012	Release of the 2013 plan creation module and Plan Benefit Package (PBP) software in HPMS.
April 6, 2012	Release of the 2013 PBP online training module

April 9, 2012	Latest date by which Applicants should submit their CMS User ID connectivity form to CMS to ensure access to Health Plan Management System (HPMS) for purposes of submission of application, formulary and plan benefit package information.
April 11-12, 2012	Medicare Advantage and Prescription Drug Plan Spring Conference.
April 12, 2012	2013 Capitated Financial Alignment Demonstration application available in HPMS.
April 17, 2012	Capitated Financial Alignment Demonstration Application training webinar for interested organizations.
April 18, 2012	Compliance Officer training on roles and responsibilities in ensuring compliance with formulary and benefits requirements on Part C & D User Call. If not already registered, register at www.mscginc.com/registration. A valid CMS contract number is required.
April 20, 2012	Release of the CY 2013 Plan Benefit Package (PBP) software patch designed for demonstration plans in HPMS.
April 24, 2012 (tentative)	Capitated Financial Alignment Demonstration plan applicant PBP training webinar.
April 30, 2012	Formulary submission due to CMS for interested organizations that are submitting a new formulary (e.g., those that have not submitted a formulary for CY 2013 for non-demonstration plans)
May 11, 2012	Plan Benefit Package (PBP) Upload Module available on HPMS.
May 14, 2012	Part D formulary crosswalks due to CMS for interested organizations that have already submitted a non-demonstration plan formulary for CY 2013 and intend to utilize that previously submitted formulary for their demonstration plans.
May 18, 2012	Release of the CY 2013 Medication Therapy Management Program (MTMP) submission module

	in HPMS.
May 24, 2012	2013 Capitated Financial Alignment Demonstration applications due to CMS.
May 25, 2012	CY 2013 Medication Therapy Management Program (MTMP) submission due to CMS.
June 4, 2012	Submission of proposed PBPs due to CMS.
June 6, 2012	Release of the HPMS CY 2013 Marketing Module, including functionality for joint CMS-State review of demonstration plan marketing materials.
June 8, 2012	Deadline for submitting Supplemental Formulary files, Free First Fill file, Partial Gap Coverage file, Excluded Drug File, Over-the-Counter Drug file, and Home Infusion file through HPMS.
June 15, 2012	Deadline for submitting Additional Medicaid Drugs supplemental formulary file to CMS.
July 2012	Submission of Medicare Plan Finder Data for test files begins.
July 30, 2012	CMS and State portions of the demonstration joint plan selection process for CY 2013 targeted for completion.
Late July – September 2012	CMS and State conduct readiness reviews for selected plans. CMS and States make final preparations for implementation, test all operational systems, and perform reviews to assure optimal preparation and adherence to contract requirements prior to implementation. CMS and States jointly confirm readiness requirements have been met.
Early August 2012	CMS releases the 2013 Part D national average bid amount.
August 20, 2012	MTMP reviews completed.
August 23-27, 2012	First CY 2013 preview of the 2013 *Medicare & You* plan data in HPMS prior to printing of the CMS publication.

August 29-31, 2012	First CY 2013 Medicare Plan Finder (MPF) preview in HPMS.
September 11-14, 2012	Second CY 2013 MPF preview in HPMS.
September 16-30, 2012	CMS mails the CY 2013 *Medicare & You* handbook to Medicare beneficiaries.
September 17, 2012 (target date)	Roll-out of MA and Part D plan landscape documents, which includes details (including high-level information about benefits and cost-sharing) about all available Medicare health and prescription drug plans for CY 2013.
September 20, 2012 (target date)	Three-way contracts among selected plans, States, and CMS must be finalized and signed.
October 1, 2012	For selected plans receiving passive enrollments of Medicare-Medicaid enrollees, notification of such enrollment and information about opt-out procedures must be sent to affected beneficiaries.
October 1, 2012	CY 2013 marketing activity begins.
October 1, 2012	Tentative date for CY 2013 plan and drug benefit data to be displayed on MPF.
October 15, 2012	2013 Annual Coordinated Election Period begins.
December 7, 2012	2013 Annual Coordinated Election Period ends.
January 1, 2013	Enrollment effective date.

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

2. INSTRUCTIONS

2.1. Overview

This application is to be completed by those organizations that intend to offer a capitated financial alignment demonstration plan during 2013.

CMS conducts technical support calls, also known as User Group calls, for Applicants and existing Medicare Advantage and Prescription Drug Plan 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. Organizations seeking to offer capitated financial alignment demonstration plans can register for the technical support calls and join the list serve to get updates on CMS guidance at www.mscginc.com/Registration/.

CMS provides two user manuals to assist applicants with the technical requirements of submitting the Part D application through the Health Plan Management System[1] (HPMS). The *Basic Contract Management User's Manual* provides information on completing and maintaining basic information required in Contract Management. The *Online Application User's Manual* provides detailed instructions on completing the various online applications for the overall Medicare Advantage and Prescription Drug Benefit programs. Both manuals can be found in HPMS by clicking on Contract Management>Basic Contract Management>Documentation.

References to CMS guidance is provided throughout the application. Links to manual chapters are included in the application to further assist Applicants. Applicants can access CMS issued guidance documents by following the path in HPMS: HPMS>In the News>Archived In the News.

2.2. Health Plan Management System (HPMS) Data Entry

Organizations that submit a Notice of Intent to Apply form are assigned a pending contract number (H number) to use throughout the application and subsequent operational processes. Once the contract number is assigned, and Applicants apply for, and receive, their CMS User ID(s) and password(s) for HPMS access, they are required to input contact and other related information into the HPMS (see section 3.1.3). 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 its application throughout the review process and ensures that CMS has the most current information for application updates, guidance and other types of correspondence.

[1] HPMS is a system that supports contract management for Medicare health plans and prescription drug plans and supports data and information exchanges between CMS and health plans. Current and prospective Medicare health plans submit applications, information about provider networks, plan benefit packages, formularies, and other information via HPMS.

In the event that an Applicant is awarded a contract, this information will also be used for frequent communications during implementation and throughout the contract year. It is important that the information in HPMS is accurate at all times.

2.3. Instructions and Format of Application

Applications may be submitted until May 24, 2012. Applicants must use the 2013 capitated financial alignment demonstration application. CMS will not accept or review any submissions using other Medicare applications (e.g., MA and Part D applications for 2013 and earlier).

2.3.1. Instructions

Applicants will complete the entire application via HPMS.

In preparing your responses to the prompts in Section 3 of this application, please mark "Yes" or "No" or "Not Applicable" in sections organized with that format within HPMS.

Within HPMS, Applicants are directed to affirm by attesting "Yes," that they meet specific Part D program requirements. By attesting "Yes," an Applicant is committing that its organization complies with the relevant requirements as of the date its application is submitted to CMS, unless a different date is stated by CMS. Due to time constraints, CMS was unable to modify any of the automated prescription drug program attestations for purposes of the capitated financial alignment demonstration application. To the extent that an attestation is not applicable for the capitated financial alignment demonstration plans, Applicants may attest "No." CMS will review all "No" responses and determine if the element is, or is not, applicable to the capitated financial alignment demonstration. For instance, the sections on Bids (section 3.2.6) and Premium Billing (section 3.23) are not applicable for purposes of the capitated financial alignment demonstrations and Applicants may answer these attestations "No." If CMS determines that an attestation is applicable (i.e., Medicare Plan Finder section 3.8) and the Applicant answered "No," CMS will communicate with the organization and provide an opportunity to cure the deficiencies.

In addition, due to time constraints, CMS was unable to modify the Medicare medical benefit attestations for purposes of the capitated financial alignment demonstration application. Because we expect that some Medicare medical benefit requirements could be modified based on State-CMS Memorandum of Understanding negotiations, and there is no ability to request waivers of these requirements in the standardized Medicare medical benefits attestations, this application does not include Medicare medical benefit attestations. However, Applicants should be aware that additional Medicare medical benefit requirements in 42 CFR Subpart 422 will be incorporated into the three-way contract with CMS and the respective State based on the specifics of each State's MOU with CMS.

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

Organizations will receive a confirmation number from HPMS upon clicking final submit. Failure to obtain a confirmation number indicates that an applicant failed to properly

submit its application by the CMS-established deadline. Any entity that experiences technical difficulties during the submission process must contact the HPMS Help Desk prior to the deadline and CMS will make case by case determinations, where appropriate, regarding the timeliness of the submission.

CMS will check the application for completeness shortly after its receipt. 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: (1) Applicants that fail to upload executed agreements or contract templates, as applicable, (2) Applicants that upload contract crosswalks instead of contracts, or (3) 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 the organization of any deficiencies and afford a courtesy opportunity to amend the applications. CMS will only review the last submission provided during the courtesy cure period. For purposes of the capitated financial alignment applications, CMS has waived the notice of intent to deny and application appeal provisions in 42 CFR §422.502(c)(2), §422.502(c)(3)(iii), §423.503(c)(2), and §423.503(c)(3)(iii). CMS waived these provisions to provide flexibility for interested organizations to demonstrate Medicare qualifications through the application process and allow for validation of such qualifications through the readiness reviews that CMS and the States will conduct with selected plans between early August and mid-September prior to entering into the three-way contract for the demonstration. The readiness reviews will test operational systems, validate medical provider networks and perform reviews to assure optimal preparation and adherence to contract requirements.

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

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

An individual with legal authority to bind the Applicant shall execute the certifications found in Sections 4 and 8. CMS reserves the right to request clarifications or corrections to a submitted application.

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

- CMS will not review applications received after 8:00 P.M. Eastern Daylight Time on May 24, 2012. CMS will lock access to application fields within HPMS as of that time. Applicants must complete the 2013 application in order to be considered to offer a plan under the capitated financial alignment demonstration in 2013.

2.3.2. Applicant Entity Same as Contracting Entity

The legal entity that submits this application must be the same entity with which CMS and the State enter into a capitated financial alignment demonstration contract.

2.3.3. Withdrawal of an Application

In those instances where an organization seeks to withdraw its application of a pending application prior to the execution of a capitated financial alignment demonstration contract, the organization must send an official notice to CMS. The notice should be on organization letterhead and clearly identify the pending application number. The notice should be delivered via email to MMCOcapsmodel@cms.hhs.gov, MA_Applications@cms.hhs.gov and drugbenefitimpl@cms.hhs.gov and the subject line of the email should read "Pending application withdrawal." The withdrawal will be considered effective as of the date of the email.

2.3.4. Technical Assistance

For technical assistance in the completion of this Application, contact MMCOcapsmodel@cms.hhs.gov.

Additional resources are available within HPMS. Multiple user guides are provided in HPMS to help Applicants complete and upload various aspects of this application. Interested organizations should click on Basic Contract Management within HPMS to locate the *Basic Contract Management User's Manual, Online Application User's Manual, MA Upload Guide, and the Part D Upload Guide.* Please note that not all components of the user manuals and guides are applicable for the capitated financial alignment demonstration (i.e., Part C attestations, and SNP data).

As stated in section 2.4 Applicants must contact the HPMS Help Desk if they are experiencing technical difficulties uploading or completing any part of this application within HPMS prior to the submission deadline. Applicants requesting technical assistance with uploading or completing any part of the online HPMS application after the published CMS application deadline will not be granted technical assistance, or the opportunity to complete their application submission.

2.4. Submission Software Training

Applicants use HPMS during the application, formulary, and plan benefit package 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 became available March 26, 2012. The deadline for new formulary submissions to CMS is 11:59 PM EDT on April 30, 2012. Those Applicants that wish to use a previously submitted CY 2013 non-demonstration plan formulary for the demonstration plan must submit a crosswalk to CMS by 11:59 PM EDT on May 14, 2012. CMS will use the last successful upload

received for an Applicant as the official formulary submission. Applicants can refer to the March 9, 2012 HPMS notice entitled "*Submission of 2013 Formularies"* and the March 30, 2012 HPMS notice entitled "*Additional Guidance on the Medicare Plan Selection Process for Organizations Interested in Offering Capitated Financial Alignment Demonstration Plans in 2013* " for additional information about formulary submission requirements.

Interested organizations will also submit a plan benefit package that details the Medicare, Medicaid and supplemental benefits they will offer for CY 2013. In order to prepare plan benefit packages, Applicants will use HPMS to define their plan structures and associated plan service areas and then download the Plan Benefit Package (PBP) software. For each plan being offered, Applicants will use the PBP software to describe the detailed structure of their Medicare, Medicaid and supplemental benefits. Each PBP must be consistent with minimum requirements for coverage for Medicare Parts A and B benefits, as well as Part D prescription drug benefits. Therefore, the formulary must accurately crosswalk to the PBP for review purposes. In addition, States will review the PBP to ensure it is consistent with their Medicaid coverage requirements, as well as demonstration plan-specific requirements (for example, inclusion of specific supplemental benefits not currently covered under Medicare Parts A and B, or under Medicaid). Applicants can refer to the March 30, 2012 guidance for additional information about PBP submission requirements.

CMS will provide technical instructions and guidance upon release of the HPMS formulary functionality as well as the PBP software. In addition, systems training will be available at the Spring Conference, April 11-12, 2012. Further information on the Spring Conference can be found at

http://CMSDrugHealthPlanEvents.org/cms/index.php/events/cms-2012-spring-conference/

2.5. System Access and Data Transmissions with CMS

2.5.1. HPMS

Applicants will use HPMS to communicate with CMS in support of the application process, formulary submission process, bid submission process, ongoing operations of the financial alignment demonstration program, and reporting and oversight activities. Applicants are required to secure access to HPMS in order to carry out these functions.

2.5.2. Enrollment

All 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 their contract, Applicants must contact the MAPD Help Desk[2] at 1-800-

[2] The MAPD HelpDesk provides technical support to CMS business partners for the implementation and operation of Medicare Parts C and D. This systems information is provided to assist external business partners with connectivity, testing and data exchange with CMS.

927-8069 for specific guidance on establishing connectivity and the electronic submission of files. Instructions are also on the MAPD Help Desk web page, www.cms.gov/mapdhelpdesk, 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. The Plan Reference Guide for CMS Part C/D systems can be found at https://www.cms.gov/MAPDHelpDesk/02_Plan_Communications_User_Guide.asp

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

2.5.3. Payment Information Form

Please complete the Payment Information form that is located at http://www.cms.gov/MedicareAdvantageApps/Downloads/pmtform.pdf. The document contains financial institution information and Medicare contractor data. If the Applicant has questions about this form, please contact Yvonne Rice at (410) 786-7626. The completed form needs to be faxed to Yvonne Rice at (410) 786-0322.

2.6. Pharmacy Access

An integral component of this Application 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 Applicant 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 plan enrollees. To implement this requirement, specific retail pharmacy access rules consistent with the standards are delineated in 42 CFR §423.120. Furthermore, Applicants 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.

2.6.1. Retail Pharmacy Access

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

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

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

Applicants may use their contracted PBM's existing 2012 Part D network to demonstrate compliance with pharmacy access standards. If an Applicant is creating a new Part D network, the submission must be based on executed contracts for Year 2013. CMS conducts the review of Retail Pharmacy Access based on the service area that the Applicant has provided in HPMS by May 24, 2012. Applicants are required to input their pending service area into HPMS per the instructions at section 3.3B and as explained in section 3.5.1B Applicants must upload the retail pharmacy list in HPMS. Based on the pending service area documented in HPMS, the retail pharmacy list uploaded by the Applicant, and the Medicare Beneficiary Count file available on the CMS application guidance website, CMS will generate access percentages for all applicants. In addition, CMS will use the information gathered from the pharmacy list upload to identify pharmacy addresses.

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

The retail pharmacy lists may contain contracted pharmacies that are outside of the Applicant's pending service area (to account for applicants who contract for a national pharmacy network); however, CMS will only evaluate retail pharmacy access for the pending service area.

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

2.6.2. 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 "*Home Infusion Pharmacies Reference File 2013_Jan_17_2012.pdf*" is provided in the zip file entitled 2013 Resources for HI LTC and ITU References located in the download section at http://www.cms.gov/PrescriptionDrugCovContra/04_RxContracting_ApplicationGuidance.asp#TopOfPage on the CMS website.

2.6.3. 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 Applicants' reporting requirements and complaints data, to evaluate initial and ongoing compliance with the convenient access standard.

2.6.4. 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 3.5.6). 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. The file entitled "*ITU Pharmacies Reference File for 2013 Application"* is provided in the zip file entitled 2013 Resources for HI LTC and ITU References located in the download section at http://www.cms.gov/PrescriptionDrugCovContra/04_RxContracting_ApplicationGuidance.asp#TopOfPage on the CMS website.

the www.cms.gov/PrescriptionDrugCovContra/ website.

2.6.5. Waivers Related to Pharmacy Access

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 MA-PD pharmacy access waivers will apply to those organizations seeking to offer a capitated financial alignment demonstration plan that meet the requirements described below.

2.6.6. Waiver of Retail Convenient Access Standards

As described in section 50.7.1 of Chapter 5 of the Prescription Drug Benefit Manual (http://www.cms.gov/PrescriptionDrugCovContra/Downloads/MemoPDBManualChapter5_09.30.11.pdf), 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. Applicants 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.

2.6.7. Waiver of Any Willing Pharmacy Requirements

As described in section 50.8.2 of Chapter 5 of the Prescription Drug Benefit Manual (http://www.cms.gov/PrescriptionDrugCovContra/Downloads/MemoPDBManualChapter5_09.30.11.pdf) , 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 Applicants that own and operate the pharmacies in their network. Applicants must demonstrate at the plan level that at least 98% of prescriptions are filled through pharmacies that are owned and operated by the Applicant in order to be granted the waiver.

2.7. Health Service Delivery (HSD) Tables Instructions

Applicants are required to demonstrate Medicare network adequacy through the submission of HSD Tables for the Medicare medical services. Detailed instructions on how to complete each of the required HSD Tables are available in the financial alignment demonstration download file in HPMS.

As part of the application module in HPMS, CMS will be providing Applicants with an automated tool for submitting network information via HSD tables. The tables will then be reviewed automatically against network adequacy criteria for each required provider type in each county. Further, CMS has made these network adequacy criteria available on http://www.cms.gov/MedicareAdvantageApps/ webpage. As such, Applicants will see the network adequacy criteria (providers and facilities of each required type in each county) that CMS requires before the module opens. Applicants who believe that CMS network adequacy criteria for a given provider type in a given county are not in line with local patterns of care may seek an exception, in which case the Applicant will submit required information to support the exception request(s). The HSD exception review will occur manually by a CMS and State reviewer. Applicants who submit HSD tables that 'clear' CMS' network adequacy criteria will still be required to submit signed contracts during the readiness reviews to demonstrate the accuracy of the HSD table submissions.

Application forms and tables associated with the applications are available in separate Microsoft Word or Excel files that are available at: http://www.cms.gov/MedicareAdvantageApps/. Microsoft Word files located on the CMS web site are posted in a .zip format and can also be found in the capitated financial alignment demonstration download file in HPMS.

Applicants must submit separate completed copies of each table template for each area/region or county that the Applicant is requesting. Specific instructions on how to complete and submit each table is outlined in the 2013 HPMS User Guide for the Part C Application. The 2013 HPMS User Guide for the Part C Application provides step-by-step instructions, including HPMS screen shots, to complete and upload required documentation for the capitated financial alignment demonstration application.

CMS issued initial guidance on January 25, 2012 that provided information for interested organizations about the capitated financial alignment demonstration. Part of that guidance articulated that Applicants will also work directly with States to satisfy State-specific network adequacy requirements for long-term care supports and services (LTSS) and any overlapping services for which, under the Memorandum of Understanding, the Medicaid standard has been agreed to by CMS and the respective State. All medical provider networks will be subject to confirmation through the readiness reviews that will be conducted prior to executing final contracts.

2.8. Model of Care

As indicated in the January 25, 2012 guidance, all Applicants are required to develop a model of care (MOC) for their enrollees that incorporate both CMS and State requirements. Applicants' MOC must be specific to the demonstration's targeted population and benefits and in a unified document account both for CMS' requirements and any additional requirements the State wishes to add. The CMS requirements include: 1) measurable goals specific to the target specials needs individuals; 2) an adequate staff structure having care management roles; 3) an interdisciplinary care team for each beneficiary; 4) a provider network having specialized expertise pertinent to the target special needs individuals; 5) training on the model of care for plan personnel and contractors; 6) comprehensive health risk assessment for each beneficiary; 7) an individualized plan of care having goals and measurable outcomes for each beneficiary; 8) a communication network that facilitates coordination of care; and 9) evaluation of the effectiveness of the model of care. The Applicant must design its model of care to accommodate the needs of the most vulnerable members of its target population. For further information related to the MOC, the CMS standards for approval and the review process see the March 30, 2012 guidance. The guidance provides detailed information on each element including the multiple factors that are used to score the MOC.

2.9. Document (Upload) Submission Instructions

Applicants must include their assigned H number in the file name of all submitted documents. Applicants are encouraged to be descriptive in naming all files. If the Applicant is required to provide multiple versions of the same document, the Applicant should insert a number, letter, or even the state name at the end of each file name for easy identification (see the Application Readme.File).

Within the capitated financial alignment demonstration template file is a Readme File that identifies each document requested as part of the application. The file further details the application section reference for the required documentation, which

applicants must complete the document, if a template is provided, the section the document must be uploaded to in HPMS, the file format, the naming convention to be used for the document, and other relevant notes such as naming conventions when multiple documents are required in one application section.

2.10. 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 and Medicare Part D programs, we would not release information under the Financial Alignment Demonstration program that would be considered proprietary in nature.

2.11. Waivers

Under section1115A(d)(1) of the Social Security Act, the Secretary may waive such requirements of Titles XI and XVIII and of sections 1902(a)(1), 1902(a)(130 and 1903(m)(2)(A)(iii) as may be necessary solely for purposes of carrying out Section 1115A with respect to testing models described in section 1115A(b).

Applicant Requests for Additional Waivers: The Secretary will consider exercising this waiver authority with respect to Part C and Part D program requirements in Title XVIII as may be necessary to develop and implement the capitated financial alignment demonstration. For each waiver request, the Applicant must provide, as an upload in HPMS, a statement that includes:

1. The Part C or D regulation reference.

2. A discussion of why such waiver is necessary for purposes of the capitated financial alignment demonstration.

CMS will notify Applicants whether their requests were approved via a CMS web posting of all approved waivers.

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 the three way contract with CMS and the respective State. This process will prevent Applicants from having to submit additional application responses after the original May 24, 2012 deadline. If, as a result of CMS' denial of its waiver request, the Applicant no longer intends to offer a capitated financial alignment demonstration plan, the Applicant must notify CMS in writing on or before July 30, 2012. CMS and the respective State will not execute a contract with Applicants that submit such a notice. This notice of withdrawal should be sent to:

Centers for Medicare & Medicaid Services (CMS)

Center for Medicare

Attention: Application Withdrawal

7500 Security Boulevard

Mail Stop S3-13-23

Baltimore, Maryland 21244-1850

3. MEDICARE PRESCRIPTION DRUG BENEFIT

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

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

3.1. Applicant Experience, Contracts, Licensure and Financial Stability

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

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

A. In HPMS, complete the table below:

Applicant must attest 'yes' or, if permitted, "NA", to each of the following qualifications to be approved for a Part D contract. Attest 'yes' or 'no' to each of the following qualifications by clicking on the appropriate response in HPMS:	**Yes**	**No**	**NA**	**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. The Medicare Prescription Drug Plan(s) currently offered by the Applicant, Applicant's parent organization, or subsidiary of the Applicant's parent organization has been operational since January 1, 2011 or earlier. (If the Applicant, Applicant's parent organization, or a subsidiary of Applicant's parent organization does not have any existing contracts with CMS to operate a Prescription Drug Plan, select "NA".)				
3. Applicant abides by all applicable Federal laws, regulations and CMS instructions.				
4. Applicant maintains contracts or other legal arrangements between or among the entities combined to meet the functions identified in subsection 3.1.1C.				
5. Applicant does not have any covered persons who also served as covered persons for an entity that nonrenewed a contract pursuant to 42 CFR §423.507(a), or that terminated its contract with CMS by mutual consent, pursuant to 42 CFR §423.508, or unilaterally, pursuant to 42 CFR §423.510, since June 6, 2011. "Covered persons", as defined at 42 CFR §§ 423.507(a)(4), 423.508(f), 423.510(e)(2), include: • All owners of nonrenewed or terminated organizations who are natural persons, other than shareholders who have an ownership interest of less than 5 percent; • An owner of a whole or part interest in a mortgage, deed of trust, note, or other obligation secured (in whole or in part) by the organization, or by any property or assets thereof, which whole or part interest is equal to or exceeds 5 percent of the total property and assets of the organization; and • A member of the board of directors or board of trustees of the entity, if the organization is organized as a corporation.				

B. Upload in HPMS, organizational background and structure information. Submit this information by downloading the appropriate template found in HPMS

that mimics the Appendix entitled, *Organization Background and Structure*. Also upload into HPMS proof of your organization's incorporation, such as articles of incorporation or a certificate of good standing from your state of incorporation.

C. First tier, Downstream and Related entities Function Chart

In HPMS, on the Contract & Management/Part D Information/Part D Data Page, provide names of the first tier, downstream and related entities you will use to carry out each of the functions listed in this chart and whether the first tier, downstream and related entities are off-shore: (Indicate with "name of Applicant's Organization" where applicant will perform those functions)	Function	First tier, Downstream and Related entities	Off-Shore yes/no
	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 or related entity identified in Sections 3.1.1 C and with any first tier, downstream, or related entity that contracts with any of the identified entities on the applicant's behalf. All contracts must:

1. Clearly identify the parties to the contract (or letter of agreement). If the applicant is not a direct party to the contract (e.g., if one of the contracting entities is entering into the contract on the applicant's behalf), the applicant must be identified as an entity that will benefit from the services described in the contract.
2. Describe the functions to be performed by the first tier, downstream or related entity, and the reporting requirements the first tier, downstream, or related entity has to the Applicant. 42 CFR §423.505(i)(4)(i)

3. Contain language clearly indicating that the first tier, downstream, or related entity has agreed to participate in your Medicare Prescription Drug Benefit program (except for a network pharmacy if the existing contract would allow participation in this program).
4. Contain flow-down clauses requiring that their activities be consistent and comply with the Applicant's contractual obligations as a Part D sponsor. 42 CFR §423.505(i)(3)(iii)
5. Describe the payment the first tier, downstream, or related entity will receive for performance under the contract, if applicable.
6. Clearly indicate that the contract is for a term of at least the initial one-year contract period (i.e., January 1 through December 31) for which this application is being submitted. Where the contract is for services or products to be used in preparation for the next contract year's Part D operations (e.g., marketing, enrollment), the initial term of such contract must include this period of performance (e.g., contracts for enrollment-related services must have a term beginning no later than October 15 extending through the full contract year ending on December 31 of the next year).
7. Be signed by a representative of each party with legal authority to bind the entity.
8. Contain language obligating the first tier, downstream, or related entity to abide by all applicable Federal laws and regulations and CMS instructions. 42 CFR §423.505(i)(4)(iv)
9. Contain language obligating the first tier, downstream, or related entity to abide by State and Federal privacy and security requirements, including the confidentiality and security provisions stated in the regulations for this program at 42 CFR §423.136.
10. Contain language ensuring that the first tier, downstream, or related entity will make its books and other records available in accordance with 42 CFR §423.505(e)(2) and 42 CFR §423.505(i)(2). Generally stated these regulations give HHS, the Comptroller General, or their designees the right to audit, evaluate and inspect any books, contracts, records, including medical records and documentation involving transactions related to CMS' contract with the Part D sponsor and that these rights continue for a period of 10 years from the final date of the contract period or the date of audit completion, whichever is later. 42 CFR §423.505(e)(2) and (i)(2)
11. Contain language that the first tier, downstream, or related entity will ensure that beneficiaries are not held liable for fees that are the responsibility of the Part D sponsor. 42 CFR §423.505(i)(3)(i)
12. Contain language that if the Applicant, upon becoming a Part D sponsor, delegates an activity or responsibility to the first tier, downstream, or related entity, that such activity or responsibility may be revoked if CMS or the Part D sponsor determines the first tier, downstream, or related entity has not performed satisfactorily. Note: The contract/administrative services agreement may include remedies in lieu of revocation to address this requirement. 42 CFR § 423.505(i)(4)(ii)

13. Contain language specifying that the Applicant, upon becoming a Part D sponsor, will monitor the performance of the first tier, downstream, or related entity on an ongoing basis. 42 CFR §423.505(i)(4)(iii)

14. If the first tier, downstream, or related entity will establish the pharmacy network or select pharmacies to be included in the network contain language that the Part D sponsor retains the right to approve, suspend, or terminate any arrangement with a pharmacy. 42 CFR §423.505(i)(5)

15. If the first tier, downstream, or related entity will establish the pharmacy network or select pharmacies to be included in the network contain language that payment to such pharmacies (excluding long-term care and mail order) shall be issued, mailed, or otherwise transmitted with respect to all clean claims submitted by or on behalf of pharmacies within 14 days for electronic claims and within 30 days for claims submitted otherwise. 42 CFR §§423.505(i)(3)(vi) and 423.520

16. If the first tier, downstream, or related entity will establish the pharmacy network or select pharmacies to be included in the network contain language that if a prescription drug pricing standard is used for reimbursement, identify the source used by the Part D sponsor for the standard of reimbursement. 42 CFR §§423.505(b)(21) and 423.505(i)(3)(viii)(B)

17. If the first tier, downstream, or related entity will establish the pharmacy network or select pharmacies to be included in the network and a prescription drug pricing standard is used for reimbursement, contain a provision that updates to such a prescription drug pricing standard occur not less frequently than once every 7 days beginning with an initial update on January 1 of each year, to accurately reflect the market price of acquiring the drug. 42 CFR §423.505(b)(21) and (i)(3)(viii)(A)

18. If the first tier, downstream, or related entity will establish the pharmacy network or select pharmacies to be included in the network contain language requiring the network pharmacies to submit claims to the Part D sponsor or first tier, downstream or related entity whenever the membership ID card is presented or on file at the pharmacy unless the enrollee expressly requests that a particular claim not be submitted. 42 CFR § 423.120(c)(3)

19. If the first tier, downstream, or related entity will adjudicate and process claims at the point of sale and/or negotiate with prescription drug manufacturers and others for rebates, discounts, or other price concessions on prescription drugs contain language that the first tier, downstream, or related entity will comply with the reporting requirements established in Section 6005 of the Affordable Care Act.

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

E. Upload in HPMS electronic lists of the contract/administrative service agreement/intercompany agreement citations demonstrating that the requirements of Section 3.1.D are included in each contract and administrative service agreement. Submit these data by downloading the appropriate spreadsheet found in HPMS that mimics the Appendix entitled, *Crosswalk of Citations of Section 3.1.1D to location in contracts/administrative service*

***agreements/intercompany agreements submitted as attachments to Section 3.1.1*. If the Applicant fails to upload crosswalks for executed agreements and contract templates, CMS cannot guarantee that the Applicant will receive notice of any deficiencies in the contracting documents as part of this courtesy review.**

F. In HPMS, complete the table below:

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

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

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

3.1.2. Program Integrity 2 CFR § 376 and Compliance Program 42 CFR § 423.504(b)(4)(vi); Prescription Drug Benefit Manual, Chapter 9 (http://www.cms.gov/PrescriptionDrugCovContra/Downloads/PDBManual_Chapter9_FWA.pdf)

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 Administration exclusion lists. Please note that this includes any member of its board of directors, and any key management or executive staff or any major stockholder. Additionally, given Medicare			

payment may not be made for items or services furnished by an excluded provider or entity, applicant should follow the guidance provided in the January 13, 2010 HPMS memo entitled *Claims for Drugs Prescribed or Dispensed by Excluded Providers.*			

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

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

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

C. In HPMS, complete and upload the appropriate template that mimics the Appendix entitled, *Compliance Plan Crosswalk* for the Compliance Plan.

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

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

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

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

Contact	Name/Title	Mailing Address (PO	Phone/Fax Numbers	Email Address

		Boxes may not be used)		
Corporate Mailing				
CEO – Sr. Official for Contracting				
Chief Financial Officer				
Medicare Compliance Officer				
Enrollment Contact				
Medicare Coordinator				
System Contact				
Customer Service Operations Contact				
General Contact				
User Access Contact				
Backup User Access Contact				
Marketing Contact				
Medical Director				
Bid Primary Contact				
Payment Contact				
Part D Claims Submission Contact				
Formulary Contact				
Pharmacy Network Management Contact				
Medication Therapy Management Contact				

Part D Benefits Contact				
Part D Quality Assurance Contact				
Part D Application Contact				
Pharmacy Director				
HIPAA Security Officer				
HIPAA Privacy Officer				
Part D Price File Contact (Primary)				
Part D Price File Contact (Back-up)				
Part D Appeals				
Government Relations Contact				
Emergency Part D Contact				
Pharmacy Technical Help Desk Contact				
Processor Contact				
CMS Casework Communication Contact				
Part D Exceptions Contact				
Coordination of Benefits Contact				
CEO – CMS Administrator Contact				
Plan to Plan				

Reconciliation Contact				
Bid Audit Contact				
Plan Directory Contact for Public Website				
CAP Report Contact for Public Website				
Financial Reporting Contact				
Best Available Evidence Contact				
Automated TrOOP Balance Transfer Contact				
Agent/Broker Compensation Data Contact				
Complaint Tracking Module (CTM) Contact				
Part D Reporting Requirement Contact				
Fraud Investigations Contact				
Reconciliation Contact				
DIR Contact				

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

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 Affordable Care Act, §3307, 42 CFR §423.120(b), 42 CFR §423.272(b)(2); Prescription Drug Benefit Manual, Chapter 6 (http://www.cms.gov/PrescriptionDrugCovContra/Downloads/Chapter6.pdf); CMS issued guidance 03/25/10

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 complies with formulary guidance that is contained in Chapter 6 of the Prescription Drug Benefit Manual, the HPMS Formulary Submission Module and Reports Technical Manual, and all other formulary instructions.			
4. Applicant agrees, when using a formulary, to meet all formulary submission deadlines established by CMS. Applicant further agrees that CMS may discontinue its review of the Applicant's formulary submission upon the Applicant's failure to meet any of the formulary submission deadlines. Applicant acknowledges that failure to receive CMS approval of its formulary may prevent CMS from approving the Applicant's bid(s) and contracting with the Applicant for the following benefit year.			
5. Applicant agrees that its formulary includes substantially all drugs in the protected classes that are specified as of			

the CMS-established formulary submission deadline. Applicant further agrees that any new drugs or newly approved uses for drugs within the protected classes that come onto the market after a CMS-established formulary submission deadline will be subject to an expedited P&T committee review. The expedited review process requires P&T committees to make a decision within 90 days, rather than the normal 180-day requirement.			
6. Applicant provides for an appropriate transition for new enrollees into Part D plans following the annual coordinated election period, newly eligible Medicare enrollees from other coverage, individuals who switch from one plan to another after the start of the contract year, and current enrollees remaining in the plan affected by formulary changes prescribed Part D drugs that are not on its formulary. This transition process satisfies the requirements specified in Chapter 6 of the Prescription Drug Benefit Manual.			
7. Applicant attests that its organization's approach to transitioning beneficiaries on drug regimens that are not on the plan's Part D approved formulary meets CMS criteria. The transition policy attestation will be completed in HPMS by close of business on the CMS-established formulary submission deadline in section 1.4.			
8. Applicant agrees to submit its organization's transition policy and a description of how the transition policy will be implemented within the applicant's claims adjudication system, including pharmacy notification via email to PartDtransition@cms.hhs.gov by close of business on the CMS-established formulary submission deadline in section 1.4.			
9. Applicant extends, where appropriate, transition periods beyond 30 days for enrollees using non-formulary drugs that have not been transitioned to a formulary drug or gone through the plan exception process within 30 days.			
10. Applicant ensures that staff is trained and information systems are in place to accommodate administration of the transition policy. This includes adoption of necessary information system overrides.			
11. Applicant provides an emergency supply of non-			

formulary Part D drugs (31-day supplies, unless the prescription is written for fewer days) for long-term care residents to allow the plan and/or the enrollee time for the completion of an exception request to maintain coverage of an existing drug based on reasons of medical necessity.			
12. Applicant has appropriate timeframes and "first fill" procedures for non-formulary Part D medications in long-term care and retail settings.			
13. Applicant abides by CMS guidance related to vaccine administration reimbursement under Part D.			

B. In HPMS, complete the table below:

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 develops and uses a P&T committee to develop and review the formulary and to ensure that the formulary is appropriately revised to adapt to both the number and types of drugs on the market. 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 first looks at medications that are clinically effective. When two or more drugs have the same therapeutic advantages in terms of safety and efficacy, the committee may review economic factors that achieve appropriate, safe, and cost-effective drug therapy.			
5. Applicant assures that the P&T committee uses appropriate scientific and economic considerations to consider utilization management activities that affect access to drugs, such as access to non-formulary drugs, prior authorization, step therapy, generic substitution, and therapeutic interchange protocols.			
6. Applicant's P&T committee reviews and approves all clinical prior authorization criteria, step therapy protocols, and quantity limit restrictions applied to each covered Part D drug.			
7. Applicant adheres to P&T guidelines that will, from time to time, be promulgated with regard to such subject areas as membership, conflict of interest, meeting schedule, meeting minutes, therapeutic classes, drug review and inclusion, formulary management, utilization management and review, formulary exceptions, and educational programs for providers.			
8. Applicant's P&T committee makes a reasonable effort to review a new FDA approved drug product within 90 days, and will make a decision on each new drug product within 180 days of its release onto the market, or a clinical justification will be provided if this timeframe is not met. These timeframes also include the review of products for which new FDA indications have been approved.			
9. Applicant's P&T committee approves inclusion or exclusion of the therapeutic classes in the formulary on an annual basis.			
10. The majority of the membership of the Applicant's P&T committee are practicing physicians and/or practicing			

pharmacists.			
11. The membership of the Applicant's P&T committee includes at least one practicing physician and at least one practicing pharmacist who are both free of conflict with respect to the Applicant organization and pharmaceutical manufacturers.			
12. The membership of the Applicant's P&T committee includes at least one practicing physician and at least one practicing pharmacist who are experts in the care of the elderly or disabled persons.			
13. Applicant's P&T committee recommends protocols and procedures for the timely use of and access to both formulary and non-formulary drug products.			
14. Applicant verifies that their P&T Committee members (listed in 3.2.1 C) do not appear on the HHS Office of Inspector General's Exclusion List. This list can be found at 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 includes 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 always covers a particular home infusion drug as part of a bundled service under Part C.			
4. If Applicant attests YES to 3.2.1D2, it ensures 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 appropriately apportions costs to Part C components of its bid to account for these drugs as a Part C supplemental benefit, as well as provides, in a supplemental formulary file submission, the home infused covered Part D drugs that are 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 (http://www.cms.gov/PrescriptionDrugCovContra/Downloads/Chapter6.pdf) and Chapter 7 (http://www.cms.gov/PrescriptionDrugCovContra/Downloads/Chapter7.pdf)

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 has incentives to reduce costs when medically appropriate such as, but not limited to encouragement of generic utilization.			
5. Applicant agrees to submit corresponding utilization management criteria for each drug identified on the Applicant's formulary flat file with prior authorization or step therapy via HPMS.			

3.2.3. Quality Assurance and Patient Safety Affordable Care Act § 3310; 42 CFR §423.153(c); Prescription Drug Benefit Manual, Chapter 7 (http://www.cms.gov/PrescriptionDrugCovContra/Downloads/Chapter7.pdf)

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 has a concurrent drug utilization review program that includes but is 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.			
4. Applicant reduces wasteful dispensing of outpatient prescription drugs in long-term care facilities by utilizing specific, uniform dispensing techniques, such as weekly, daily, or automated dose dispensing as established by CMS.			

3.2.4. Medication Therapy Management 42 CFR §423.153(d); The Affordable Care Act § 10328; Prescription Drug Benefit Manual, Chapter 7 (http://www.cms.gov/PrescriptionDrugCovContra/Downloads/Chapter7.pdf)

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 develops and implements 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 develops the MTM program in cooperation with licensed and practicing pharmacists and physicians.			
3. Applicant targets beneficiaries for enrollment in the MTM program based on all three of the following criteria: • Beneficiary must have multiple chronic diseases, with three chronic diseases being the maximum number an Applicant may require for targeted enrollment; • Beneficiary must be taking multiple covered Part D drugs, with eight Part D drugs being the maximum number of drugs an Applicant may require for targeted enrollment; and • Beneficiary must be identified as likely to incur annual costs for covered Part D drugs in an amount greater than or equal to $3000 increased by the annual percentage specified in 42 CFR § 423.104(d)(5)(iv).			
4. Applicant has an appropriate MTM enrollment policy which enrolls targeted beneficiaries using an opt-out method of enrollment only.			
5. Applicant has an appropriate MTM enrollment policy which targets beneficiaries for enrollment at least quarterly during each year.			
6. Applicant has appropriate policies and procedures for offering a minimum level of MTM services for each beneficiary enrolled in the MTMP that includes all of the following: • Interventions for both beneficiaries and prescribers; • An annual comprehensive medication review (CMR) with written summaries. The CMR must include an interactive, person-to-person , or telehealth consultation performed by a pharmacist or other qualified provider unless the beneficiary is in a long-term care setting. The Summary resulting from the CMR must comply with the requirements for a standardized format as specified by CMS, and • Quarterly targeted medication reviews with follow-up			

interventions when necessary.			
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 has an appropriate policy on how they will set MTM fees paid to pharmacists or others providing MTM services for covered Part D drugs. The policy will explain how the Applicant's fee or payment structure takes into account the resources used and the time required for those providing MTM services.			
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 has appropriate policies and procedures to meet CMS expectations for administering the MTM program, including, but not limited to, services, payments and criteria used for identifying beneficiaries eligible for the MTM program. Such expectations include: • 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 (http://www.cms.gov/PrescriptionDrugCovContra/Downloads/Chapter7.pdf) ; 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 supports and complies with electronic prescription standards relating to covered Part D drugs for Part D enrollees.			

2. Applicant has an electronic prescription drug program that complies with final Part D standards for transmitting, directly or through an intermediary, prescriptions and prescription-related information using electronic media for covered Part D drugs for Part D eligible individuals.			
3. Applicant obtains the Prescription Origin Code on original prescriptions submitted via the NCPDP 5.1 option field 419 DJ and reports this code on their PDE submissions.			
4. Applicant agrees that as it implements, acquires, or upgrades health information technology (HIT) systems, where available, the HIT systems and products meet standards and implementation specifications adopted under section 3004 of the Public Health Services Act as added by section 13101 of the American Recovery and Reinvestment Act of 2009, P.L. 111-5.			

3.2.6. Bids 42 CFR § 423.104, §423.265 and §423.272

A. In HPMS, complete the table below:

Applicant must attest 'yes' to each of the following qualifications to be approved for a Part D contract. Attest 'yes' or 'no' to each of the following qualifications by clicking on the appropriate response in HPMS:	**Yes**	**No**
1. Applicant limits the number of submitted bids in a service area to those that would demonstrate meaningful differences in benefit packages or plan costs to a beneficiary.		
2. Applicant has reviewed Section 2.4 of this application and understands that for the purpose of assigning autoenrollments, all bids that are below the low income subsidy threshold for all PDP contracts offered by the applicant's parent organization, its affiliates and itself will be counted as one.		
3. Applicant agrees to offer the plan to all Part D eligible beneficiaries residing in the applicant's service area; and at a uniform premium, with uniform benefits and level of cost-sharing throughout the plan service area.		

3.3. Service Area/Regions 42 CFR §423.112; Prescription Drug Benefit Manual, Chapter 5 (http://www.cms.gov/PrescriptionDrugCovContra/Downloads/MemoPDBManualChapter5_09.30.11.pdf)

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 offers 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 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 (http://www.cms.gov/PrescriptionDrugCovContra/Downloads/MemoPDBManualChapter5_09.30.11.pdf)

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 uses a contracted network of pharmacies and therefore meets the retail pharmacy convenient access standards; LTC and I/T/U pharmacy convenient access standards; and home infusion pharmacy adequate			

access standards. Note: If answer Yes, Applicant must complete all of Section 3.5.			
2. If Applicant attests 'NO' to 3.4A1, Applicant provides coverage for drugs purchased from all pharmacies, regardless of whether they are network pharmacies.			
3. If Applicant attests 'NO' to 3.4A1, Applicant does not charge additional cost-sharing to beneficiaries for obtaining their drugs at a non-network pharmacy.			
4. If Applicant attests 'NO' to 3.4A1, Applicant provides access at non-network pharmacies by reimbursing the pharmacy its Usual and Customary price (defined as the price an out of network pharmacy charges a customer who does not have any form of prescription drug coverage for a covered Part D drug) minus any applicable beneficiary cost sharing.			
5. If Applicant attests 'NO' to 3.4A1, Applicant does not routinely rely on billing practices that require enrollee to pay the usual and customary price upfront and then submit a paper claim to the applicant for reimbursement.			
6. If Applicant attests 'NO' to 3.4A1, Applicant has policies and procedures appropriately restricting the use of paper claims only to the situations in which online claims processing is not available at the point of sale in order to promote accurate TrOOP accounting, as well as to minimize administrative costs to the Part D plans and the Medicare program and opportunities for fraudulent duplicate claims reimbursement.			
7. If Applicant attests 'NO' to 3.4A1, Applicant arranges for automated, online billing at non-network pharmacies (similar to the way in which our point-of-sale contractor has allowed for online billing by non-contracted pharmacies).			

Note: Only if 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

(http://www.cms.gov/PrescriptionDrugCovContra/Downloads/MemoPDBManualChapter5_09.30.11.pdf)

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

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

- Crosswalk for Retail Pharmacy Contracts
- Crosswalk for Mail Order Pharmacy Contracts

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

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

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

3.5.1. Retail Pharmacy 42 CFR §423.120(a); 42 CFR §423.859(c); Prescription Drug Benefit Manual, Chapter 5 (http://www.cms.gov/PrescriptionDrugCovContra/Downloads/MemoPDBManualChapter5_09.30.11.pdf)

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 meets the CMS Standards for Convenient Access [42 CFR §423.120 (a)(1) and (2) no later than the application submission date.			
2. Applicant agrees that when Applicant is offering extended supplies via mail order, it also has contracts with a sufficient number of network retail pharmacies so as to ensure that enrollees have reasonable access to the same extended day supply benefits at retail that are available at mail-order.			

B. Upload in HPMS the Retail Pharmacy List:

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

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

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

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

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

D. In HPMS, indicate whether you are seeking a waiver of the convenient access standards for the territories in which your organization intends to offer the Part D benefit. If your organization is not intending to offer the Part D benefit in the territories check N/A within HPMS.

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

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

1. Explain why your organization cannot demonstrate compliance with the access standards or why these standards cannot be met.

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

F. In HPMS complete the table below:

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

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

G. In HPMS complete the table below:

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

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

3.5.2. Out of Network Access 42 CFR §423.124; Prescription Drug Benefit Manual, Chapter 5 (http://www.cms.gov/PrescriptionDrugCovContra/Downloads/MemoPDBManualChapter5_09.30.11.pdf)

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 that enrollees have adequate access to covered Part D drugs dispensed at out-of-network			

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

3.5.3. Mail Order Pharmacy 42 CFR §423.120(a)(10); Prescription Drug Benefit Manual, Chapter 5 (http://www.cms.gov/PrescriptionDrugCovContra/Downloads/MemoPDBManualChapter5_09.30.11.pdf)

A. In HPMS, complete the table below:

Applicants may offer a mail order option in addition to			**Requesting**

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	Waiver? *Yes or No*
1. Applicant offers mail order pharmacy as part of its Part D plans.			
2. If Applicant attests 'Yes' to 3.5.3A1, does Applicant's mail order contract include an extended (e.g., 90) day supply?			
3. If Applicant attests 'YES' to 3.5.3A2, then Applicant includes in its contracts with at least some retail pharmacies a provision that allows a retail pharmacy to offer an extended supply of drugs to any Plan beneficiary at the same price, reimbursement rate and cost sharing as the Plan's mail order pharmacy or pharmacies—the network mail order pharmacy rate; or an Applicant may use an alternative retail/mail order pharmacy rate with a higher contracted reimbursement rate provided that any differential in charge between the Network Mail Order Pharmacy rate and the higher contract reimbursement rate would be reflected in higher cost sharing paid by the beneficiary. Applicant must ensure that the availability of an extended day supply at retail does not increase the costs to the government and that enrollee cost-sharing for an extended day supply never exceeds what the enrollee would have paid had he/she filled his/her prescription in multiple one-month supply increments at retail pharmacy rates.			

B. Mail Order Pharmacy List

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

3.5.4. Home Infusion Pharmacy 42 CFR §423.120(a)(4); Prescription Drug Benefit Manual, Chapter 5 (http://www.cms.gov/PrescriptionDrugCovContra/Downloads/MemoPDBManualChapter5_09.30.11.pdf)

A. Home Infusion Pharmacy List

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

3.5.5. Long -Term Care (LTC) Pharmacy 42 CFR §423.120(a)(5); Prescription Drug Benefit Manual, Chapter 5 (http://www.cms.gov/PrescriptionDrugCovContra/Downloads/MemoPDBManualChapter5_09.30.11.pdf); 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 offers standard contracting terms and conditions to all long-term care pharmacies in its service area. These terms and conditions must include all the performance and service criteria for long-term care pharmacies that are cited in section 50.5.2 of Chapter 5 of the Prescription Drug Benefit Manual.			
2. Applicant agrees that all of the Part D contracted pharmacies in Applicant's LTC network have signed directly or through a power of attorney a contract that meets the LTC performance and service criteria established by CMS.			
3. Applicant recognizes the CMS special election period (SEP) or open enrollment period for institutionalized individuals for Part D drug plan enrollment and disenrollment for beneficiaries entering, living in, or leaving a long-term care facility.			
4. Applicant ensures convenient access to network LTC pharmacies for all of their enrollees residing in an IMD or ICF-MR designated by the State as an institution and in which any institutionalized individuals reside.			
5. Applicant provides convenient access to network LTC pharmacies for all of their enrollees who are inpatients in a hospital that is a "medical institution" under section 1902(q)(1)(B) of the Act – and therefore would meet the Part D definition of a LTC facility – and whose Part A benefits have been exhausted.			
6. Applicant contracts with a sufficient number of LTC pharmacies to provide all of the plan's institutionalized enrollees' convenient access to the plan's LTC			

pharmacies.			
7. Applicant does not rely upon beneficiary SEPs or on out-of-network access in lieu of contracting with a sufficient number of pharmacies to ensure that an enrollee can remain in his or her current plan for as long as he/she reside in an LTC facility in Applicant's service area.			
8. Applicant ensures that LTC pharmacy contracting activity is ongoing as Applicant continues to identify LTC facilities and LTC pharmacies, and as Applicant examines auto-enrollment assignments and incoming enrollments.			
9. Applicant agrees that the appropriate action to take when a beneficiary is enrolled in its plan and Applicant does not have a contract with an LTC pharmacy that can serve the LTC facility in which that enrollee resides is to sign a contract with the facility's contracted pharmacy, or – if that pharmacy will not sign a contract – with another pharmacy that can serve that facility. Applicant recognizes that, in some cases, a retroactive contract may be necessary to ensure convenient access to LTC pharmacies.			
10. Applicant readily negotiates with States with regard to contracting with State-run and operated LTC pharmacies in facilities such as ICFs/MR, IMDs, and LTC hospitals. States may not be able to agree to certain clauses in some LTC standard contracts because of constitutional and legal restraints. Applicants should be prepared to negotiate with States to address these issues.			
11. Applicant utilizes CMS data on beneficiary residence in LTC facilities to facilitate its LTC contracting efforts.			
12. Applicant, in contracting with LTC pharmacies, does not agree to particular contracting terms and conditions containing provisions that have the net result of creating a non-uniform benefit for plan enrollees served by those LTC pharmacies relative to those residing in LTC facilities serviced by other network LTC pharmacies whose contracts with the Applicant may not include the same provisions.			

B. LTC Pharmacy List

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

3.5.6. 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 (http://www.cms.gov/PrescriptionDrugCovContra/Downloads/MemoPDBManualChapter5_09.30.11.pdf)

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**
1. Using the list of I/T/U pharmacies provided at the www.cms.gov/PrescriptionDrugCovContra/ indicate whether your service area includes at least one state in which an I/T/U pharmacy resides.			
Not all Part D regions have I/T/U pharmacies. If the Applicant's service area covers <u>any</u> region that includes I/T/U pharmacies, then the Applicant must attest 'yes' to each of the following qualifications to be approved for a Part D contract. If <u>all</u> of the Applicant's service area <u>does not</u> include I/T/U pharmacies, then the Applicant may answer 'no' or n/a and still be approved for a Part D contract since these requirements do not apply. Attest 'yes,' 'no' or n/a to each of the following qualifications by clicking on the appropriate response in HPMS:			
2. Applicant offers standard terms and conditions that conform to the model contract addendum provided by CMS to all I/T/U pharmacies in its service area by sending a conforming contract offer to all such pharmacies. The model contract addendum is posted on the www.cms.gov/PrescriptionDrugCovContra/ website. The model contract addendum account for differences in the operations of I/T/U pharmacies and retail pharmacies.			
3. Applicant agrees to submit documentation upon CMS' request to demonstrate offering all I/T/U pharmacies in its service area a conforming contract. Such documentation may be proof of fax or U.S. postage or other carrier's receipt of delivery.			

B. I/T/U Pharmacy List

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 (http://www.cms.gov/PrescriptionDrugCovContra/Downloads/MemoPDBManualChapter5_09.30.11.pdf)

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 does not restrict access to Part D drugs by limiting distribution through a subset of network pharmacies, except when necessary to meet FDA limited distribution requirements or to ensure the appropriate dispensing of Part D drugs that require extraordinary special handling, provider coordination, or patient education when such extraordinary requirements cannot be met by a network pharmacy. Applicant agrees that additional education or counseling alone does not qualify a drug for limited distribution within the overall pharmacy network.			
2. Applicant does not restrict access solely on the placement of a Part D drug in a "specialty/high cost" tier because this tier placement alone is not indicative of any special requirements associated with such drug. Applicant further agrees that any drug-by-drug requirements for network pharmacies only apply to special handling and dispensing that may be required for a particular "specialty" drug and not to reimbursement or other standard terms and conditions.			
3. Applicant does not require a pharmacy to be a "specialty" pharmacy in order to dispense any drug that requires special handling if the network pharmacy is			

capable of appropriately dispensing the particular Part D drug or drugs in question.			

3.6. Enrollment and Eligibility 42 CFR §423.30 and 42 CFR §423.44 ; Prescription Drug Benefit Manual, Chapters 3 (http://www.cms.gov/MedicarePresDrugEligEnrol/01_Overview.asp, 4 (http://www.cms.gov/MedicarePresDrugEligEnrol/02_CreditableCoverageLateEnrollmentPenalty.asp), and 13 (http://www.cms.gov/PrescriptionDrugCovContra/Downloads/Chapter13.pdf); Plan Communications User Guide; 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 complies with the CMS Eligibility and Enrollment and Disenrollment Guidance documents that are provided on the www.cms.hhs.gov/ website.			
2. Applicant identifies full dual and other LIS eligible individuals enrolled in MA-only plans and conducts auto- and facilitated enrollment of these individuals in accordance with the guidance provided by CMS.			
3. Applicant complies with CMS operational guidance on Creditable Coverage and the Late Enrollment Penalty.			
4. Applicant has business processes for quickly resolving urgent issues affecting beneficiaries, such as late changes in enrollment or copay status, in collaboration with CMS caseworkers.			
5. Applicant queries 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 collects, reviews, and transmits creditable coverage information in accordance with CMS guidance and policies.			
7. Applicant uses 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 adheres to CMS's Best Available Evidence policy under 42 CFR § 423 .800(d), under which an individual can provide acceptable evidence supporting a revised cost-sharing amount that the sponsor must accept for the purpose of administering the benefit, and to submit information to CMS with respect to Best Available Evidence in accordance with CMS procedures outlined in Chapter 13 of the Prescription Drug Benefit Manual.			
9. Applicant has 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 does not 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 does not disenroll a member or initiate the disenrollment process if the organization has been notified that a State Pharmaceutical Assistance Program			

(SPAP) or other payer intends to pay the entire Part D premium on behalf of an individual.			
12. Applicant downloads at least daily and processes all enrollment elections made via the on-line enrollment center (OEC) hosted by CMS.			
13. Applicant transmits enrollment and disenrollment and change transactions within the timeframes provided in CMS Enrollment and Disenrollment guidance and in accordance with the published MARx Monthly Processing calendar.			
14. Applicant reviews all systems responses, files and reports received from CMS and compares these to its internal data to identify discrepancies and reconcile enrollment information, beneficiary status (such as LIS) and payment data.			
15. Applicant completes the reconciliation of all enrollment, membership, and payment data, and submits requests for valid discrepancy corrections in compliance with the 45-day schedule to submit the monthly CEO certification of enrollment data for payment.			

3.7. Complaints Tracking Prescription Drug Benefit Manual, Chapter 7 (http://www.cms.gov/PrescriptionDrugCovContra/Downloads/Chapter7.pdf); CMS issued guidance 11/16/06, 07/28/2008, and 12/09/08

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 resolves 95% of complaints designated as immediate needs complaints via the CMS Complaints Tracking Module within 2 calendar days.			
2. Applicant is expected to resolve at least 95% of complaints designated as "urgent" via the CMS Complaints Tracking Module in accordance with CMS issued guidance.			

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

3.8. Medicare Plan Finder Prescription Drug Benefit Manual, Chapter 7 (http://www.cms.gov/PrescriptionDrugCovContra/Downloads/Chapter7.pdf); CMS issued guidance 07/17/06, 11/20/07, 08/21/08, and 05/20/10

A. In HPMS, complete the table below:

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

4. Applicant agrees to respond to CMS' MPF quality assurance outlier emails as directed by CMS, and agrees that failure to respond in accordance with these directions will result in the suppression of the Applicant's pricing data from the website.			

3.9. Grievances 42 CFR Part 423 Subpart M; Prescription Drug Benefit Manual, Chapter 18 (http://www.cms.gov/MedPrescriptDrugApplGriev/01_Overview.asp)

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 processes beneficiary grievances consistent with 42 CFR §423 subpart M.			
2. Applicant abides by Chapter 18 of the Prescription Drug Benefit Manual.			
3. Applicant, consistent with 42 CFR §423.564 : • Tracks and addresses enrollees' grievances, • Processes enrollees' grievances within the appropriate timeframes, • Works with the QIO to resolve quality of care grievances when appropriate, • Provides appropriate and timely notification enrollees of grievance dispositions, and • Trains relevant staff and first tier, downstream and related entities on all regulatory requirements.			
4. Applicant informs enrollees about the grievance process through information and outreach materials.			
5. Applicant accepts grievances from enrollees at least by telephone and in writing (including facsimile).			
6. Applicant maintains, and provides to CMS upon request, records on all grievances received both orally and in			

writing. At a minimum, such records must track the: • 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 (http://www.cms.gov/MedPrescriptDrugApplGriev/01_Overview.asp); Part D QIC Reconsideration Procedures Manual

A. In HPMS, complete the table below:

Applicant must attest 'yes' to each of the following qualifications to be approved for a Part D contract. Attest 'yes' or 'no' to each of the following qualifications by clicking on the appropriate response in HPMS:	**Yes**	**No**	**Requesting Waivers? *Yes or No***
1. Applicant processes beneficiary coverage determinations (including exceptions) and appeals consistent with 42 CFR Part 423 subpart M and relevant provisions of subpart U.			
2. Applicant uses a uniform exceptions and appeals process, including procedures for accepting oral and written requests for coverage determinations and			

redeterminations per 42 CFR § 423.128(b)(7) and (d)(1)(iii). Applicant ensures access to a uniform model form to request a coverage determination and redetermination, to the extent such model forms have been approved for use by CMS. Applicant provides immediate access to the coverage determination and redetermination processes via an Internet Website.			
3. Applicant employs a medical director who is a physician with a current and unrestricted license to practice medicine in a State, Territory, Commonwealth of the United States, or the District of Columbia, per the requirements set forth in 42 CFR § 423.562(a)(5). The medical director is responsible for ensuring the clinical accuracy of all coverage determinations and redeterminations involving medical necessity.			
4. Applicant retains the services of physicians or other appropriate health care professionals per the requirements in 42 CFR §423.566(d) for medical necessity reviews in cases where the applicant expects to issue a partially or fully adverse coverage determination.			
5. Applicant abides by the coverage determination and appeals policies contained in Chapter 18 of the Prescription Drug Benefit Manual and the Part D QIC Reconsideration Procedures Manual.			
6. Applicant has arrangements with its network pharmacies for the standardized pharmacy notice ("Notice: Your Prescription Cannot be Filled"/CMS-10147) to be distributed to enrollees in accordance with the requirements set out in 42 CFR §§423.562 (a)(3) and 423.128(b)(7)(iii).			
7. Applicant, in accordance with 42 CFR Part 423 subpart M: • Tracks coverage determination (including exceptions) and redetermination requests received both orally and in writing, • Processes coverage determinations (including exceptions) and redeterminations within the appropriate timeframes, • Provides appropriate and timely notification to enrollees			

(and prescribing physicians or other prescribers, when appropriate) of coverage determination (including exceptions) and redetermination decisions, and • Trains relevant staff and first tier, downstream and related entities on all regulatory requirements.			
8. At a minimum, Applicant must track the: • Date and time 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 and time of receipt of a physician's or other prescriber's supporting statement (for an exception request), • Disposition of request, and • Date and time of decision notice to the enrollee and/or prescriber.			
9. Applicant notifies the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of an expedited coverage determination for benefits as expeditiously as the enrollee's health condition requires, but no later than 24 hours after receipt of the request.			
10. Applicant ensures that an enrollee is notified of a standard coverage determination for benefits as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receipt of the request.			
11. Applicant ensures that an enrollee is notified of a standard coverage determination regarding reimbursement and receives reimbursement (when appropriate) no later than 14 calendar days after receipt of the request.			
12. Applicant ensures that an enrollee is notified of a decision on an exception request in accordance with regulatory timelines applicable to coverage determinations. For exceptions involving requests for benefits, the processing timeframe begins upon receipt			

of the physician's or other prescriber's supporting statement. For exceptions involving requests for payment, the processing timeframe begins upon receipt of the request for payment.			
13. Applicant notifies the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of an expedited redetermination as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receipt of the request.			
14. Applicant ensures that an enrollee is notified of standard redeterminations as expeditiously as the enrollee's health condition requires, but no later than 7 calendar days after receipt of the request.			
15. Applicant automatically forwards coverage determination (including exception) and redetermination requests to the Independent Review Entity (IRE) when the notification timeframes are not met, consistent with the rules set forth in Chapter 18 of the Medicare Prescription Drug Benefit Manual. Applicant auto-forwards cases timely to the proper IRE filing location and notifies the enrollee that the case has been sent to the IRE.			
16. Applicant maintains an exceptions process that includes a written description of how the organization will provide for standard and expedited tiering exception requests and non-formulary exception requests (including exceptions to utilization management tools), and how the organization will comply with such description. Such policies and procedures will be made available to CMS on request.			
17. Applicant complies with 42 CFR §423.578(a) and (b) which require a PDP sponsor to: • 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.			

18. Applicant's exceptions process is not overly burdensome or onerous. For example, a Part D Sponsor may not require that ALL exception requests be accompanied by laboratory evidence.			
19. Applicant's approved non-formulary drugs are assigned to a single existing tier, unless Applicant elects to apply a second less expensive level of cost sharing for approved formulary exceptions for generic drugs, so long as the second level of cost sharing is associated with an existing formulary tier and is applied uniformly to all approved formulary exceptions for generic drugs. Applicant may not create a tier specifically designed for non-formulary exceptions.			
20. Applicant does not restrict the number of exception requests submitted by an enrollee.			
21. Applicant will: • 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.			
22. Applicant will timely forward case files to the IRE (upon request by the IRE) when an enrollee requests a reconsideration by the IRE and will prepare and submit the case file consistent with instructions in the Part D QIC's Reconsideration Procedures Manual.			
23. Applicant informs its enrollees about the coverage determination (including exceptions) and appeals process through information provided in the Evidence of Coverage and outreach materials.			
24. Applicant makes available to CMS upon request, coverage determination (including exceptions) and appeals records and is able to track all levels of appeal by the appeal number assigned by the adjudicator (e.g., IRE).			

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

(http://www.cms.gov/PrescriptionDrugCovContra/Downloads/Chapter14.pdf)

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 complies with Chapter 14 of the Prescription Drug Benefit Manual.			
2. Applicant has a system for notifying enrollees when CMS' systems indicate other prescription drug coverage, and requesting enrollees to concur with new/changed information.			
3. Applicant permits SPAPs, ADAPs, IHS, and other third party payers to coordinate benefits as required by the regulations in 42 CFR Part 423, Subpart J, and Chapter 14 of the Prescription Drug Benefit Manual. For example, an SPAP may require agreements be signed in order for the state to pay premiums on behalf of a beneficiary. CMS expects Part D sponsors to execute these trading partner agreements within a reasonable timeframe.			
4. Applicant pays user fees as required under 42 CFR §423.6 and as may be required under 42 CFR §423.464 (c).			
5. Applicant does not impose fees on SPAPs or other third-party insurers that are unreasonable and/or unrelated to the cost of coordination of benefits.			
6. Applicant sends updated information captured in the beneficiary COB notification process about its enrollees' other sources of prescription drug coverage via electronic updates to the COB contractor.			
7. Applicant agrees to receive COB files from CMS and update its systems with these data at least weekly in accordance with the most current version of the Plan Communications User Guide.			

8. When a supplemental payer wishes to pay premiums on behalf of plan enrollees, Applicant: • As may be required by a supplemental payer, enter into agreements with, and accept premium payments made by these supplemental payers; • Suppresses premium billing to the beneficiaries for whom it accepts premium payments from supplemental payers; • Informs enrollees not to use the SSA withhold when another payer is paying their premium (in whole or in part); and • Ensures that, the overall premium payment made by or on behalf of a beneficiary does not vary among plan enrollees (e.g., Sponsor cannot charge a different premium to SPAPs for their members versus all 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: • Enters into an agreement to receive such subsidies; • Applies such subsidies to the first dollar of beneficiary cost sharing under the Applicant's Part D plan; and • Submits claims information to the State to support reconciliation.			
11. Applicant provides clear and prominently displayed information identifying the SPAP as a co-sponsor of benefits when the Applicant participates in a risk- or non-risk lump sum per capita contract with an SPAP to provide wrap-around benefits to Part D enrollees.			
12. Applicant receives and processes plan to plan reconciliation reports on a monthly basis.			

13. Applicant coordinates the reconciliation of claims when a Part D sponsor other than the Part D sponsor 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.			
14. Applicant coordinates benefits with SPAPs, other entities providing prescription drug coverage, beneficiaries, and others paying on the beneficiaries' behalf for a period not to exceed three years from the date on which the prescription for a covered Part D drug was filled.			

3.12. Tracking Out-of Pocket Costs (TrOOP) Affordable Care Act § 3314; 42 CFR Part 423 Subpart J; Prescription Drug Benefit Manual, Chapters 13 (http://www.cms.gov/PrescriptionDrugCovContra/Downloads/Chapter13.pdf) and Chapter 14 (http://www.cms.gov/PrescriptionDrugCovContra/Downloads/Chapter14.pdf)

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 tracks each enrollee's true out of pocket (TrOOP) costs reflecting the amount the enrollee has spent out of pocket during a program year on covered Part D drugs.			
2. Applicant accepts data concerning third party payers in a format specified by CMS and uses these data in the Applicant's TrOOP calculation process.			
3. Applicant processes claims and tracks TrOOP in real time using the current HIPAA-approved NCPDP standard.			
4. Applicant provides enrollees with a report on their TrOOP status at least monthly if the enrollee's TrOOP status has changed.			

5. Applicant provides enrollees daily access to their current TrOOP status through the organization's toll-free customer service phone number.			
6. In the event of disenrollment, Applicant provides the TrOOP status of the beneficiary as of the effective date of the disenrollment to the beneficiary, if there has been a change in these data since the last report to the beneficiary.			
7. Applicant retroactively adjusts claims and recalculates TrOOP balances based on Nx transactions received from the TrOOP Facilitation Contractor that were created based on other than real-time TrOOP-eligible claims.			
8. Applicant retroactively adjusts claims and recalculates TrOOP balances based on receipts received from its Medicare enrollees that reflect amounts the enrollee paid on other than real-time TrOOP-eligible claims.			
9. Applicant agrees that when it receives an Nx transaction, but has no supplemental payer information on file to identify the payer, the Applicant contacts the beneficiary to identify the payer and sends the payer information to the COB Contractor via ECRS verification.			
10. Applicant retroactively adjusts claims, recalculates TrOOP balances, and reimburses other payers (when applicable) whenever it receives information (e.g., an LIS status change) that affects how the Applicant previously adjudicated a claim, or that indicates an error in the order of payment when another payer(s) was involved.			
11. Applicant may count other payer paid amounts as satisfying the Part D deductible whether or not the entire amount counts toward TrOOP.			
12. Applicant has the systems capability to receive and respond to real-time (or batch) transactions requesting TrOOP-related data for disenrolling Part D beneficiaries as well as to receive these data for newly enrolling Part D beneficiaries transferring mid-year from another plan.			
13. Applicant agrees that, when an exception to the ATBT process is required, the Applicant sends TrOOP-related data manually for disenrolling Part D beneficiaries as well			

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

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

3.13. Medicare Secondary Payer 42 CFR §423.462; Prescription Drug Benefit Manual, Chapter 14 (http://www.cms.gov/PrescriptionDrugCovContra/Downloads/Chapter14.pdf)

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 adheres to MSP laws and any other Federal and State laws in establishing payers of last resort.			
3. Applicant follows the Rules for Coordination of Benefits adopted in the most current National Association of Insurance Commissioner Coordination of Benefits Model Regulation.			
4. Applicant processes claims in real time to support the TrOOP facilitation process when it is a secondary payer in accordance with the application of MSP rules.			
5. Applicant collects mistaken primary payment from insurers, group health plans, employer sponsors,			

enrollees and other entities.			
6. Applicant agrees that in situations involving workers' compensation, Black Lung, No-Fault, or Liability coverage to make conditional primary payment and recover any mistaken payments, unless the Applicant is already aware that the enrollee has workers' compensation, Black Lung, No-Fault, or Liability coverage and has previously established that a certain drug is being used exclusively to treat a related injury.			

3.14. Marketing/Beneficiary Communications 42 CFR §423.128; 42 CFR §423.505; Prescription Drug Benefit Manual, Chapter 2 (http://www.cms.gov/PrescriptionDrugCovContra/Downloads/MMG_05.11.pdf)

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 complies with marketing guidelines and approval procedures that are contained with Chapter 2 of the Prescription Drug Benefit Manual and posted on the www.cms.gov/ website, including the requirements of the File and Use Certification process.			
2. Applicant makes available to beneficiaries only those marketing materials, notices, and other standardized letters that comply with CMS' marketing guidelines and have been appropriately filed with CMS through HPMS.			
3. Annually and at the time of enrollment, the Applicant provides enrollees information about the following Part D features, as described in the marketing guidelines: • 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 • Plan ratings information			
4. Applicant provides general coverage information, as well as information concerning utilization, grievances, appeals, exceptions, quality assurance, and sponsor financial information to any beneficiary upon request.			
5. Applicant discloses to its enrollees and potential enrollees information concerning the organization's performance and contract compliance deficiencies as described by CMS.			
6. Applicant makes marketing materials available in any language that is the primary language of at least 5% of the general population in an Applicant's plan benefit package service area.			
7. Applicant maintains a toll-free customer service call center that provides customer telephone service to current and prospective enrollees in compliance with CMS standards. This means that the Applicant complies with at least the following: • Call center operates during normal business hours, seven days a week from 8:00 AM to 8:00 PM for all time zones in which the Applicant offers a Part D plan during the annual enrollment period and 45 days thereafter. • On Saturdays, Sundays and holidays, from February 15 until the following annual enrollment period, a customer service representative or an automated phone system may answer beneficiary calls. • If a beneficiary is required to leave a message in voice mail box due to the utilization of an automated phone system, the applicant ensures that a return call to a beneficiary is made in a timely manner, but no later than one business day from the leaving of the message by the beneficiary. • The average hold time for a beneficiary to reach a customer service representative is 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 provides service to non-English speaking, limited English proficient (LEP), and hearing impaired beneficiaries.			
8. Applicant operates an Internet Web site that includes all items identified in Chapter 2 of the Prescription Drug Benefit Manual, 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.			
9. Applicant ensures that the marketed and adjudicated formularies are consistent with the HPMS approved formulary file.			
10. Applicant provides its plan enrollees, in a form understandable to enrollees and on at least a monthly basis for those months in which the enrollees use their Part D benefits, an explanation of benefits that states a) the item or service for which payment was made; b) notice of the enrollee's right to an itemized statement; c) a year-to-date statement of the total Part D benefits provided in relation to deductibles, coverage limits, and annual out-of-pocket thresholds; d) cumulative year-to-date total of incurred costs; and e) applicable formulary changes.			
11. Applicant does not include co-branding names and/or logos of contracted providers or names and/or logos that are substantially similar to a contracted provider's name and/or logo on member identification cards.			
12. Applicant agrees that the subsequent CY Annual Notice of Change (ANOC) / Summary of Benefits (SB) / Formulary must be received by members (if applicable) no			

later than 15 days prior to the start of the annual election period.			
13. Applicant notifies its enrollees that the Applicant will release the enrollee's information, including the enrollee's prescription drug event data, to CMS which may release it for research and other purposes consistent with all applicable Federal statutes and regulations.			

3.15. Provider Communications Prescription Drug Benefit Manual, Chapter 2 (http://www.cms.gov/PrescriptionDrugCovContra/Downloads/MMG_05.11.pdf)

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 operates a toll-free call center to respond to inquiries from pharmacies and providers regarding the Applicant's Medicare prescription drug benefit. Inquiries will concern such operational areas as claims processing, benefit coverage, claims submission, and claims payment. This means that the Applicant complies with at least the following: • 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 is two minutes or less. • The disconnect rate of all incoming calls does not exceed 5 percent.			
2. Applicant agrees that has a "one-stop" area on its website that provides needed information on the procedures, the forms and the contact information for their prior authorization, coverage determination (including exceptions), and appeals processes.			
3. Applicant operates a toll-free call center to respond to			

physicians and other prescribers for information related to prior authorizations, coverage determinations (including exceptions), and appeals requests. The call center operates during normal business hours and never less than 8:00 a.m. to 6:00 p.m., Monday through Friday according to the time zones for the regions in which their plans operate. 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. Reporting Requirements Affordable Care Act § 6005; 42 CFR §423.514; 2010 Reporting Requirements

A. In HPMS, complete the table below:

Applicant must attest 'yes' to each of the following qualifications to be approved for a Part D contract. Attest 'yes' or 'no' to each of the following qualifications by clicking on the appropriate response in HPMS:	**Yes**	**No**	**Requesting Waiver?** ***Yes or No***
Reporting Requirements Guidance			
1. Applicant complies with the Reporting Requirements Guidance that is posted on the www.cms.gov/ website.			
2. Applicant agrees that an individual with authority to sign on behalf of your organization attests that the reporting requirements data has been audited internally for			

accuracy.			
3. Applicant subjects reporting requirement data to a yearly independent audit to determine its reliability, validity, completeness, and comparability in accordance with CMS guidance.			
Business Transactions and Financial Requirements			
4. Applicant notifies CMS of any loans or other special financial arrangements made with contractors, first tier, downstream and related entities as that term is defined in 42 CFR §423.501.			
5. Applicant submits audited financial statements to CMS annually.			
Claims Data			
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 collecting, storing and protecting electronic eligibility and claims data. Data to be collected encompasses quantity, type, and costs of pharmaceutical prescriptions filled for enrollees. The plan must link this information to Medicare beneficiary identification numbers (HIC#s).			
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 creating and submitting PDE records for Medicare enrollees for every Part D drug prescription in the format required by CMS, using batch submission processes. Data to be submitted encompasses quantity, type and costs of pharmaceutical prescriptions filled for enrollees. The plan must link this information to Medicare beneficiary identification numbers (HIC#s).			
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 submitting data to CMS via the Medicare Data Communications Network (MDCN).			
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 performing data edit and quality control procedures (including resolution of rejected claims) to ensure accurate and complete prescription drug data.			
10. The Applicant or the Applicant's representative, such as a first tier, downstream or related entity, has data management processes and data systems capable of correcting all data errors identified by CMS.			
11. The Applicant or the Applicant's representative, such as a first tier, downstream or related entity, has data management processes and data systems capable of collecting data for dates of service within the coverage year with a 3-month closeout window for the submission of remaining unreported claims data.			
12. The Applicant or the Applicant's representative, such as a first tier, downstream or related entity, has data management processes and data systems capable of 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			
13. The Applicant reports direct and indirect remuneration (DIR) dollars for payment reconciliation on an annual basis at the Plan Benefit Package (PBP) level/plan level in the manner specified by CMS. In addition, the Applicant maintains records and documentation to verify the DIR data reported to CMS.			
Other Data			
14. Applicant reports at a frequency determined by CMS specified data (pursuant to 42 CFR §423.514(a)) on a variety of measures to support payment, program integrity, program management, and quality improvement activities in a manner prescribed by CMS. Such data submissions will be accurate and timely.			
15. The Applicant provides CMS with routine administrative reports (pursuant to 42 CFR §423.514 (a)) on a variety of measures that concern the Applicant's performance in			

the administration of the Part D benefit. Such reports shall be submitted according to instructions issued with timely notice by CMS.			
Supporting www.medicare.gov			
16. The Applicant submits 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 are posted on www.cms.gov by April of the prior year.			
Conflict of Interest			
17. The Applicant provides financial and organizational conflict of interest reports to CMS.			
PBM Transparency			
18. The Applicant's PBM provides information related to PBM transparency as specified in Section 6005 of the Affordable Care Act.			

3.17. 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 uses HPMS to communicate with CMS in support of the application process, formulary submission process, bid submission process, ongoing operations of the Part D program, and reporting and oversight activities. Part D sponsors are required to secure access to HPMS in order to carry out these functions.			
2. Applicant establishes connectivity to CMS as noted in the instructions provided by the MAPD Help Desk at 1-			

800-927-8069 or via the MAPD HelpDesk webpage, www.cms.gov/mapdhelpdesk, in the Plan Reference Guide for CMS Part C/D system link.			
3. Applicant has a CMS User ID and Password.			
Enrollment & Payment			
4. Applicant reconciles Part D data to CMS enrollment/payment reports received daily, weekly and monthly.			
5. Applicant completes the review of monthly reports, including submitting all requests for discrepancy corrections, and submits the CEO Certification of enrollment data for plan payment within 45 days of CMS monthly membership payment report availability.			
6. Applicant participates in connectivity testing and other system testing measures as provided to the Applicants prior to contract execution to validate system setup.			
7. Applicant has system(s) to process enrollment and payment transactions as exchanged with CMS in accordance with system development lifecycle standards.			
8. Applicant ensures appropriate security safeguards and protocols are in place to protect the protected health information in the system(s).			
9. Applicant maintains all pertinent system security and disaster recovery plans and procedures.			
10. In accordance with 42 CFR §423.322, the Applicant provides CMS with any data required to ensure accurate prospective, interim, and/or final reconciled payments including, but not limited to, the following: test data, Prescription Drug Event (PDE) records, enrollment transactions, Direct and Indirect Remuneration (DIR) data, discrepancy records, and premium payment data.			

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

A. In HPMS, complete the table below:

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 complies with all applicable standards, implementation specifications, and requirements in the Standards for Privacy of Individually Identifiable Health Information, and Security Standards under 45 CFR Parts 160, 162, and 164.			
2. Applicant encrypts all hard drives or other storage media within the device as well as all removable media.			
3. Applicant has policies addressing the secure handling of portable media that is accessed or used by the organization.			
4. Applicant complies with all applicable standards, implementation specifications, and requirements in the Standard Unique Health Identifier for Health Care Providers final rule under 45 CFR Parts 160 and 162.			
5. Applicant agrees that when its organization receives a National Provider Identifier (NPI) in prescription drug event data, that the organization must report an NPI.			
6. Applicant agrees to implement a contingency plan related to compliance with the NPI provisions.			
7. Applicant complies with all applicable standards, implementation specifications, and requirements in the Standards for Electronic Transactions under 45 CFR Parts 160 and 162.			
8. Applicant transmits payment and remittance advice consistent with the HIPAA-adopted ACS X12N 835, Version 4010/4010A1: Health Care Claim Payment and			

Remittance Advice Implementation Guide (“835”).			
9. Applicant submits the Offshore Subcontract Information and Attestation via HPMS for each offshore subcontractor (first tier, downstream and related entities) (including downstream offshore subcontractors’ first tier, downstream and related entities) that receive, process, transfer, handle, store, or access Medicare beneficiary protected health information (PHI) by the last Friday in September for the upcoming contract year.			

3.19. Prohibition on Use of SSN or Medicare ID number on Enrollee ID Cards Prescription Drug Benefit Manual, Chapter 2 (http://www.cms.gov/PrescriptionDrugCovContra/Downloads/MMG_05.11.pdf)

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

3.20. 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 maintains books, records, documents, and other evidence of accounting procedures and practices consistent with 42 CFR §423.505(d).			
2. Applicant has pharmacies, contracted for the Part D benefit, maintain prescription records in their original format for the greater of 3 years or the period required by State law and allow those records to be transferred to			

an electronic format that replicates the original prescription for the remaining 7 years of the 10 year record retention requirement.			
3. Applicant keeps all other records—except prescription records—that must be retained for Medicare under Part C and Part D in the format(s) required by State law or at the Applicant's discretion.			

3.21. Prescription Drug Event (PDE) Records; 42 CFR Part 423 Subpart G; CMS issued guidance 04/27/2006, 06/23/2006, 12/17/20101, 03/01/2011, 03/04/2011, 04/28/2011, 05/16/2011

Applicant must attest 'yes' to each of the following qualifications to be approved for a Part D contract. Attest 'yes' or 'no' to each of the following qualifications by clicking on the appropriate response in HPMS:	**Yes**	**No**	**Requesting Waiver? *Yes or No***
1. Applicant abides by CMS guidance related to PDE data. Such guidance includes the 2008 Regional Prescription Drug Event Data Participant Training Guide and Technical Assistance Resource Guide which can be found at www.csscoperations.com/new/pdic/pdd-training/pdd-training.html.			
2. Applicant submits data and information necessary for CMS to carry out payment provisions.			
3. Applicant submits PDE data on the schedule required by applicable regulations and CMS guidance.			
4. Applicant submits the PDE data in the format described by CMS and in accordance with the National Council for Prescription Drug Programs (NCPDP) industry standard format.			
5. Applicant provides diagnosis data for risk adjustment as required by CMS.			
6. Applicant meets all data submission deadlines.			
7. Applicant pays all Plan-to-Plan payables on time.			
8. Applicant complies with Medicare Coverage Gap Discount Program requirements.			

9. Applicant complies with timely response requirements for PDE Data Quality Reviews posted on the Data Quality Validation website.			

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

A. In HPMS, complete the table below:

Applicant must attest 'yes' to each of the following qualifications to be approved for a Part D contract. Attest 'yes' or 'no' to each of the following qualifications by clicking on the appropriate response in HPMS:	**Yes**	**No**	**Requesting Waiver? *Yes or No***
1. Applicant has 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 has 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 has 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); • System volume in covered lives, including the number of transactions the system can support per day and per			

hour.			
4. Applicant has available to CMS upon request policies and procedures that include a complete description and flow chart detailing the claims adjudication process for each: • 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 has 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 has available to CMS upon request policies and procedures that include a complete description of the accessibility of this information for data capture purposes and flow chart of the claims data retrieval process for each: • 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 has a robust testing process that will identify and correct any plan configuration errors prior to			

implementation.			
8. Applicant uses HIPAA compliant transactions where applicable.			
9. Applicant documents the manner and extent to which it has tested benefit designs such as drug exclusions or quantity limitations and plan parameters such as co-payments and benefit intervals (phases).			
10. Applicant rapidly adopts any new messaging approved by the NCPDP Workgroup to adjudicate a Part D claim and appropriately coordinate benefits in real time.			
11. Applicant regularly updates their systems with the most current information on sanctioned providers and has processes in place to identify and prevent payment of Part D claims at point-of-sale when such claims have been prescribed by excluded providers.			
12. Applicant assigns and exclusively uses unique Part D identifiers (RxBin or RxBin/RxPCN) for each individual Part D member.			
13. Applicant agrees when it receives information that necessitates a retroactive claims adjustment, the applicant processes the adjustment and issue refunds or recovery notices within 45 days of the applicant's receipt of complete information regarding the claims adjustment.			

3.23. 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 takes steps to ensure that members are not over billed or double billed for their monthly premiums. The Applicant will promptly refund members when billing errors occur.			

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

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

A. In HPMS, complete the table below:

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

Note: Nothing in this section is intended to supersede the regulations at 42 CFR Part 422. Failure to reference a regulatory requirement in this application does not affect the applicability of such requirement, and Applicants are required to comply with all applicable requirements of the regulations in Part 422 of 42 CFR. In particular, this application does not include attestations related to Part 422 of 42 CFR as such requirements will be incorporated into a final contract with the Applicant.

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

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

5.1. Experience & Organizational History 42 CFR §422.502(b) and 503(b)

A. Upload in HPMS in the MA Supporting Files Experience & History Upload Section, organizational background and structure information. Submit this information by downloading the appropriate template found in HPMS that mimics the Appendix entitled, *History/Structure/Organizational Charts.* This is a brief summary of the Applicant's history, structure and ownership. Include organizational charts to show the structure of ownership, subsidiaries, and business affiliations.

5.2. Key Management Staff 42 CFR §422.503(b)(4)(ii)

A. Upload in HPMS in the MA Supporting Files Key Management Staff Upload Section, the position descriptions for the key management staff and an organizational chart showing the relationships of the various departments.

5.3. Fiscal Soundness

A. In HPMS, upload in the MA Supporting Files Fiscal Soundness Upload Section, the most recent Audited Financial Statement that is available and the most recent Quarterly NAIC Health Blank or other form of quarterly financials if the NAIC Health Blank is not required by your State. CMS reserves the right to request additional financial information as it sees fit to determine if the Applicant is maintaining a fiscally sound operation.

Note: If the Applicant was not in business in 2010, and has less than six months of operation in 2011, it must electronically upload the financial information it submitted to the State at the time the State licensure was requested. If the Applicant has a parent company, it must submit the parent's 2011 Audited Financial Statement. If the parent's 2011 Audited Financial Statement is not available at the time of the submission of the application, the Applicant must submit the parent's 2010 Audited Financial Statement and the parent's 2011 Annual NAIC Health Blank or other form of quarterly financials if the NAIC Health Blank is not required by your State.

B. If the Applicant is not in compliance with all State requirements, the Applicant must upload in HPMS, in the MA Supporting Files Fiscal Soundness Upload Section, a document which details a discussion of the State's reasons for the increased oversight and measures the Applicant is undertaking to address the reasons for the increased oversight.

5.4. Licensure

A. For those Applicants that are licensed under State law as a risk-bearing entity eligible to offer health insurance or health benefits coverage in each State in which the Applicant proposes to offer the managed care product, upload in HPMS, in the MA Supporting Files State Licensure Upload Section, an executed copy of a State licensing certificate and the CMS State Certification Form for each State being requested.

B. For those Applicants that are currently under some type of supervision, corrective action plan or special monitoring by the State licensing authority in any State, upload in HPMS, in the MA Supporting Files State Licensure Upload Section, an explanation of the specific actions taken by the State licensing authority.

C. For those Applicants that are conducting business as "doing business as" (d/b/a) or use a name different than the name shown on its Articles of Incorporation, upload in HPMS in the MA Supporting Files State Licensure Upload Section a copy of the State approval for the d/b/a.

5.5. Partial County Service Area

A. Per the instructions in section 3.3B of this application, the Applicant must enter the State and county information for the area the Applicant proposes to serve. For those Applicants, that cannot meet the county integrity rule as outlined in Chapter 4 of the Medicare Managed Care Manual (MMCM) (https://www.cms.gov/manuals/downloads/mc86c04.pdf) and cannot serve the entire county, upload in HPMS, in the MA Supporting Files Service Area Upload Section, a document that mimics the Appendix entitled, *Partial County Justification*.

5.6. CMS Medical Provider Participation Contracts & Agreements

This section contains addresses the requirements of 42 CFR 422.504, which require that organizations have oversight for contractors, subcontractors, and other entities. The intent of the regulations is to ensure services provided by these parties meet contractual obligations, laws, regulations, and CMS instructions. The organization offering the capitated financial alignment demonstration plan is held responsible for the compliance of its providers and subcontractors with all contractual, legal, regulatory, and operational obligations. Beneficiaries shall be protected from payment or fees that are the obligation of the organization offering the capitated financial alignment demonstration plan. Further guidance is provided in Chapter 11 of the MMCM (https://www.cms.gov/manuals/downloads/mc86c11.pdf).

A. In HPMS, in the MA Supporting Files Provider Contracts & Agreements Upload Section, upload a template copy of each first tier provider contract(s) and/or agreement(s) between the Applicant and its health care contractors (i.e., direct contracts with physicians, medical groups, IPAs, PHOs, hospitals, skilled nursing facilities, etc.).

B. In HPMS, in the MA Supporting Files Provider Contracts & Agreements Upload Section, upload a template copy of each downstream subcontract that may exist between a Medical group(s), IPA(s), PHO(s), etc. and its downstream providers (e.g., individual physicians). (For example: If the Applicant contracts with an IPA, which contracts with individual physicians, the Applicant must provide in HPMS a sample copy of the contract/agreement between the IPA and physicians in addition to the contract between the Applicant and the IPA referenced in section B above).

C. In HPMS, in the MA Supporting Files Provider Contracts & Agreements Upload Section, upload a completed "CMS Medical Provider Contract Template Matrix", which is a crosswalk to show where in each provider contract/agreement template the referenced CMS regulations are included. Applicant should list each contracted (including sub-contracted) provider template on the matrix.

D. In HPMS, in the MA Supporting Files Provider Contracts & Agreements Upload Section, upon request, upload a completed "Contract Signature Page Sample Matrix", which is a document that must accompany the sample of contract signature pages that CMS will request during the application review process. **This document is not required for application submission; this document will be required for the readiness review that occurs after plan selection. Applicants will receive an email notification when this material is due to CMS.**

E. In HPMS, in the MA Supporting Files Provider Contracts & Agreements Upload Section, upload a completed "Contract and Signature Index-Providers", which is an index to link contracted primary care and specialty physicians listed in the *MA Provider Table* to the template contract(s) listed in the CMS Provider Contract Template and indicate which contract(s) execute the relationship between the applicant and the provider.

F. In HPMS, in the MA Supporting Files Provider Contracts & Agreements Upload Section, upload a completed "Contract and Signature Index-Facilities", which is an index to link contracted ancillary or hospital providers listed in the *MA Facility Table* to the template contract(s) listed in the CMS Provider Contract Template Matrix and indicate which contract(s) execute the official relationship between the applicant and the provider.

G. In HPMS, in the MA Supporting Files Provider Contracts & Agreements Upload Section, upload a completed "MA Signature Authority Grid", which is a grid to document whether physicians/practitioners of a contracted provider group are employees of the medical practice or under an alternate arrangement (e.g., medical practice partnership) through which another individual can sign on the provider's behalf. The grid should display the medical group, the person authorized to sign contracts on behalf of the group, and the roster of employed/partner physicians/practitioners of that group.

5.7. Contracts for Administrative & Management Services

This section describes the requirements the Applicant must demonstrate to ensure that any contracts for administrative/management services comply with the requirements of all Medicare laws, regulations, and CMS instructions in accordance with 42 CFR 422.504(i)(4)(v). Further guidance is provided in Chapter 11 of the MMCM (https://www.cms.gov/manuals/downloads/mc86c11.pdf).

A. Using the following pathway in HPMS: Contract Management>Basic Contract Management>Part C Data, complete the following Delegated Business Function Table.

First tier, Downstream and Related entities Function Chart

In HPMS, on the Contract Management/Part C and D Information/Part C 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 and whether the first tier, downstream and related entities	Function	First tier, Downstream and Related entities	Off-Shore yes/no
	Administrative/Management Staffing		
	Systems and/or Information Technology		
	Claims Administration, Processing and/or Adjudication		
	Enrollment, Disenrollment and Membership		

are off-shore: (Indicate with "name of Applicant's Organization" where applicant will perform those functions)	Marketing and/or Sales Brokers and Agents		
	Credentialing		
	Utilization and/or Quality Improvement Operations		
	Part C Call Center Operations		
	Financial Services		

Note: If the Applicant plans to delegate a specific function but cannot at this time name the entity with which the Applicant will contract, enter "Not Yet Determined" so that CMS is aware of the Applicant's plans to delegate that function. If the Applicant delegates a particular function to a number of different entities (e.g., claims processing to multiple medical groups), then list the five most significant entities for each delegated business function identified and in the list for the sixth, enter "Multiple Additional Entities".

B. In HPMS, in the MA Supporting Files – Contracts for Administrative & Management Services Section upload a completed CMS Administrative/Management Delegated Contracting or Arrangement Matrix.

C. In HPMS, in the MA Supporting Files – Contracts for Administrative & Management Services Section upload executed management contracts or letters of agreement for each contractor or subcontractor (first tier, downstream, and related entities).

6. MODEL OF CARE

Applicants should complete and upload in HPMS, in the HSD Tables --CMS Directed Upload section, a written narrative for the Model of Care based on the guidance in section I.G and Appendix 2 of the March 30, 2012 guidance. The written narrative must address, at a minimum the following clinical and non-clinical elements:

- Description of the Plan-specific Target Population
- Measurable Goals
- Staff Structure and Care Management Goals
- Interdisciplinary Care Team
- Provider Network having Specialized Expertise and Use of Clinical Practice Guidelines and Protocols
- MOC Training for Personnel and Provider Network
- Health Risk Assessment

- Individualized Care Plan
- Integrated Communication Network
- Care Management for the Most Vulnerable Subpopulations
- Performance and Health Outcomes Measurement

Our expectation is that the MOC narrative will be a unified document that accounts both for CMS' requirements (the 11 elements described above) and any additional requirements the State with which the Applicant intends to enter into a three-way contract wishes to include. Interested organizations should work with their respective States to ensure that they are aware of any State-specific requirements that must be included in their unified MOC narrative.

Applicants must also complete and upload the appropriate template found in HPMS that mimics the Appendix entitled, *Model of Care Matrix Upload Document*. In this document, Applicants will provide a crosswalk to a page number in their submitted written narrative MOC for each element in that MOC.

*Note – any additional State elements for the MOC will be collected through this application and reviewed by the State.

7. MEDICARE HEALTH SERVICE DELIVERY (HSD) 42 CFR §422.112, AND 422.114

A. In HPMS, in the HSD Tables section, upload the MA Provider Table and the MA Facility Table.

Applicants should review the *HSD Instructions for CY 2013 Applications* included in the capitated financial alignment demonstration templates. The instructions contain the information necessary to complete the HSD tables required for the online application process. It also contains frequently asked questions regarding the HSD submission, processing, guidance on developing valid addresses and field edits for the MA Provider and MA Facility tables.

Upload in HPMS, in the MA Supporting Files Part C Application Certification Section, upload in a .pdf format, the following certification:

8. MEDICARE MEDICAL BENEFIT CERTIFICATION

I, _____, attest to the following:

(NAME & TITLE)

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.

1. 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.
2. I agree that if my organization meets the minimum qualifications set forth in Sections 5-7 of this Application and is Medicare-approved with CMS, I will abide by the requirements contained in Sections 5-7 of this Application and provide the services outlined in my application.
3. 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 that preclude full compliance by January 1 of the upcoming contract year with the requirements stated here in this application as well as in Part 422 of 42 CFR of the regulation.
4. 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.
5. 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 capitated financial alignment demonstration contract with CMS and the respective State.
6. 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 application acknowledge that they will comply with such guidance,

as applicable, should they be approved for a capitated financial alignment demonstration contract.

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

9. APPENDICES

APPENDIX I --Organization Background and Structure

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

A. Legal Entity Background

Date Legal Entity Established: _____

State of Incorporation

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

B. Management of Legal Entity

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

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

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

C. Parent Organization Information

Name of Parent Organization

Date Parent Organization established

D. Organizational Charts

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

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

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

	ending on December 31 of the next year).	
3.1.1D7	Are signed by a representative of each party with legal authority to bind the entity.	
3.1.1D8	Language obligating the first tier, downstream, or related entity to abide by all applicable Federal laws and regulations and CMS instructions. 42 CFR §423.505(i)(4)(iv)	
3.1.1D9	Language obligating the first tier, downstream, or related entity to abide by State and Federal privacy and security requirements, including the confidentiality and security provisions stated in the regulations for the program at 42 CFR §423.136.	
3.1.1D10	Language ensuring that the first tier, downstream, or related entity will make its books and other records available in accordance with 42 CFR 423.505(e)(2) and 42 CFR 423.505(i)(2). Generally stated these regulations give HHS, the Comptroller General, or their designees the right to audit, evaluate and inspect any books, contracts, records, including medical records and documentation involving transactions related to CMS' contract with the Part D sponsor and that these rights continue for a period of 10 years from the final date of the contract period or the date of audit completion, whichever is later. 42 CFR §423.505	
3.1.1D11	Language stating that the first tier, downstream, or related entity will ensure that beneficiaries are not held liable for fees that are the responsibility of the Applicant. 42 CFR §423.505(i)(3)(i)	
3.1.1D12	Language ensuring that if the Applicant, upon becoming a Part D sponsor, delegates an activity or responsibility to the first tier, downstream, or related entity, that such activity or responsibility may be revoked if CMS or the Part D sponsor determines the first tier, downstream, or related entity has not performed satisfactorily. Note: The contract/administrative services agreement may include remedies in lieu of revocation to address this requirement. 42 CFR §423.505(i)(4)(ii)	
3.1.1D13	Language specifying that the Applicant, upon becoming a Part D sponsor, will monitor the performance of the first	

	tier, downstream, or related entity on an ongoing basis. 42 CFR §423.505(i)(4)(iii)	
3.1.1D14	Language that the Part D sponsor retains the right to approve, suspend, or terminate any arrangement with a pharmacy if the first tier, downstream, or related entity will establish the pharmacy network or select pharmacies to be included in the network. 42 CFR §423.505(i)(5)	
3.1.1D15	Language that if the first tier, downstream, or related entity will establish the pharmacy network or select pharmacies to be included in the network contain language that payment to such pharmacies (excluding long-term care and mail order) shall be issued, mailed, or otherwise transmitted with respect to all clean claims submitted by or on behalf of pharmacies within 14 days for electronic claims and within 30 days for claims submitted otherwise. 42 CFR §423.505(i)(3)(vi)	
3.1.1D16	Language that if the first tier, downstream, or related entity will establish the pharmacy network or select pharmacies to be included in the network and a prescription drug pricing standard is used for reimbursement identifies the source used by the Part D sponsor for the prescription drug pricing standard of reimbursement. 42 CFR §423.505(i)(3)(viii)(B)	
3.1.1D17	If the first tier, downstream, or related entity will establish the pharmacy network or select pharmacies to be included in the network and a prescription drug pricing standard is used for reimbursement, a provision requiring that updates to such a standard occur not less frequently than once every 7 days beginning with an initial update on January 1 of each year, to accurately reflect the market price of acquiring the drug. 42 CFR §423.505(i)(3)(viii)(A)	
3.1.1D18	If the first tier, downstream, or related entity will establish the pharmacy network or select pharmacies to be included in the network, language requiring the network pharmacies to submit claims to the Part D sponsor or first tier, downstream or related entity whenever the membership ID card is presented or on file at the pharmacy unless the enrollee expressly requests that a particular claim not be submitted. 42 CFR §423.120(c)(3)	

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

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

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

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

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

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

3.4A3	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 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, and describes the reporting requirements the first tier, downstream, or related entity identified in Section 3.1.1C of the application has to the Applicant. 42 CFR §423.505(i)(4)(i)	
3.1.1D8	Language obligating the first tier, downstream, or related entity to abide by all applicable Federal laws and regulations and CMS instructions. 42 CFR §423.505(i)(4)(iv)	
3.1.1D9	Language obligating the first tier, downstream, or related entity to abide by State and Federal privacy and security requirements, including the confidentiality and security provisions stated in the regulations for the program at 42 CFR §423.136.	
3.1.1D10	Language ensuring that the first tier, downstream, or related entity will make its books and other records available in accordance with 42 CFR 423.505(e)(2) and 42 CFR 423.505(i)(2). Generally stated these regulations give HHS, the Comptroller General, or their designees the right to audit, evaluate and inspect any books, contracts, records, including medical records and documentation involving transactions related to CMS' contract with the Part D sponsor and that these rights continue for a period of 10 years from the final date of the contract period or the date of audit	

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

	or related entity whenever the membership ID card is presented or on file at the pharmacy unless the enrollee expressly requests that a particular claim not be submitted. 42 CFR §423.120(c)(3)	
3.4A3	Provisions governing submitting claims to a real-time claims adjudication system. 42 CFR §423.505(j) and §423.505(b)(17) Note: Applicant may indicate for I/T/U pharmacies and for certain pharmacies that are allowed to submit claims in the X 12 format that these may be batch processed.	
3.4A4	Provisions governing providing Part D enrollees access to negotiated prices as defined in 42 CFR 423.100. 42 CFR §423.104(g)	
3.4A5	Provisions regarding charging/applying the correct cost-sharing amount. 42 CFR §423.104	
3.4A6	Provisions governing informing the Part D enrollee at the point of sale (or at the point of delivery for mail order drugs) of the lowest-priced, generically equivalent drug, if one exists for the beneficiary's prescription, as well as any associated differential in price. 42 CFR §423.132	
3.4.4A5	Provisions ensuring that before dispensing home infusion drugs, pharmacy ensures that the professional services and ancillary supplies are in place.423.120(a)(4)(iii)	
3.4.4A6	Provisions ensuring that a pharmacy that delivers home infusion drugs provides delivery of home infusion drugs within 24 hours of discharge from an acute care setting, or later if so prescribed. 423.120(a)(4)(iv)	

APPENDIX VI – 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 identify where specifically (i.e., the .pdf page number) in each contract template the following elements are found.

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

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

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

3.4A5	Provisions regarding charging/applying the correct cost-sharing amount. 42 CFR §423.104	
3.4A6	Provisions governing informing the Part D enrollee at the point of sale (or at the point of delivery for mail order drugs) of the lowest-priced, generically equivalent drug, if one exists for the beneficiary's prescription, as well as any associated differential in price. 42 CFR §423.132	
	Provide that long-term care pharmacies must have not less than 30 days, nor more than 90 days, to submit to the Part D Sponsor claims for reimbursement under the plan. 42 CFR § 423.504(b)(20)	
	Provisions requiring that long-term care pharmacies dispense drugs and report information as required by 42 CFR §423.154.	
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 must, at a minimum, incorporate these criteria in ALL LTC pharmacy network contracts.		
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 is proficient in the NLTCP's processes for ordering and receiving of medications. NLTCP must be responsible for return and/or disposal of unused medications following discontinuance, transfer, discharge, or death as permitted by State Boards of Pharmacy. Controlled substances and out of date substances must be disposed of within State and Federal guidelines.	
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 VII – Crosswalk for Indian Tribe and Tribal Organization, and Urban Indian Organization (I/T/U) Pharmacy Access Contracts

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

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

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

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

3.4A3	Provisions governing submitting claims to a real-time claims adjudication system. 42 CFR §423.505(j) and §423.505(b)(17) Note: Applicant may indicate for I/T/U pharmacies and for certain pharmacies that are allowed to submit claims in the X 12 format that these may be batch processed.	
3.4A4	Provisions governing providing Part D enrollees access to negotiated prices as defined in 42 CFR 423.100. 42 CFR §423.104(g)	
3.4A5	Provisions regarding charging/applying the correct cost-sharing amount. 42 CFR §423.104	
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 at Appendix X and at** http://www.cms.gov/PrescriptionDrugCovContra/04_RxContracting_ApplicationGuidance.asp **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 VIII – Applicant Submission of P&T Committee Member List and Certification Statement

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

I. P&T Committee Member Disclosure to CMS

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

In the event the Part D Applicant/Sponsor has entered into a 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.

II. Instructions to Plans and PBMs

A. If the Part D Applicant sub-contracts with a PBM for its P&T Committee and operates under a Confidentiality Agreement (such that its members are not disclosed to the Part D Applicant) then the Applicant must (1) complete the attached Certification in HPMS, and (2) forward the attached P&T Committee Member Disclosure form to the sub-contracted PBM and direct the PBM to submit the form to CMS by February 21, 2012. The PBM should email the P&T Committee Member Disclosure form to the following email box: drugbenefitimpl@cms.hhs.gov.

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 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. In the case of a Part D Sponsor utilizing its PBM's confidential P&T Committee, the Part D Sponsor is responsible for assuring the PBM completes the Pharmacy and Therapeutics Committee Member Disclosure form, and emails it to drugbenefitimpl@cms.hhs.gov within 30 days of the effective date of the change.

III. PHARMACY AND THERAPEUTICS COMMITTEE MEMBER DISCLOSURE

PBM must email the following form to drugbenefitimpl@cms.hhs.gov by February 21, 2012.

Name of Part D Plan or PBM: _____
If Part D Plan, provide Part D Contract number(s):_____
Contact Person: _____
Phone Number: _____
Email: _____

A. Complete the table below.

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

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

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

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

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

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

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

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

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

Part D Applicant's Contract Number: _____

_____ _____

Authorized Representative Name (printed) Title

_____ _____

Authorized Representative Signature Date (MM/DD/YYYY)

APPENDIX IX – I/T/U Revised Addendum

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

Indian Health Addendum to Medicare Part D Plan Agreement

1. Purpose of Indian Health Addendum; Supersession.

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

2. Definitions.

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

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

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

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

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

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

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

(g) The term "tribal organization" has the meaning given than term in Sec. 4 of the 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 an IHS Provider operates more than one pharmacy or dispensary all such pharmacies and dispensaries are covered by this Addendum.

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

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

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

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

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

5. Persons eligible for services of Provider.

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

may provide services to non-IHS eligible persons only under certain circumstances set forth in IHCIA section 813(c) and in emergencies under section 813(d) 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 CFR Part 423;

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

(3) 42 CFR Part 136; and

(4) The terms of the contract, compact or grant issued to the Provider by the IHS for operation of a health program.

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

6. Applicability of other Federal laws.

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

(a) An IHS provider:

(1) The Anti-Deficiency Act 31 U.S.C. § 1341;

(2) The Indian Self Determination and Education Assistance Act ("ISDEAA"); 25 USC § 450 *et seq.;*

(3) The Federal Tort Claims Act ("FTCA"), 28 U.S.C. § 2671-2680;

(4) The Federal Medical Care Recovery Act, 42 U.S.C. §§ 2651-2653;

(5) The Federal Privacy Act of 1974 ("Privacy Act"), 5 U.S.C. § 552a, 45 CFR Part 5b;

(6) Confidentiality of Alcohol and Drug Abuse Patient Records, 42 CFR Part 2;

(7) The Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), 45 CFR Parts 160 and 164; and

(8) The 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;

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

(6) Sec. 206(e)(3) of the IHCIA, 25 USC § 1624e(e)(3), regarding recovery from tortfeasors.

(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; and

(4) Sec. 206(e)(3) of the IHCIA, 25 USC §1621e(e)(3), regarding recovery from tortfeasors, as made applicable to urban Indian organizations by Sec. 206(i) of the IHCIA.

7. Non-taxable entity.

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

8. Insurance and indemnification.

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

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

9. Licensure.

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

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

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

10. Provider eligibility for payments.

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

11. Dispute Resolution.

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

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

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

12. Governing Law.

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

13. Pharmacy/Dispensary Participation.

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

14. Acquisition of Pharmaceuticals.

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

15. Drug Utilization Review/Generic Equivalent Substitution.

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

16. Claims.

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

17. Payment Rate.

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

18. Information, Outreach, and Enrollment Materials.

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

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

19. Hours of Service.

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

20. Endorsement

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

21. Sovereign Immunity

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

Signature of Authorized Representative	Printed Name of Authorized Representative
Title of Authorized Representative	

APPENDIX X – Compliance Program Crosswalk

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

first tier, downstream or related entity.	
2. The compliance officer and the compliance committee must periodically report directly to the governing body of the MA applicant on the activities and status of the compliance program, including issues identified, investigated, and resolved by the compliance program.	
3. The governing body of the MA applicant must be knowledgeable about the content and operation of the compliance program and must exercise reasonable oversight with respect to the implementation and effectiveness of the compliance programs.	
C. Establish, implement and provide effective training and education for employees including the chief executive and senior administrators or managers, governing body members, first tier, downstream, and related entities must include the following components:	**§ 423.504(b)(4)(vi)(C)**
1. Training and education must occur at least annually and must be part of the orientation for new employees, new first tier, downstream and related entities, and new appointments to chief executive, senior administrator, or governing body member.	
2. An indication that first tier, downstream, and related entities who have met the fraud, waste, and abuse certification requirements through enrollment into the Medicare program or accreditation as a Durable Medical Equipment, Prosthetics, Orthotics, and supplies (DMEPOS) are deemed to have met the training and educational requirements for fraud, waste, and abuse.	
D. Establishment and implementation of effective lines of communication, ensuring confidentiality, between:	**§ 423.504(b)(4)(vi)(D)**
1. The compliance officer, members of the compliance committee, the MA applicant's employees, managers and governing body.	
2. The MA applicant's first tier, downstream, and related entities.	
3. Such lines of communication must be accessible to all.	
4. Allow compliance issues to be reported, including a method for anonymous and confidential good faith reporting of potential compliance issues, as they are identified.	
E. Well-publicize disciplinary standards and implementation of procedures, which encourage good faith participation in the	**§ 423.504(b)(4)(vi)(E)**

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

APPENDIX XI – History/Structure/Organizational Charts

Note: CMS REQUESTS THAT YOU LIMIT THIS DOCUMENT TO EIGHT (8) PAGES.

SECTION 1: All Applicants must complete this section.

1. Attach resumes of all key personnel.

2. Attach a diagram of the Applicant's relation to its subsidiaries, as well as its business affiliations.

SECTION II: All Applicants must complete this section.

1. Please provide the date of the company's last financial audit.

2. What were the results of that audit?

3. Briefly describe the financial status of the Applicant's company.

4. Briefly explain the Applicant's marketing philosophy.

5. Who in the Applicant's organization can appoint and remove the executive manager?

6. Please submit a brief description and/or a flow chart of the Applicant's claims processing systems and operations.

7. Please submit a brief description and/or flow chart of the Applicant's grievances process.

8. Please provide a brief description and flow chart of the Applicant's appeals process.

9. If applicable, please provide the name of the claims systems that Applicant tested to demonstrate the systems' ability to pay Medicare FFS payments.

APPENDIX XII – CMS State Certification Form

INSTRUCTIONS

(Capitated Financial Alignment Demonstration State Certification Form)

General:

This form is required to be submitted with all capitated financial alignment demonstration applications. The Applicant is required to complete the items above the line (items 1 - 3), then forward the document to the appropriate State Agency Official who should complete those items below the line (items 4-7). After completion, the State Agency Official should return this document to the Applicant organization for submission to CMS as part of its application for a capitated financial alignment demonstration contract.

The questions provided must be answered completely. If additional space is needed to respond to the questions, please add pages as necessary. Provide additional information whenever you believe further explanation will clarify the response.

The State Certification Form demonstrates to CMS that the capitated financial alignment demonstration contract being sought by the Applicant organization is within the scope of the license granted by the appropriate State regulatory agency, that the organization meets state solvency requirements and that it is authorized to bear risk. A determination on the organization's capitated financial alignment demonstration application will be based upon the organization's entire application that was submitted to CMS, including documentation of appropriate licensure.

Items 1 - 3 (to be completed by the Applicant):

1. List the name, d/b/a (if applicable) and complete address of the organization that is seeking to enter into the capitated financial alignment demonstration contract with CMS.
2. Indicate the type of license (if any) the Applicant organization currently holds in the State where the Applicant organization is applying to offer a capitated financial alignment demonstration contract.
3. Specify the type of capitated financial alignment demonstration contract the Applicant organization is seeking to enter into with CMS and the respective State.

New Federal Preemption Authority – The Medicare Modernization Act amended section 1856(b)(3) of the SSA to significantly broaden the scope of Federal preemption of State laws governing plans serving Medicare beneficiaries. Current law provides that the

provisions of Title XVIII of the SSA supersede State laws or regulations, other than laws relating to licensure or plan solvency, with respect to MA plans.

Items 4 - 7 (to be completed by State Official):

4. List the reviewer's pertinent information in the event CMS needs to communicate with the individual conducting the review at the State level.
5. List the requested information regarding other State departments/agencies required to review requests for licensure.
6. A. Circle where appropriate to indicate whether the Applicant meets State financial solvency requirements.

   B. Indicate State Agency or Division, including contact name and complete address, that is responsible for assessing whether the Applicant meets State financial solvency requirements.
7. A. Circle where appropriate to indicate whether the Applicant meets State licensure requirements.

   B. Indicate State Agency or Division, including contact name and complete address, that is responsible for assessing whether the Applicant meets State licensing requirements.

CAPTITATED FINANCIAL ALIGNMENT DEMONSTRATION
STATE CERTIFICATION REQUEST

Applicants should complete items 1-3.

1. Applicant Information (Organization that has applied for capitated financial alignment demonstration MA contract):

   Name
   _____

   D/B/A (if applicable)
   _____

   Address
   _____

   City/State/Zip
   _____

2. Type of State license or Certificate of Authority currently held by referenced Applicant: (Circle more than one if entity holds multiple licenses)

   ● HMO ● PSO ● PPO ● Indemnity ● Other _____

   Comments:

3. Type of MA application filed by the Applicant with the Centers for Medicare & Medicaid Services (CMS): (Circle all that are appropriate)

   ● HMO ● PPO

   Requested Service Area:
   _____

I certify that _____’s application to CMS is for the type of capitated financial alignment demonstration plan(s) and the service area(s) indicated above in questions 1-3.

_____

Applicant

_____ _____

Date CEO/CFO Signature

_____

Title

(An appropriate State official must complete items 4-7.)

Please note that under section 1856(b)(3) of the SSA and 42 CFR 422.402, other than laws related to State licensure or solvency requirements, the provisions of title XVIII of the SSA preempt State laws with respect to capitated financial alignment demonstration plans.

4. State official reviewing State Certification Request:

   Reviewer's Name: _____

   State Oversight/Compliance Officer: _____

   Agency Name: _____

   Address: _____

   Address: _____

   City/State: _____

   Telephone: _____

   E-Mail Address: _____

5. Name of other State agencies (if any) whose approval is required for licensure:

   Agency: _____

   Contact Person: _____

   Address: _____

   City/State: _____

   Telephone: _____

   E-Mail Address: _____

6. Financial Solvency:

   Does the Applicant organization named in item 1 above meet State financial solvency requirements? (Please circle the correct response)

   ● Yes ● No

   Please indicate which State Agency or Division is responsible for assessing whether the named Applicant organization meets State financial solvency requirements.

7. State Licensure:

   Does the Applicant organization named in item 1 above meet State Licensure requirements? (Please circle the correct response)

   ● Yes ● No

   Please indicate which State Agency or Division is responsible for assessing whether this organization meets State licensure requirements.

   _____

State Certification

I hereby certify to the Centers for Medicare & Medicaid Services (CMS) that the above organization (doing business as (d/b/a) _____) is:

(Check one)

_____ licensed in the State of _____ as a risk bearing entity, or

_____ authorized to operate as a risk bearing entity in the State of _____

And

(Check one)

_____ is in compliance with State solvency requirements, or

_____ State solvency requirement not applicable [please explain below].

By signing the certification, the State of _____ is certifying that the organization is licensed and/or that the organization is authorized to bear the risk associated with the capitated financial alignment demonstration product circled in item 3 above. The State is not being asked to verify plan eligibility for the Medicare managed care products(s) or CMS contract type(s) requested by the organization, but merely to certify to the requested information based on the representation by the organization named above.

_____
Agency

_____ _____
Date Signature

_____
Title

APPENDIX XIII -- CMS Medical Provider Contract Template Matrix

Instructions for CMS Medical Provider Contract Template Matrix

This matrix must be completed by Applicants and should be used to indicate the location of the Medicare requirements in each template contract / agreement for the Applicant's first tier, downstream and related entity providers providing medical services. The applicant must match the templates listed in this matrix to the actual providers / facilities (by name) by completing the CMS MA Contract & Signature Indices for Facilities and Providers elsewhere in this application.

Instructions:

1. Upload in the HPMS, in the MA Supporting Files Provider Contracts & Agreements, using a PDF format, a separate matrix for each county or partial county.

2. Enter the name of the contract template (e.g., inpatient hospital, primary care physician, etc.) for each provider(s)/group(s) or entity with which the Applicant contracts to provide medical services to Medicare enrollees, including all first tier, downstream and related entity providers. In the instance that a provider's contract does not match a template or any other provider's contract, you may enter the provider's name as the template name in the column heading and indicate "no template" to show that the contract does not match any submitted templates.

3. Designate if the template applies to a first tier contracted medical provider with a "(1)" next to the name of that template agreement.

4. Designate downstream contract templates for provider(s), group(s), or other entity with a "(DS)".

5. In each column, list the page number where the provision that meets the regulatory requirement can be found in each of the contracts / agreements templates listed.

Note: This matrix contains a brief description of Medicare medical benefit regulatory requirements; please refer to full regulatory citations for an appropriate response.

CMS Medical Provider Contracts Template Matrix

COUNTY:_____

IPA/Group/Provider Contract Template Name **(e.g., Medical Group (1);, Primary Care Physician (DS))**					
CMS REGULATIONS – 42 CFR 422•	**Section/Page**	**Section/Page**	**Section/Page**	**Section/Page**	**Section/Page**
All Medical Provider Contracts					
Record Retention HHS, the Comptroller General or their designees have the right to audit, evaluate and inspect any pertinent information including books, contracts, records, including medical records, and documentation related to CMS' contract with the MAO for a period of 10 years from the final date of the contract period or the completion of any audit, whichever is later. 422.504(i)(2)(i) and (ii)					
Privacy and Accuracy of Records Providers and suppliers agree to safeguard beneficiary privacy and confidentiality and ensure the accuracy of beneficiary health records.					

• In addition to the CFR citations provided above, the following contract provisions are required in agreements between MAOs and provider and suppliers of health care as stated in Chapter 11, section 100.4, of the MMCM .

IPA/Group/Provider Contract Template Name **(e.g., Medical Group (1);, Primary Care Physician (DS))**					
CMS REGULATIONS – 42 CFR 422•	**Section/Page**	**Section/Page**	**Section/Page**	**Section/Page**	**Section/Page**
422.504(a)13					
Hold Harmless Providers may not hold beneficiaries liable for payment of fees that are the legal obligation of the MAO. 422.504(g)(1)(i); 422.504(i)(3)(i)					
Hold Harmless for MAs offering plans with dual eligible enrollees For all MAOs with enrollees eligible for both Medicare and Medicaid, specify in contracts with providers that such enrollees will not be held liable for Medicare Part A and B cost sharing when the State is responsible for paying such amounts, and inform providers of Medicare and Medicaid benefits and rules for enrollees eligible for Medicare and Medicaid. The MA plans may not impose cost-sharing that exceeds the amount of cost-sharing that would be permitted with respect to the individual under title XIX if the individual were not enrolled in such a plan. The contracts must state that providers will – (A) Accept the MA plan payment as payment in full, or (B) Bill the appropriate State source." 422.504(g)(1)(iii)					
Compliance with MAO's contractual obligations					

IPA/Group/Provider Contract Template Name **(e.g., Medical Group (1);, Primary Care Physician (DS))**					
CMS REGULATIONS – 42 CFR 422•	**Section/Page**	**Section/Page**	**Section/Page**	**Section/Page**	**Section/Page**
A provision requiring that any services or other activity performed by a first tier, downstream, or related entity in accordance with a contract or written agreement are consistent and comply with the MAO's contractual obligations. 422.504(i)(3)(iii)					
<u>Prompt Payment</u> The agreement specifies a prompt payment requirement, the terms and conditions of which are developed and agreed to by the MAO and contracted providers and suppliers. 422.520(b)					
<u>Delegated Activities: Selection of Providers</u> If the MAO delegates a selection of providers, written arrangements must state the MAO retains the right to approve, suspend, or terminate such arrangement. 422.504(i)(5)					
<u>Delegated Activities – List of Delegated Activities and Reporting Responsibilities</u> The contract must clearly state the delegated activities and reporting					

IPA/Group/Provider Contract Template Name **(e.g., Medical Group (1);, Primary Care Physician (DS))**					
CMS REGULATIONS – 42 CFR 422•	**Section/Page**	**Section/Page**	**Section/Page**	**Section/Page**	**Section/Page**
responsibilities. 422.504(i)(4)(i)					
Delegated Activities – Revocation Agreement provides for the revocation of the delegated activities and reporting requirements or specifies other remedies in instances when CMS or the MAO determines that such parties have not performed satisfactorily. 422.504(i)(4)(ii)					
Delegated Activities – Monitoring Agreement provides that the performance of the parties is monitored by the MAO on an ongoing basis. 422.504(i)(4)(iii)					
Delegated Activities - Credentialing The credentials of medical professionals affiliated with the party or parties will either be reviewed by the MAO OR the credentialing process will be reviewed and approved by the MAO and the MAO must audit the credentialing process on an ongoing basis. 422.504(i)(4)(iv)					

IPA/Group/Provider Contract Template Name **(e.g., Medical Group (1);, Primary Care Physician (DS))**					
CMS REGULATIONS – 42 CFR 422•	**Section/Page**	**Section/Page**	**Section/Page**	**Section/Page**	**Section/Page**
<u>Compliance with A-applicable Medicare Laws and Regulations</u> Must comply with all applicable Medicare laws, regulations, and CMS instructions. 422.504(i)(4)(v)					
Date and Signature Line					

APPENDIX XIV -- CMS Contract Signature Page Sample Matrix

Instructions: The applicant must submit a completed CMS Contract Signature Page Sample Matrix to accompany the sample of medical provider/facility contract signature pages requested by CMS. It is CMS' expectation that each contract requested in this sample matches up with a template already submitted to CMS in the initial application submission. If this is not the case, the applicant must indicate "NO" in the column titled "Contract Template Already Submitted" and upload the template contract and Matrix along with the signature page sample request. Add rows as necessary.

Contract Number:							
Organization Name:							
Date Submitted:							

	Name of Medical Provider / Physician (IPA Medical Group)	Type of Medical Provider / Specialty	Name of Signatory to Contract (If different from column B, explain in Comments column)	Date Contract Signed	Term of Contract	Name of Medical Provider's / Physician's Contract Template	Contract Template Already Submitted in Application? (YES / NO) If NO, submit Medical Provider / Physician Contract and Accompanying Matrix-1	Comments (e.g., Explain if no medical provider contract, signatory different from provider, relationship between applicant and provider, etc.)
1								
2								
3								
4								
5								

Appendix XV – CMS MA Contract Index – Medical Providers

The purpose of this index is to link contracted primary care and specialty physicians listed in the *MA Medical Provider Table* to the template contract(s) listed in the CMS Medical Provider Contract Template Matrix and indicate which contract(s) execute the relationship between the applicant and the medical provider.

Column Explanations:

A. PCP/Specialist – Enter the contracted provider's name as indicated in the CMS MA Medical Provider Table for all contracted PCPs and specialists.

B – D. Contract Template – Enter the names of the templates (currently listed as A, B, C, etc.) that you entered on the CMS Template Medical Provider Contract Matrix. Indicate the specific contract template(s) executed between the applicant and the physician reflected in the PCP/Specialist column. For direct contracted physicians, the applicant must list and indicate a single template. For a physician affiliated with an IPA or medical group whose contracted relationship with the applicant is downstream, the applicant must list and indicate the first tier template contract as well as all downstream template contracts.

PCP / Specialist/ Medical Group	Contract Templates			
	Template A	Template B	Template C	Template D

Appendix XVI – CMS MA Contract Index – Facilities

The purpose of this index is to link contracted ancillary or hospital providers listed in the *MA Facility Table* to the template contract(s) listed in the CMS Medical Provider Contract Template Matrix and indicate which contract(s) execute the official relationship between the applicant and the provider.

Column Explanations:

A. Ancillary/Hospital – Enter the contracted medical provider/facility name as indicated in the *MA Facility Table* for all ancillary and hospital contracts.

B – E. Contract Template – Enter the names of the templates (currently listed as A, B, C, etc.) that you entered on the CMS Template Medical Provider Contract Matrix. Indicate the specific contract template(s) executed between the applicant and the facility reflected in the Ancillary / Hospital column.

Ancillary / Hospital	Contract Templates			
	Template A	Template B	Template C	Template D

Appendix XVII – CMS MA Signature Authority Grid

The purpose of this grid is to document whether physicians/practitioners of a contracted provider group are employees of the medical practice or under an alternate arrangement (e.g., medical practice partnership) through which another individual can sign on the medical provider's behalf. The grid should display the medical group, the person authorized to sign contracts on behalf of the group, and the roster of employed/partner physicians/practitioners of that group.

Column Explanations:

A. **Practice Name** – The name of the provider group for which a single signature authority exists on behalf of the group.

B. **Signature Authority** – The representative of the medical practice with authority to execute arrangements on behalf of the group.

C. **Physicians –** List all of the physicians/practitioners on the MA Medical Provider Table for which the signature authority is applicable.

CMS MA SIGNATURE AUTHORITY GRID		
PRACTICE NAME	SIGNATURE AUTHORITY	PHYSICIANS/PRACTITIONER

Appendix XVIII – CMS Administrative/ Management Delegated Contracting Matrix

Administrative Contracting Requirements for Management/Delegation of Contracts and/or Agreements

(For contracts and/or agreements that directly relate to MAO's core functions under its contract with CMS – see Section 5.7 of the Capitated Financial Alignment Demonstration Application)

NAME OF CONTRACTOR (FIRST TIER, DOWNSTREAM and RELATED ENTITY)					
CMS REGULATIONS – 42 CFR 422•	**Section/Page**	**Section/Page**	**Section/Page**	**Section/Page**	**Section/Page**
Record Retention HHS, the Comptroller General or their designees have the right to audit, evaluate and inspect any pertinent information including books, contracts, records, including medical records, and documentation related to CMS' contract with the MAO for a period of 10 years from the final date of the contract period or the completion of any audit, whichever is later. 422.504(i)(2)(i) and (ii)					

• In addition to the CFR citations provided above, the following contract provisions are required in agreements between MAOs and provider and suppliers of health care as stated in Chapter 11, section 100.4 of the MMCM.

NAME OF CONTRACTOR (FIRST TIER, DOWNSTREAM and RELATED ENTITY)					
CMS REGULATIONS – 42 CFR 422•	**Section/Page**	**Section/Page**	**Section/Page**	**Section/Page**	**Section/Page**
Privacy and Accuracy of Records Providers and suppliers agree to safeguard beneficiary privacy and confidentiality and ensure the accuracy of beneficiary health records. 422.504(a)13					
Hold Harmless Providers may not hold beneficiaries liable for payment of fees that are the legal obligation of the MAO. 422.504(g)(1)(i); 422.504(i)(3)(i)					
Delegated Activities: Compliance with MAO's contractual obligations A provision requiring that any services performed will be consistent and comply with the MAO's contractual obligations. 422.504(i)(3)(iii)					
Delegated Activities: Selection of Providers If the MAO delegates the selection of providers, written arrangements must state the MAO retains the right to approve,					

NAME OF CONTRACTOR (FIRST TIER, DOWNSTREAM and RELATED ENTITY)					
CMS REGULATIONS – 42 CFR 422•	**Section/Page**	**Section/Page**	**Section/Page**	**Section/Page**	**Section/Page**
suspend, or terminate such arrangement. 422.504(i)(5)					
Delegated Activities: List of Delegated Activities and Reporting Responsibilities The contract must clearly state the delegated activities and reporting responsibilities. 422.504(i)(4)(i)					
Delegated Activities: Revocation Agreement provides for the revocation of the delegated activities and reporting requirements or specifies other remedies in instances when CMS or the MAO determines that such parties have not performed satisfactorily. 422.504(i)(3)(ii); 422.504(i)(4)(ii)					
Delegated Activities: Monitoring Agreement provides that the performance of the parties is monitored by the MAO on an ongoing basis. 422.504(i)(3)(ii); 422.504(i)(4)(iii)					

NAME OF CONTRACTOR (FIRST TIER, DOWNSTREAM and RELATED ENTITY)					
CMS REGULATIONS – 42 CFR 422•	**Section/Page**	**Section/Page**	**Section/Page**	**Section/Page**	**Section/Page**
Delegated Activities: Credentialing The credentials of medical professionals affiliated with the party or parties will either be reviewed by the MAO OR the credentialing process will be reviewed and approved by the MAO; and the MAO must audit the credentialing process on an ongoing basis. 422.504(i)(4)(iv)(A)(B)					
Compliance with Applicable Medicare Laws and Regulations Must comply with all applicable Medicare laws, regulations, and CMS instructions. 422.504(i)(4)(v)					
Dated and Signed					

Appendix XIX – Model of Care Matrix Upload Document

Please complete and upload this document into HPMS, in the HSD Tables - CMS Directed Upload section.

2013 Capitated Financial Alignment Demonstration Plan Model of Care Matrix Upload Document

Applicant's Contract Name (as provided in HPMS)

Enter contract name here.

Applicant's CMS Contract Number

Enter contract number here.

Care Management Plan Outlining the Model of Care

In the following table, list the document, page number, and section of the corresponding description in your care management plan for each model of care element.

Model of Care Elements	Corresponding Document Page Number/Section
1. Description of the plan-specific Target Population (based on target population of full duals as defined by the State)	
2. Measurable Goals a. Describe the specific goals including: • Improving access to essential services such as medical, mental health, and social services • Improving access to affordable care • Improving coordination of care through an identified point of contact (e.g., gatekeeper) • Improving seamless transitions of care across healthcare settings, providers, and health services • Improving access to preventive health services • Assuring appropriate utilization of services • Improving beneficiary health outcomes (specify organization selected health outcome measures) b. Describe the goals as measurable outcomes and indicate how the organization will know when goals are met c. Discuss actions the organization will take if goals are not met in the	

expected time frame	
3. Staff Structure and Care Management Roles a. Identify the specific employed or contracted staff to perform **administrative** functions (e.g., process enrollments, verify eligibility, process claims, etc.) b. Identify the specific employed or contracted staff to perform **clinical** functions (e.g., coordinate care management, provide clinical care, educate beneficiaries on self-management techniques, consult on pharmacy issues, counsel on drug dependence rehab strategies, etc.) c. Identify the specific employed or contracted staff to perform **administrative and clinical oversight** functions (e.g., verifies licensing and competency, reviews encounter data for appropriateness and timeliness of services, reviews pharmacy claims and utilization data for appropriateness, assures provider use of clinical practice guidelines, etc.)	
4. Interdisciplinary Care Team (ICT) a. Describe the composition of the ICT and how the organization determined the membership b. Describe how the organization will facilitate the participation of the beneficiary whenever feasible c. Describe how the ICT will operate and communicate (e.g., frequency of meetings, documentation of proceedings and retention of records, notification about ICT meetings, dissemination of ICT reports to all stakeholders, etc.)	
5. Provider Network having Specialized Expertise and Use of Clinical Practice Guidelines and Protocols a. Describe the specialized expertise in the organization's provider network that corresponds to the target population including facilities and providers (e.g., medical specialists, mental health specialists, dialysis facilities, specialty outpatient clinics, etc.) b. Describe how the organization determined that its network facilities and providers were actively licensed and competent c. Describe who determines which services beneficiaries will receive (e.g., is there a gatekeeper, and if not, how is the beneficiary connected to the appropriate service provider, etc.) d. Describe how the provider network coordinates with the ICT and the beneficiary to deliver specialized services (e.g., how care needs are communicated to all stakeholders, which personnel assures follow-up is scheduled and performed, how it assures that specialized services are delivered to the beneficiary in a timely and quality way, how reports on services delivered are shared with the plan and ICT for maintenance of a complete beneficiary record and incorporation into the care plan, how services are delivered across care settings and providers, etc.) e. Describe how the organization assures that providers use evidence-based clinical practice guidelines and nationally recognized protocols (e.g., review of medical records, pharmacy records, medical specialist reports, audio/video-conferencing to discuss protocols and clinical guidelines, written protocols providers send to the organization's Medical Director for	

review, etc.)	
6. Model of Care Training for Personnel and Provider Network a. Describe how the organization conducted initial and annual model of care training including training strategies and content (e.g., printed instructional materials, face-to-face training, web-based instruction, audio/video-conferencing, etc.) b. Describe how the organization assures and documents completion of training by the employed and contracted personnel (e.g., attendee lists, results of testing, web-based attendance confirmation, electronic training record, etc.) c. Describe who the organization identified as personnel responsible for oversight of the model of care training d. Describe what actions the organization will take when the required model of care training has not been completed (e.g., contract evaluation mechanism, follow-up communication to personnel/providers, incentives for training completion, etc.)	
7. Health Risk Assessment a. Describe the health risk assessment tool the organization uses to identify the specialized needs of its beneficiaries (e.g., identifies medical, psychosocial, functional, and cognitive needs, medical and mental health history, etc.) b. Describe when and how the initial health risk assessment and annual reassessment is conducted for each beneficiary (e.g., initial assessment within 90 days of enrollment, annual reassessment within one year of last assessment; conducted by phone interview, face-to-face, written form completed by beneficiary, etc.) c. Describe the personnel who review, analyze, and stratify health care needs (e.g., professionally knowledgeable and credentialed such as physicians, nurses, restorative therapist, pharmacist, psychologist, etc.) d. Describe the communication mechanism the organization institutes to notify the ICT, provider network, beneficiaries, etc. about the health risk assessment and stratification results (e.g., written notification, secure electronic record, etc.)	
8. Individualized Care Plan a. Describe which personnel develops the individualized plan of care and how the beneficiary is involved in its development as feasible b. Describe the essential elements incorporated in the plan of care (e.g., results of health risk assessment, goals/objectives, specific services and benefits, outcome measures, preferences for care, add-on benefits and services for vulnerable beneficiaries such as disabled or those near the end-of-life, etc) c. Describe the personnel who review the care plan and how frequently the plan of care is reviewed and revised (e.g., developed by the interdisciplinary care team (ICT), beneficiary whenever feasible, and other pertinent specialists required by the beneficiary's health needs; reviewed and revised	

annually and as a change in health status is identified, etc.) d. Describe how the plan of care is documented and where the documentation is maintained (e.g., accessible to interdisciplinary team, provider network, and beneficiary either in original form or copies; maintained in accordance with industry practices such as preserved from destruction, secured for privacy and confidentiality, etc.) e. Describe how the plan of care and any care plan revisions are communicated to the beneficiary, ICT, organization, and pertinent network providers	
9. Communication Network a. Describe the organization's structure for a communication network (e.g., web-based network, audio-conferencing, face-to-face meetings, etc.) b. Describe how the communication network connects the plan, providers, beneficiaries, public, and regulatory agencies c. Describe how the organization preserves aspects of communication as evidence of care (e.g., recordings, written minutes, newsletters, interactive web sites, etc.) d. Describe the personnel having oversight responsibility for monitoring and evaluating communication effectiveness	
10. Care Management for the Most Vulnerable Subpopulations a. Describe how the organization identifies its most vulnerable beneficiaries b. Describe the add-on services and benefits the organization delivers to its most vulnerable beneficiaries	
11. Performance and Health Outcome Measurement a. Describe how the organization will collect, analyze, report, and act on to evaluate the model of care (e.g., specific data sources, specific performance and outcome measures, etc.) b. Describe who will collect, analyze, report, and act on data to evaluate the model of care (e.g., internal quality specialists, contracted consultants, etc.) c. Describe how the organization will use the analyzed results of the performance measures to improve the model of care (e.g.,, internal committee, other structured mechanism, etc.) d. Describe how the evaluation of the model of care will be documented and preserved as evidence of the effectiveness of the model of care (e.g., electronic or print copies of its evaluation process, etc.) e. Describe the personnel having oversight responsibility for monitoring and evaluating the model of care effectiveness (e.g., quality assurance specialist, consultant with quality expertise, etc.) f. Describe how the organization will communicate improvements in the model of care to all stakeholders (e.g., a webpage for announcements, printed newsletters, bulletins, announcements, etc.)	
NOTE TO APPLICANT: THE FOLLOWING ROWS WILL CAPTURE ANY ADDITIONAL MOC ELEMENTS	

REQUIRED BY THE STATE IN WHICH YOUR DEMONSRATION PLAN WILL OPERATE, IF APPLICABLE. CMS WILL NOT REVIEW THESE ADDITIONAL ELEMENTS BUT WILL SHARE THEM WITH THE STATE FOR STATE-ONLY REVIEW. ONLY POPULATE THESE ROWS IF THE STATE IN WHICH YOUR PLAN WILL OPERATE HAS SPECIFICALLY REQUIRED THAT YOUR MOC INCLUDE ADDITIONAL ELEMENTS BEYOND THE 11 ELEMENTS CMS WILL REVIEW.	
12. Additional Element #1	
13. Additional Element #2	
14. Additional Element #3	
15. Additional Element #4	
16. Additional Element #5	

Appendix XX – Partial County Justification

Instructions: Applicants requesting service areas that include one or more partial counties must upload a Partial County Justification with this Application.

Complete and upload in HPMS in the MA Supporting Files Service Area section, the Partial County Justification form for each partial county in your proposed service area.

NOTE: CMS requests that you limit this document to 20 pages.

SECTION I: Partial County Explanation

_____ Check here if the State where your organization will be offering a capitated financial alignment demonstration plan requires a service area that includes a partial county. Do not complete Sections II-IV.

_____ Check here if the State where your organization will be offering a capitated financial alignment demonstration plan is NOT requiring a service area that includes a partial county but your organization is proposing to cover a partial county. Using just a few sentences, briefly describe why you are proposing a partial county.

SECTION II: Partial County Requirements

The Medicare Managed Care Manual Chapter 4, Section 150.3 provides guidance on partial county requirements. The following questions pertain to those requirements; refer to Section 150.3 when responding to them.

Explain how and submit documentation to show that the partial county meets <u>all three</u> of the following criteria:

1. <u>Necessary</u> – Check the option(s) that applies to your organization, *and provide documentation to support your selection(s)*:
   - ☐ You cannot establish a provider network to make health care services available and accessible to beneficiaries residing in the excluded portion of the county.
   - ☐ You cannot establish economically viable contracts with sufficient providers to serve the entire county.

   Describe the evidence that you are providing to substantiate the above statement(s) and (if applicable) attach it to this form:

2. Non-discriminatory – You must be able to substantiate *both* of the following statements:
   - ☐ The racial and economic composition of the population in the portion of the county you are proposing is comparable to the excluded portion of the county.

     Using U.S. census data (or data from another comparable source), compare the racial and economic composition of the included and excluded portions of the proposed county service area.

   - ☐ The anticipated health care costs of the portion of the county you are proposing to serve is similar to the area of the county that will be excluded from the service area.

     Describe the evidence that you are providing to substantiate the above statement and (if applicable) attach it to this form:

3. In the best interest of beneficiaries – The partial county must be in the best interest of the beneficiaries who are in the pending service area.

   Describe the evidence that you are providing to substantiate the above statement and (if applicable) attach it to this form:

SECTION III: Geography

1. Describe the geographic areas for the county, both inside and outside the proposed service area, including the major population centers, transportation arteries, significant topographic features (e.g., lakes, mountain ranges, etc.), and any other geographic factors that affected your service area designation.

SECTION IV: Provider Network Assessment

1. Provide the number of Medicare eligible beneficiaries for each significant city / town in the requested partial county service area.

2. Partial County Network Assessment Table (template provided in the Capitated Financial Alignment Demonstration Template file)

   CMS holds partial county applicants to the same network criteria (time and distance standards) as full-county applicants. Because HPMS cannot measure contracted providers and facilities against requirements at a level smaller than a full county, you must submit access data for your network in the partial-county service area you are requesting.

   Soon after your initial application submission, CMS will issue its first review notice and, in that notice, will name six cities / towns in your proposed service area that you will use to complete the Partial County Network Assessment Table. *You should upload the table as part of your response to that first notice*, which may also name deficiencies elsewhere in your capitated financial alignment demonstration application. *Do not upload the Partial County Network Assessment Table in your initial application submission.*

   To complete the Partial County Network Assessment Table, you will list the CMS-selected cities / towns as the column headers and provide the time (minutes) and distance (miles) from each of those locations to the closest contracted provider / facility of each type as listed on the Table.

   Where you do not meet the CMS time and distance requirements for a particular provider / facility shown on the HSD Criteria Reference Tables (available at http://www.cms.gov/MedicareAdvantageApps/), you must submit a network justification, including your strategy for ensuring access to the applicable services and the local patterns of care for that particular service. CMS recommends that you use the HSD Exception Request Template for your justification and attach the form(s) to your Partial County Network Assessment Table. This is not an official Exception Request but serves the same purpose within the Partial County review strategy.