2015 CAPITATED FINANCIAL ALIGNMENT 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 Medicare-Medicaid enrollees. Please submit your application according to the process described in Section 2.0.

1.2. Background

The Patient Protection and Affordable Care Act as amended 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 Medicare-Medicaid plan (MMP) 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 improve the beneficiary care experience and 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 Medicare and Medicaid authorities to test a new payment and service delivery model to achieve a more seamless care system that improves the

quality and reduces the costs of the two programs while preserving or enhancing the quality of care furnished to Medicare-Medicaid enrollees.

MMPs 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 MMPs will be required to meet established quality thresholds.

MMPs 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 MMP in Rhode Island or Idaho. Organizations that applied to operate an MMP for 2014 in a selected state do not need to complete this application.

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1.4. Schedule

APPLICATION REVIEW PROCESS	
Date	**Milestone**
November 14, 2013	Recommended date by which Applicants should submit their Notice of Intent to Apply Form to CMS to ensure access to Health Plan Management System (HPMS) by the date applications are released.
December 5, 2013	CMS User ID form due to CMS
January 13, 2014	Final Application posted by CMS and available in HPMS
January 31, 2014	Deadline for NOIA form submission to CMS
February 25, 2014	Applications due
February 28, 2014	CMS releases guidance concerning updates to Parent Organization designations in HPMS
March 14, 2014	Parent Organization Update requests from sponsors due to CMS (instructional memo to be released in February (2014)
April 2014	Release of the 2015 Plan Benefit Package (PBP) online training module

April 2014	Release of the 2015 Plan Creation Module, PBP software in HPMS
April 2014	Release of the CY 2015 Medication Therapy Management Program (MTMP) submission module in HPMS
May 2014	MTMP submissions due
May 2014	Release of HPMS Part D formulary submission module for CY 2015
Late-May 2014	CMS sends contract eligibility determinations to Applicants, based on review of application.
Late-May 2014	Formulary submission due to CMS Transition Policy Attestations and Policy due to CMS PA/ST Attestations due to CMS P&T Attestations due to CMS
June 2, 2014	Submission of proposed PBPs due to CMS
Early-June 2014	Deadline for submitting Additional Demonstration Drug file and Part D supplemental formulary files (Free First Fill file, Over-the-Counter Drug file, and Home Infusion file) through HPMS.
Early August 2014	CMS releases the 2015 Part D national average bid amount.
August 2014	MTMP reviews completed.
September 2014	CMS mails the CY 2015 *Medicare & You* handbook to Medicare beneficiaries.
September 2014	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 2015.
September 2014	Three-way contracts among selected plans, States, and CMS must be finalized and signed for a January 1 start date.

October 1, 2014	CY 2014 marketing activity begins for Medicare Advantage and Part D. Demonstration marketing will be specific to State MOUs.
October 1, 2014	Medicare Plan Finder on www.medicare.gov goes live for CY 2015
October 15, 2014	2015 Annual Coordinated Election Period begins.
December 7, 2014	2015 Annual Coordinated Election Period ends.
January 1, 2015	Enrollment effective date.

NOTE: This timeline does not represent an all-inclusive list of key dates. CMS reserves the right to amend or cancel this application at any time. CMS also reserves the right to revise the capitated financial alignment 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 new Medicare-Medicaid plan (MMP) during 2015.

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 MMPs 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 specific manual chapters are included in the application to further assist Applicants. Applicants can also link to the Medicare Managed Care Manual table of contents at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS019326.html and the Prescription Drug Benefit Manual table of contents at http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals.html. In many instances, existing manual chapters may be updated to address criteria specific to the Capitated Financial Alignment Demonstration and MMPs. Guidance is available at http://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialModelstoSupportStatesEffortsinCareCoordination.html. Applicants can access CMS issued guidance documents by following the path in HPMS: HPMS>In the News>Archived In the News.

[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.

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 3.2.5). Applicants are required to provide prompt entry and ongoing maintenance of data in HPMS. By keeping the information in HPMS current, the Applicant facilitates the tracking of its application throughout the review process and ensures that CMS has the most current information for application updates, guidance and other types of correspondence.

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

2.3. Instructions and Format of Application

Applications may be submitted until February 25, 2014. Applicants must use the 2015 capitated financial alignment application. CMS will not accept or review any submissions using other Medicare applications (e.g., MA and Part D applications for 2014 and earlier).

2.3.1. Instructions

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

CMS will communicate with all Applicants via email. The email notifications will be generated through HPMS, so organization must ensure that the Application Contact 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.

Organizations will receive a confirmation number from HPMS upon clicking final submit. Failure to obtain a confirmation number indicates that the 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 submission deadline**, and CMS will make case by case determinations where appropriate regarding the timeliness of the application submission.

2.3.2. Completion of Attestations

In preparing your responses to the attestations in Section 3 of this application, please mark "Yes" or "No" or "Not Applicable" in HPMS.

In many instances, Applicants are directed to affirm within HPMS that they meet particular requirements by indicating "Yes," next to a statement of a particular program

requirement. By providing such attestation, an Applicant confirms 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.

2.3.3. Application Review Standard

CMS will check the application for completeness shortly after its receipt. Consistent with the Medicare 2010 Call Letter (http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/2010CallLetter.pdf), CMS will make determinations concerning the validity of each organization's submission. Some examples of invalid submissions include but are not limited to the following:

- Applicants that fail to upload executed administrative agreements and pharmacy and medical provider/facility agreements or contract templates
- Applicants that upload contract crosswalks or matrices instead of contracts
- Applicants that fail to upload pharmacy access reports
- Applicants that fail to upload health service delivery tables

CMS will notify any Applicants that are determined to have provided invalid submissions. In accordance with 42 CFR §§422.502(a) and 423.503(a), Applicants must demonstrate that they meet all (not "substantially all") program requirements to qualify as a MMP sponsor in the proposed service area.

2.3.4. Application Review Process and Cure Periods

For those Applicants with valid submissions, CMS will notify your organization of any deficiencies and afford a courtesy opportunity to amend the application. The application status emails are accessible in HPMS at the "Communications History" link in Contract Management>Basic Contract Management>Submit Application Data. CMS will only review the last submission provided during the courtesy cure period.

As with all aspects of an Applicant's operations under its contract with CMS and the respective State, we may verify a MMP sponsor's compliance with qualifications it attests it meets through on-site visits at the MMP sponsor's facilities and through other program monitoring techniques, including readiness reviews. Failure to meet the requirements attested to in this solicitation and failure to operate its plans consistent with the requirements of the applicable statutes, regulations, call letter, guidance and the three-way contract may delay an Applicant's marketing and enrollment activities or, if corrections cannot be made in a timely manner, the Applicant will be disqualified from participation.

An individual with legal authority to bind the Applicant must execute the certification found in Section 4 and the template provided in HPMS entitled "Medicare-Medicaid Plan Certification." CMS reserves the right to request clarifications or corrections to a submitted application. Failure to provide requested clarifications within the time period specified by CMS for responding could result in the Applicant not receiving a three-way contract.

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

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 prior to entering into the three-way contract for the demonstration. The readiness reviews will test operational systems, validate medical, pharmacy, behavioral health, and long-term supports and service provider networks and perform reviews to assure optimal preparation and adherence to contract requirements.

CMS will not review applications received after 8:00 P.M. Eastern Daylight Time on February 25, 2013. CMS will lock access to application fields within HPMS as of that time. Applicants must complete the 2015 application in order to be considered to offer a plan under the capitated financial alignment in 2015.

2.3.5. 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 contract.

2.3.6. Withdrawal of an Application

In those instances where an organization seeks to withdraw its submission of a pending application prior to the execution of a MMP 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 PartD_Applications@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.

2.3.7. 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, and the MMP Upload Guide.*

As stated in section 2.3.1 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 will be available in May 2014. Guidance will be issued with the deadline for new formulary submissions to CMS. CMS will use the last successful upload received for an Applicant as the official formulary submission. Applicants can refer to the December 19, 2012 HPMS notice entitled "*CY 2014 Formulary Submission Deadline"* and the December 21, 2013 State Guidance entitled "*States Planning to Implement Capitated Financial Alignment Demonstrations in 2014*" for additional information about formulary submission requirements until the 2015 guidance is released.

Interested organizations will also submit a plan benefit package that details the Medicare, Medicaid and supplemental benefits they will offer for CY 2015. 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 capitated financial alignment plan-specific requirements (for example, inclusion of specific supplemental benefits not currently covered under Medicare Parts A and B, or under Medicaid).

CMS will provide technical instructions and guidance upon release of the HPMS formulary functionality as well as the PBP software.

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 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 1-800-927-8069 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. Please submit the following documents along with the Payment Information form:

- Fax cover sheet that includes the effective month and year
- Completely filled out Payment Information Form
- Voided Check or confirmation letter from bank
- W-9 Form

If the Applicant has questions about this form, please contact Louise Matthews at (410) 786-6903. The completed form needs to be faxed to Louise Matthews 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

[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.

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. 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 pharmacy benefit manager's (PBM) existing 2014 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 2015.

CMS conducts the review of retail pharmacy access based on the service area that the Applicant has provided in HPMS by February 25, 2014. Applicants are required to input their pending service area into HPMS per the instructions at section 3.1 and as explained in section 3.5.1B, Applicants must upload the retail pharmacy list in HPMS. Based on the information provided by the Applicant and the Medicare Beneficiary Count file available on the CMS application guidance website, CMS will generate access percentages for all applicants.

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 "*Adequate Access to Home Infusion Pharmacies*" is provided in the zip file entitled 2014 Resources for HI LTC and ITU References (v01.09.13) located in the download section at http://www.cms.gov/PrescriptionDrugCovContra/04_RxContracting_ApplicationGuidance.html 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"* is provided in the zip file entitled 2015 Resources for HI LTC and ITU References located in the download section at http://www.cms.gov/PrescriptionDrugCovContra/04_RxContracting_ApplicationGuidance.html.

2.6.5. Waivers Related to Pharmacy Access

CMS guidance regarding waivers of the pharmacy access and any willing pharmacy requirements for certain Applicants is contained at sections 50.7 and 50.8.1 of Chapter 5 of the Prescription Drug Benefit Manual. These pharmacy access waivers will apply to those organizations seeking to offer a capitated financial alignment 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 Applicants sponsors must offer their Medicare prescription drug plan benefit through a contracted retail pharmacy network that meets CMS convenient access standards is waived for Applicants that operate their own pharmacies. Applicants must demonstrate 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 50.8.1 of Chapter 5 of the Prescription Drug Benefit Manual (http://www.cms.gov/PrescriptionDrugCovContra/Downloads/MemoPDBManualChapter5_09.30.11.pdf), the requirement that Applicants must offer a network pharmacy contract to any willing pharmacy that agrees to accept the Applicant's standard terms and conditions is waived for Applicants that own and operate the pharmacies in their network. Applicants must demonstrate 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 Medicare-Medicaid plan 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 will be submitting the HSD tables based on their intended medical/facility network. A column is included in the HSD tables to indicate if the medical provider/facility is already contracted with your organization to participate in its Medicare line of business.

Once CMS and the respective State announce rates, the medical provider/facility networks will be validated during the readiness review process. This validation process will provide 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 the opportunity to seek an exception. CMS will provide further instruction, at that time of what information the Applicant must submit to support the exception request(s). The HSD exception review will occur manually by CMS and the respective State. Applicants who submit HSD tables that 'clear' CMS' network adequacy criteria will still be required to submit signed contracts and other documentation that demonstrate the accuracy of the HSD table submissions during the readiness review.

CMS will be providing training to Applicants on the automated system, the HSD tables and the default values for determining network adequacy after the application module opens, and expects to annually post the default values for determining network adequacy in the Fall of each year.

Application forms and tables associated with the applications can be found in the Medicare-Medicaid plan 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 2015 HPMS User Guide for the MMP Application. The 2015 HPMS User Guide for the MMP Application provides step-by-step instructions, including HPMS screen shots, to complete and upload required documentation for the capitated financial alignment 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. Starting with the CY 2015 application cycle, the CMS requirements include: 1) description of the target population; 2) care coordination; 3) provider network; and 4) MOC quality measurement and performance improvement. CMS will review and approve MOC submissions based on the same elements and scoring standards CMS has established for approval of Medicare Advantage Special Needs Plans. Interested organizations will have two opportunities to correct any deficiencies identified during the review process. Per the Announcement of Calendar Year 2013 Medicare Advantage Capitation Rates and

Medicare Advantage and part D Payment Policies and Final Call Letter, , interested organizations will only be allowed to resubmit their MOCs if they score below 70 percent. Interested organizations that score above 70 percent will not be permitted to resubmit their MOC to further improve their score and obtain a longer approval period for their MOC. In addition, any interested organization that has to resubmit their MOC to cure a deficiency will only be eligible to have a one-year approval period regardless of its score.

Additional information related to the MOC elements and the CMS standards for approval will be provided separately by CMS.

2.9. First Tier, Downstream, and Related Entities

An MMP Applicant may meet program requirements by delegating the performance of certain required functions to entities with which it contracts directly, referred to in the Medicare Advantage and Medicare Part D regulations (42 CFR §§ 422.500 and 423.501) as "first tier entities." These entities may in turn contract with other entities, defined as "downstream entities," for the performance of the delegated function. A related entity is an entity that is a parent, subsidiary, or subsidiary of the parent of the MMP Applicant. A related entity may be either a first tier or downstream entity.

Where an Applicant has elected to use subcontractors to meet MMP requirements, it must demonstrate that it has binding contracts in place that reflect these relationships. The contracts serve as the legal links that form the Applicant's "chain of delegation," extending from the Applicant to the entities (first tier or downstream) that will actually perform the stated function on the Applicant's behalf. Where the function is to be performed by a downstream entity, there must be contracts in place through which the Applicant has delegated a function to a first tier entity, which has in turn delegated that function to the downstream entity.

Applicants must identify in Sections 3.2.1C and 3.2.1F, the first tier and downstream entities with which it has contracted to perform the identified functions.

Note concerning parent and subsidiary relationships: In establishing its subcontracting arrangements, an Applicant must clearly demonstrate that it has elected to delegate certain MMP functions to first tier and downstream entities. Where an Applicant is a subsidiary to a parent organization and that organization purports to contract with other entities on the Applicant's behalf, the Applicant must consider the parent organization a first tier entity and provide a contract between itself and its parent that meets the MMP requirements. CMS will not consider any other types of materials, including articles of incorporation, organizational charts, or lists of board members or senior executives that the Applicant might believe demonstrate that the parent is authorized to contract on the Applicant's behalf.

2.10. Document (Upload) Submission Instructions

Applicants must include their assigned H number in the file name of all submitted documents. Within the Medicare-Medicaid plan 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.

2.11. Protection of Confidential Information

Applicants may seek to protect their information from disclosure under the Freedom of Information Act (FOIA) by claiming that FOIA Exemption 4 applies. The Applicant is required to label the information in question “confidential” or “proprietary”, and explain the applicability of the FOIA exemption it is claiming. This designation must be in writing.

When there is a request for information that is designated by the Applicant as confidential or that could reasonably be considered exempt under Exemption 4, CMS is required by its FOIA regulation at 45 CFR §5.65(d) and by Executive Order 12,600 to give the submitter notice before the information is disclosed. To decide whether the Applicant’s information is protected by Exemption 4, CMS must determine whether the Applicant has shown that:

- Disclosure of the information might impair the government's ability to obtain necessary information in the future;
- Disclosure of the information would cause substantial harm to the competitive position of the submitter;
- Disclosure would impair other government interests, such as program effectiveness and compliance; or
- 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 program that would be considered proprietary in nature.

3. APPLICATION

Nothing in this application is intended to supersede the regulations at 42 CFR Parts 422 and 423, the Medicare Managed Care Manual, the Prescription Drug Benefit Manual, or any other CMS guidance or instructions related to the operation of the Capitated Financial Alignment Demonstration. Failure to reference a regulatory requirement or CMS instruction in this application does not affect the applicability of such requirement. 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 Medicare prescription drug or medical benefit requirements.

For most of the program requirements described in this application, CMS has issued operational policy guidance that provides more detailed instructions. 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.

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

3.1. Service Area/Regions 42 CFR §422.2

Medicare Managed Care Manual, Chapter 4 (http://www.cms.gov/manuals/downloads/mc86c04.pdf)

A. In HPMS, in the Contract Management/Contract Service Area/Service Area Data page, enter the state and county information for the area the Applicant proposes to serve.

B. If serving a partial county, upload in HPMS MMP Supporting Files Service Area section the template entitled "Partial County Justification" document

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 medical provider/facility and 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 MMP Provider Table, MMP Facility Table and the pharmacy lists that are provided as part of this application.

3.2. Applicant Experience, Contracts, Licensure and Financial Stability

3.2.1. Management and Operations 42 CFR Parts 422 and 423 Subpart K

Medicare Managed Care Manual, Chapter 11 (https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c11.pdf); CMS issued guidance 08/15/06 and 08/26/08

A. In HPMS, complete the table below:

Attest 'yes,' 'no,' or 'NA' to the following qualification by clicking on the appropriate response in HPMS:	Yes	No	NA
1. If Applicant, Applicant's parent organization, or any subsidiaries of Applicant's parent organization has an existing contract(s) with CMS to operate a Medicare Advantage, Prescription Drug Plan, or Medicare-Medicaid Plan, at least one of those contracts has been in effect since January 1, 2013 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 Medicare Advantage, Prescription Drug Plan, or Medicare-Medicaid Plan select "NA".)			
2. Applicant has reviewed, understands, and complies with the regulations, as applicable, at 42 CFR Part 422 Subpart K and Part 423 Subpart K and all CMS-issued guidance related to management and operations.			
3. Applicant maintains contracts or other legal arrangements between or among the entities combined to meet the functions identified in the Medicare-Medicaid Plan Medical Benefit (subsection 3.2.1C) and Prescription Drug Benefit (subsection 3.2.1F) First tier, Downstream, and Related entities function charts in HPMS.			
4. Applicant does not have any covered persons who also served as covered persons for an entity that nonrenewed a contract pursuant to 42 CFR §422.506 (a) or §423.507(a), or that terminated its contract with CMS by mutual consent, pursuant to 42 CFR § 422. 508, or §423.508, or unilaterally, pursuant to 42 CFR §422.512, or §423.510, since January 1, 2012. "Covered persons", as defined at 42 CFR §§ 422.506(a)(5), 422.508(d), 422.512(e)(2), 423.507(a)(4), 423.508(f), 423.510(e)(2) • 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, MMP Supporting Files Contracting/Experience/History, the 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, MMP Supporting Files Contracting/Experience/History, proof of your organization's incorporation, such as articles of incorporation or a certificate of good standing from your state of incorporation.

C. Medicare Medical Benefit First tier, Downstream and Related Entities Function Chart

Complete the table below in HPMS. Refer to Section 2.9 for further clarification.

In HPMS, on the Contract Management/MMP Information/Medical Benefit 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
	Administrative/Management Staffing		
	Systems and/or Information Technology		
	Claims Administration, Processing and/or Adjudication		
	Enrollment, Disenrollment and Membership		
	Marketing and/or Sales Brokers and Agents		
	Credentialing		
	Utilization and/or Quality Improvement Operations		
	Part C Call Center Operations		
	Financial Services		
	Health Risk Assessments		

Note: 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".

D. In HPMS, MMP Supporting Files Medical Benefit Administrative Contracting, upload copies of executed management 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 Section 3.2.1 C and with any first tier, downstream, or related entity that contracts with any of the identified entities on the Applicant's behalf for the following functions:
    - Administrative/Management Staffing
    - Claims Administration, Processing and/or Adjudication
    - Utilization and/or Quality Improvement Operations
    - Part C Call Center Operations
    - Health Risk Assessments

All contracts must include the following provisions:

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 §422.504(i)(4)(i)
3. Contain language clearly indicating that the first tier, downstream, or related entity has agreed to participate in your Medicare-Medicaid Plan product offering (except for a network provider/facility 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 with CMS. 42 CFR §422.504(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 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 Medicare laws and regulations and CMS instructions. 42 CFR §422.504(i)(4)(v)
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 §422.118.
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 §422.504(e) and 42 CFR §422.504(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 Applicant 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 §422.504(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 Applicant. 42 CFR §422.504(i)(3)(i)
12. Contain language that if the Applicant 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 Applicant 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 § 422.504(i)(4)(ii)
13. Contain language specifying that the Applicant will monitor the performance of the first tier, downstream, or related entity on an ongoing basis. 42 CFR §422.504(i)(4)(iii)
14. If the first tier, downstream or related entity is performing credentialing activities, the Applicant contains language that the credentials of medical professionals affiliated with the party or parties will be either reviewed by the Applicant; or the credentialing process will be reviewed and approved by the Applicant and the Applicant must audit the credentialing process on an ongoing basis. 42 CFR 422.504(i)(4)(iv)
15. If the first tier, downstream, or related entity delegates selection of the providers, contractors, or subcontractor to another organization, the Applicant contains language that the Applicant retains the right to approve, suspend, or terminate any such arrangement. 42 CFR §422.504(i)(5)

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

E. Upload in HPMS, MMP Supporting Files Medical Benefit Administrative Contracting, a completed CMS Administrative/Management Delegated Contracting or Arrangement Matrix for MMPs. If the Applicant fails to upload the appropriate matrix 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. Medicare Prescription Drug Benefit First tier, Downstream and Related entities Function Chart

Complete the table below in HPMS. Refer to Section 2.9 for further clarification.

In HPMS, on the Contract & Management/MMP Information/Prescription Drug Benefit 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.		

G. In HPMS, MMP Supporting Files Contracting/Experience/History, 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 Section 3.2.1F 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-Medicaid Plan product offering (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 with CMS. 42 CFR §423.505(i)(3)(iii)
5. Describe the payment or other consideration the first tier, downstream, or related entity will receive for performance under the contract.
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 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 Applicant 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 Applicant. 42 CFR §423.505(i)(3)(i)
12. Contain language that if the Applicant 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 Applicant 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 will monitor the performance of the first tier, downstream, or related entity on an ongoing basis. The contract must explicitly provide that the Applicant itself will perform ongoing monitoring. Language indicating that the Applicant has the right to monitor is not sufficient; the contract must affirmatively state that the Applicant will monitor the 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 Applicant 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 Applicant 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 Applicant 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 42 CFR 423.514(d) and (e).

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

H. Upload in HPMS, MMP Supporting Files Contracting/Experience/History, electronic lists of the contract/administrative service agreement/intercompany agreement citations demonstrating that the requirements of Section 3.2.1F 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, *Crosswalks of Prescription Drug Benefit Requirements in Part D-Related First Tier, Downstream and Related Entity Contracts*. 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.

3.2.2. State Licensure 42 CFR §§ 422.400, 422.402

*Medicare Managed Care Manual, Chapter 10 (**http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R7MCM.pdf**); CMS issued guidance 08/15/06 and 08/26/08*

A. 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 licensed under state law as a risk-bearing entity eligible to offer health insurance or health benefits coverage in the state the Applicant proposes to offer the Medicare-Medicaid plan product. In addition, the scope of the license or authority allows the Applicant to offer the type of managed care product that it intends to offer in the state.		
2. Applicant is applying to operate as a Medicare-Medicaid plan sponsor through a joint enterprise agreement.		
3. Applicant is currently under some type of supervision, corrective action plan or special monitoring by the state licensing authority in any state. This means that the Applicant has to disclose actions in any state against the legal entity which filed the application.		
4. Applicant conducts business as "doing business as" (d/b/a) or uses a name different than the name shown on its Articles of Incorporation.		

5. For states whose license renews after the first Monday in June, Applicant agrees to upload into HPMS the renewed license no later than the final upload opportunity. If the renewed license is not available at that time, Applicant agrees to (1) upload, in place of the license, a copy of its completed license renewal application or other documentation (e.g., invoice from payment of renewal fee) to show that the renewal process is being completed in a timely manner, and (2) electronically send a copy of the renewed license to the CMS Regional Office Account Manager promptly upon issuance. . • Note: If the Applicant does not have a license that renews after the first Monday in June, then Applicant should respond "No".		
6. Applicant has marketing representatives and/or agents who are licensed or regulated by the State in which the proposed services are located. • Note: If the State in which the proposed service area is located doesn't require marketing representatives/agents to be licensed, Applicant should respond "N/A".		

B. If Applicant answered 3.2.2A1 (table above) as YES; upload an executed copy of the State Licensing Certificate and the CMS _MMP State Certification Form in HPMS MMP Supporting Files State Licensure section.

C. If Applicant answered 3.2.2A2 (table above) as YES, then Joint Enterprise Applicants must upload in HPMS MMP Supporting Files Medical Benefit Administrative Contracting (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 capitated financial alignment 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.

D. If Applicant answered 3.2.2A3 as YES, upload the State Corrective Plans/State Monitoring Explanation (as applicable) in HPMS MMP Supporting Files State Licensure section.

E. If Applicant answered 3.2.2A4 as YES, upload the state approval for the d/b/a in HPMS MMP Supporting Files State Licensure section.

F. In HPMS, on the Contract Management/General Information/NAIC Data Page, provide the National Association of Insurance Commissioners (NAIC) number if

currently licensed. Note that Applicants for new MMPs will not be able to complete this section in HPMS until after the courtesy review period is over.

3.2.3. Fiscal Soundness 42 CFR §§ 422.2 and 422.504(a)(14)

A. 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 maintains a fiscally sound operation and maintains a positive net worth (Total Assets exceed Total Liabilities).		

B. In HPMS MMP Supporting Files Fiscal Soundness section, upload the most recent Audited Financial Statement that are available and the most recent Quarterly NAIC Health Blank or other form of quarterly financials if the NAIC 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 2012, and has less than six months of operation in 2013, 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 2013 Audited Financial Statement. If the parent's 2013 Audited Financial Statement is not available at the time of the submission of the application, the Applicant must submit the parent's 2012 Audited Financial Statement and the parent's 2013 Annual NAIC Health Blank or other form of quarterly financials if the NAIC Health Blank is not required by your State.

3.2.4. Program Integrity 2 CFR Part 376 and Compliance Program 42 CFR §§ 42 CFR 422.503(b)(4)(vi) and 423.504(b)(4)(vi)

Medicare Managed Care Manual, Chapter 21

(https://hpms.cms.gov/hpms/upload_area/NewsArchive_MassEmail/000005674/Compliance%20Program%20Guidelines_PDB%20Ch%209_MMC%20Ch%2021.pdf)

Prescription Drug Benefit Manual, Chapter 9
(https://hpms.cms.gov/hpms/upload_area/NewsArchive_MassEmail/000005674/Compliance%20Program%20Guidelines_PDB%20Ch%209_MMC%20Ch%2021.pdf)

CMS Guidance issued 01/11/2013

A. 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, 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 MMP Supporting Files Program Integrity, in a .pdf format, a copy of your organization's Medicare-Medicaid Plan Compliance Program that you intend to use for this contract.

The Medicare-Medicaid plan compliance program must be in accordance with 42 CFR 422.503(b)(4)(vi) and 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 Medicare-Medicaid plan compliance program must include all seven elements in the regulation and in Chapters 21 and 9 of the Medicare Managed Care Manual and the Prescription Drug Benefit Manual respectively. The compliance plan must explicitly state that it encompasses the capitated financial alignment product. 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 Medicare-Medicaid plan compliance program. 42 CFR § 422.504(b)(vi)(B)(1) and 423.504(b)(vi)(B)(1) and section 40 of Chapter 21 of the Medicare Managed Care Manual and Chapter 9 of the Prescription Drug Benefit Manual indicate 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 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, MMP Supporting Files Program Integrity complete and upload the appropriate template that mimics the Appendix entitled, *MMP Compliance Plan Crosswalk* for the Compliance Plan.

3.2.5. HPMS Medicare-Medicaid Plan Contacts; 42 CFR §422.503(b)(4)(ii)

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. The CEO, Chief Financial Officer, Chief Operating Officer, and Medicare Compliance Officer must be employees of the Applicant, the Applicant's parent organization, or a subsidiary of the Applicant's parent organization. Please note that it is CMS' expectation that the Application contact be a direct employee of the Applicant.

Contact	Name/Title	Mailing Address (PO Boxes may not be used)	Phone/Fax Numbers	Email Address
Corporate Mailing				
CEO – Sr. Official for Contracting				
Chief Financial Officer				
Medicare Compliance Officer				
Enrollment Contact				
Medicare Coordinator				
System Contact				
Customer Service Operations Contact				
General Contact				
User Access Contact				
Backup User Access Contact				
Marketing Contact				
Medical Director				

Bid Primary Contact				
Payment Contact				
Part D Claims Submission Contact				
Formulary Contact				
Pharmacy Network Management Contact				
Medication Therapy Management Contact				
Part D Benefits Contact				
Part D Quality Assurance Contact				
Part D Application Contact				
Pharmacy Director				
HIPAA Security Officer				
HIPAA Privacy Officer				
Part D Price File Contact (Primary)				
Part D Price File Contact (Back-up)				
Part D Appeals				
Government Relations Contact				
Emergency Part D Contact				
Pharmacy Technical Help Desk Contact				
Processor Contact				

CMS Casework Communication Contact				
Part D Exceptions Contact				
Coordination of Benefits Contact				
CEO – CMS Administrator Contact				
Plan to Plan Reconciliation Contact				
Bid Audit Contact				
Plan Directory Contact for Public Website				
CAP Report Contact for Public Website				
Financial Reporting Contact				
Best Available Evidence Contact				
Automated TrOOP Balance Transfer Contact				
Agent/Broker Compensation Data Contact				
Complaint Tracking Module (CTM) Contact				
Part D Reporting Requirement Contact				
Fraud Investigations Contact				

Reconciliation Contact				
DIR Contact				

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

Attest 'yes' or 'no' to the following qualification by clicking on the appropriate response in HPMS:	**Yes**	**No**
1. Applicant agrees that CMS may release contact information to States, SPAPs, providers, Medicare Advantage, Part D sponsors, and others who need the contact information for legitimate purposes.		

3.3. Benefit Design

3.3.1. Formulary/Pharmacy and Therapeutics (P&T) Committee Social Security Act §1860D-4(b)(3)(G), 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);

2014 Call Letter (http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/RateNotice.pdf);

CMS issued guidance 03/25/10

A. 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 will submit a formulary to CMS for the Part D benefit by the date listed in section 1.4. 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.		
2. Applicant has reviewed, understands, and complies with formulary guidance that is contained in the Code of Federal Regulations (42 CFR §423.120(b)), Chapter 6 of the Prescription Drug Benefit Manual, the HPMS Formulary Submission Module and Reports Technical Manual, and all other formulary instructions.		
3. 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.		
4. Applicant agrees to provide all Medicaid-covered drugs as part of its formulary submission to CMS.		
5. Applicant is using the P&T Committee of its PBM for purposes of the Part D benefit.		
6. 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*.		
7. Applicant has reviewed, understands, and complies with the requirements related to the use and development of a P&T committee contained in the Code of Federal Regulations (42 CFR §423.120(b)(1)), Chapter 6 of the Prescription Drug Benefit Manual, the HPMS Formulary Submission Module and Reports Technical Manual, and all other guidance related to P&T committees. 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.		

B. If Applicant intends to use a formulary for its Part D benefit, then the names of P&T committee members must be provided to CMS either directly by the Applicant or by the Applicant's PBM. To provide names of P&T committee members directly, enter names in HPMS' Contract Management/Part D Data page. If the PBM operates under confidentiality agreement (where the Applicant does not know the membership of the PBM's P&T Committee) refer to the Appendix entitled Applicant Submission of P & T Committee Member List and Certification Statement for additional instructions.

3.3.2. Medical Benefit 42 CFR §§422.100-102

Medicare Managed Care Manual, Chapter 4

(http://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/index.html)

A. 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 has reviewed, understands, and complies with Medicare Parts A/B requirements in 42 CFR §§422.100-102, Chapter 4 of the Medicare Managed Care Manual and all related guidance.		

3.3.3. Utilization Management Standards 42 CFR §423.153(b)

Prescription Drug Benefit Manual, Chapter 6 (http://www.cms.gov/PrescriptionDrugCovContra/Downloads/Chapter6.pdf);

Prescription Drug Benefit Manual, Chapter 7 (http://www.cms.gov/PrescriptionDrugCovContra/Downloads/Chapter7.pdf);

2013 Call Letter (http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/RateNoticeA.pdf);

2014 Call Letter (http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/RateNotice.pdf)

A. In HPMS, complete the table below:

Attest 'yes' or 'no' to the following qualification by clicking on the appropriate response in HPMS:	Yes	No
2. Applicant has reviewed, understands, and complies with utilization management requirements in 42 CFR 423.153(b), Chapters 6 and 7 of the Prescription Drug Benefit Manual and all related guidance.		

3.3.4. Quality Assurance and Patient Safety Social Security Act §1860D-4(c)(3); 42 CFR §§ 422.152 and 423.153(c)

Medicare Managed Care Manual, Chapter 5

(https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c05.pdf)

Medicare Managed Care Manual, Chapter 16B

(https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R98MCM.pdf)

Prescription Drug Benefit Manual, Chapter 7 (http://www.cms.gov/PrescriptionDrugCovContra/Downloads/Chapter7.pdf);

2013 Call Letter (http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/RateNoticeA.pdf);

2014 Call Letter (http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/RateNotice.pdf)

A. 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 has reviewed, understands, and complies with requirements related to a quality improvement program (QIP) in 42 CFR §422.152, Chapter 5 of the Medicare Managed Care Manual, and all related guidance.		
2. Applicant has reviewed, understands, and complies with requirements related to a Model of Care consistent with Section 90 of Chapter 16B of the Medicare Managed Care Manual and applicable State requirements.		
3. Applicant has reviewed, understands, and complies with requirements related to quality assurance and patient safety in section 1860D-4(c)(3) of the Act, 42 CFR §423.153 (c), Chapter 7 of the Prescription Drug Benefit Manual, and related CMS guidance. This includes requirements related to drug utilization review, medication error identification, and prevention of wasteful dispensing of prescription drugs.		

B. In HPMS, MMP Supporting Files Model of Care upload a copy of the Applicant's Model of Care.

C. In HPMS, MMP Supporting Files Model of Care complete and upload the Appendix entitled *MMP Model of Care Matrix Upload Document*.

3.3.5. Medication Therapy Management Social Security Act §1860D-4(c)(2); 42 CFR §423.153(d)

Prescription Drug Benefit Manual, Chapter 7 (http://www.cms.gov/PrescriptionDrugCovContra/Downloads/Chapter7.pdf);

2013 Call Letter (http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/RateNoticeA.pdf);

2014 Call Letter (http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/RateNotice.pdf)

A. 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 has reviewed, understands and complies with requirements related to developing and implementing a Medication Therapy Management (MTM) Program described section 1860D-4(c)(2) of the Act, 42 CFR §423.153(d), Chapter 7 of the Prescription Drug Benefit Manual and all related guidance.		
2. The Applicant agrees to submit a description of its MTM program, including, but not limited to, policies, procedures, services, payments and criteria 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.		

3.3.6. 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 (http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/2010CallLetter.pdf)

A. 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 has reviewed, understands, and complies with electronic prescription and Health Information Technology requirements contained in P.L. 111-5 (2009), 42 CFR §423.159, Chapter 7 of the Prescription Drug Benefit Manual, and all related guidance.		

3.4. Medical Benefit Access 42 CFR §§422.112 and 114, 504

Medicare Managed Care Manual, Chapter 4

(http://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/index.html)

Medicare Managed Care Manual, Chapter 11

*(**https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c11.pdf**)*

A. 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 has reviewed, understands, and complies with requirements related to medical benefit access and contracting contained in 42 CFR §§422.112 and 114, Chapter 4 of the Medicare Managed Care Manual, and all related guidance.		
2. Applicant has reviewed, understands, and complies with all applicable provider requirements in 422 subpart E, 422.504 and Chapter 11 of the Medicare Managed Care Manual, and all related guidance.		

B. In HPMS, using the instructions provided in the HPMS Medicare-Medicaid plan download file, upload the following completed HSD tables for your intended medical provider/facility network:

- CMS MMP Provider Table CY 2015
- CMS MMP Facility Table 2015

The HSD submission may be based on your intended network; you must identify those providers/facilities (if any) that are already contracted to provide Medicare services for your organization. CMS will review exceptions and validate the provider/facility networks during readiness reviews, after rates have been announced.

C. In HPMS MMP Supporting Files Medical Provider Contracts and Agreements, upload a completed CMS Medical Provider Contract Template Matrix for MMPs and the provider contracts templates that your organization and your first tier or downstream entities will use for future contracting of its provider and facility networks once rates have been announced.

Applicants must submit the direct and downstream provider contract templates that include the provisions cited in the Appendix entitled CMS Medical Provider Contract Template Matrix for MMPs used for future contracting for:

- Medical Provider
- Medical Group Provider
- Hospital Provider
- Facility Provider

3.5. 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:

Attest 'yes' or 'no' to the following qualification by clicking on the appropriate response in HPMS:	**Yes**	**No**

1. Applicant has reviewed, understands, and complies with requirements related to pharmacy access and contracting contained in 42 CFR §423.120(a), Chapter 5 of the Prescription Drug Benefit Manual, and all related guidance.		
2. Applicant agrees to notify CMS when the Applicant changes its pharmacy benefit manager.		
3. 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 MMP Supporting Files Contracting/Experience/History, 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 Access Contracts
- Crosswalk for Mail Order Pharmacy Access Contracts
- Crosswalk for Home Infusion Pharmacy Access Contracts
- Crosswalk for Long-Term Care Pharmacy Access Contracts
- Crosswalk for I/T/U Pharmacy Access Contracts.

C. Upload in HPMS MMP Supporting Files Contracting/Experience/History 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 Access Contracts
- Crosswalk for Mail Order Access 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:

Attest 'yes' or 'no' to the following qualification by clicking on the appropriate response in HPMS:	**Yes**	**No**
1. Applicant has reviewed, understands, and complies with all requirements related to retail pharmacy access contained in 42 CFR §§423.120(a) & 423.859(c), Chapter 5 of the Prescription Drug Benefit Manual, and all related guidance.		

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. In HPMS complete the table below:

Waiver of Retail Convenient Access Standards for Medicare-Medicaid Plan Applicants	
Provide the number of prescriptions provided in 2013 by retail pharmacies owned and operated by Applicant.	
Provide the number of prescriptions provided in 2013 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.

D. In HPMS complete the table below:

Waiver of Any Willing Pharmacy Requirements for Medicare-Medicaid Plan Applicants	
Provide the number of prescriptions provided in 2013 by all pharmacies owned and operated by Applicant.	
Provide the number of prescriptions provided in 2013 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:

Attest 'yes' or 'no' to the following qualification by clicking on the appropriate response in HPMS:	Yes	No
1. Applicant has reviewed, understands, and complies with requirements related to access to drugs at out-of-network pharmacies contained in 42 CFR §423.124, Chapter 5 of the Prescription Drug Benefit Manual, and all related guidance.		

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)

2014 Call Letter

(http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/RateNotice.pdf)

A. 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 offers mail order pharmacy as part of its Medicare-Medicaid plans.		

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:

Attest 'yes' or 'no' to the following qualification by clicking on the appropriate response in HPMS:	**Yes**	**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 has reviewed, understands, and complies with requirements related to long term care pharmacy access and contracting contained in 42 CFR §423.120(a)5), Chapter 5 of the Prescription Drug Benefit Manual, and all related guidance.		
3. 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.		

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:

Not all Part D regions have I/T/U pharmacies. If the Applicant's service area covers <u>any</u> region that includes	**Yes**	**No**	**N/A**

I/T/U pharmacies, then the Applicant must attest 'yes' to each of the following qualifications to be approved for a contract. To determine if I/T/U pharmacies reside in your service area, review the I/T/U reference file located on the CMS webpage: http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxContracting_ApplicationGuidance.html. Attest 'yes,' 'no' or n/a to each of the following qualifications by clicking on the appropriate response in HPMS:			
1. Applicant has reviewed, understands, and complies with requirements related to I/T/U access and contracting contained in 42 CFR §423.120(a)(6), Chapter 5 of the Prescription Drug Benefit Manual, and all related guidance.			

B. I/T/U Pharmacy List

In order to demonstrate that an 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). 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 and include all I/T/U pharmacies residing in any and all counties/states within its service area, 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.

Attest 'yes' or 'no' to the following qualification by clicking on the appropriate response in HPMS:	Yes	No
1. Applicant has reviewed, understands, and complies with all requirements related to specialty pharmacies contained in Chapter 5 of the Prescription Drug Benefit Manual and all related guidance.		

3.6. Enrollment and Eligibility 42 CFR 422 Subpart B

Medicare Managed Care Manual, Chapter 2

(http://www.cms.gov/Medicare/Eligibility-and-Enrollment/MedicareMangCareEligEnrol/Downloads/FINAL_MA_Enrollment_and_Disenrollment_Guidance_Update_for_CY2012_-_Revised_872012_for_CY2013.pdf)

Prescription Drug Benefit Manual, Chapter 13 (http://www.cms.gov/PrescriptionDrugCovContra/Downloads/Chapter13.pdf); Plan Communications User Guide; CMS issued guidance 07/21/09

Medicare Medicaid Plan Enrollment and Disenrollment Guidance

(http://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialModelstoSupportStatesEffortsinCareCoordination.html)

A. 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 has reviewed, understands, and complies with applicable requirements related to enrollment, disenrollment, and eligibility contained in 42 CFR §§422.50, Chapter 2 of the Medicare Managed Care Manual, the Plan Communications User Guide, and all related enrollment and disenrollment guidance and technical specifications.		

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, 12/09/08, and 06/08/12

A. 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 has reviewed, understands, and complies with all requirements related to complaints tracking and resolution contained in Chapter 7 of the Prescription Drug Benefit Manual and all related guidance.		

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, 05/20/10

A. In HPMS, complete the table below:

Attest 'yes' or 'no' to the following qualification by clicking on the	Yes	No

appropriate response in HPMS:		
1. Applicant has reviewed, understands, and complies with all requirements related to data submission and quality assurance for Medicare Plan Finder data contained in Chapter 7 of the Prescription Drug Benefit Manual and all related guidance.		

3.9. Grievances 42 CFR Parts 422 and 423 Subpart M

Medicare Managed Care Manual, Chapter 13

*(**https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c13.pdf**)*

Prescription Drug Benefit Manual, Chapter 18 (http://www.cms.gov/MedPrescriptDrugApplGriev/01_Overview.asp)

A. 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 has reviewed, understands, and complies with all applicable requirements related to beneficiary grievances contained in 42 CFR 422 Subpart M, 42 CFR 423 Subpart M, Chapter 18 of the Prescription Drug Benefit Manual, and all related guidance.		

3.10. Coverage Determinations (including Exceptions) and Appeals 42 CFR Parts 422 and 423 Subpart M

Medicare Managed Care Manual, Chapter 13

*(**https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c13.pdf**)*

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:

Attest 'yes' or 'no' to the following qualification by clicking on the appropriate response in HPMS:	Yes	No
1. Applicant has reviewed, understands, and complies with all applicable requirements related to beneficiary coverage determinations (including exceptions) and appeals contained in 42 CFR Parts 422 subpart M and 423 subparts M and U, Chapter 13 of the Medicare Managed Care Manual, Chapter 18 of the Prescription Drug Benefit Manual, the Part D QIC Reconsiderations Procedures		

Manual, and all related guidance.		

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:

Attest 'yes' or 'no' to the following qualification by clicking on the appropriate response in HPMS:	Yes	No
1. Applicant has reviewed, understands, and complies with requirements related to coordination of benefits contained in 42 CFR Part 423 Subpart J, Chapter 14 of the Prescription Drug Benefit Manual, and all related guidance.		

3.12. Tracking True Out-of Pocket Costs (TrOOP) Social Security Act §1860D-2(b)(4); 42 CFR Part 423 Subpart J

Prescription Drug Benefit Manual, Chapters 13 and 14 (http://www.cms.gov/PrescriptionDrugCovContra/Downloads/Chapter13.pdf) (http://www.cms.gov/PrescriptionDrugCovContra/Downloads/Chapter14.pdf)

A. 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 has reviewed, understands, and complies with requirements for tracking each enrollee's true out of pocket (TrOOP) costs contained in section 1860D-2(b)(4) of the Act, 42 CFR Part 423 subpart J, Chapters 13 and 14 of the Prescription Drug Benefit Manual, and all related guidance.		

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 §§422.108 and 423.462

Prescription Drug Benefit Manual, Chapter 14 (http://www.cms.gov/PrescriptionDrugCovContra/Downloads/Chapter14.pdf); CMS issued guidance 04/23/13

Attest 'yes' or 'no' to the following qualification by clicking on the	Yes	No

appropriate response in HPMS:		
1. Applicant has reviewed, understands, and complies with all Medicare Secondary Payer requirements, including those contained in 42 CFR §§422.108 and 423.462, and Chapter 14 of the Prescription Drug Benefit Manual, and all related guidance.		
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.		

A. In HPMS, complete the table below:

3.14. Marketing/Provider/Beneficiary Communications 42 CFR §§422.2260-2276, 423.128, and 423.505

Medicare Managed Care Manual, Chapter 3

(http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/mc86c08.pdf)

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

Marketing Guidance and Model Materials for Medicare Medicaid Plans

(http://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialModelstoSupportStatesEffortsinCareCoordination.html)

A. 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 has reviewed, understands, and complies with all applicable requirements related to marketing and beneficiary communications, including those contained in 42 CFR §§422.2260 – 422.2276, 42 CFR§§ 423.128 & 423.505, Chapters 3 and 2 of the Medicare Managed Care Manual and the Prescription Drug Benefit Manual respectively, and all related guidance.		

3.15. Reporting Requirements Social Security Act §1150A; 42 CFR §§422.516 and 423.514

2014 Part C, Part D, and MMP Reporting Requirements

A. 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 has reviewed, understands, and complies with the Reporting Requirements Guidance that is posted on the www.cms.gov/ website.		
2. The Applicant has reviewed, understands, and complies with requirements for reporting financial and business transaction information to CMS, including those contained in 42 CFR §§422.516(b), 423.514(b) and 423.501.		
3. The Applicant's PBM provides information related to PBM transparency as specified in section 1150A of the Act and 42 CFR §§423.514(d) and (e).		

3.16. Data Exchange between Medicare-Medicaid Plan Sponsor and CMS 42 CFR §§422.310, 422.504(b) and (l), 423.322, and 423.505(c) and (k)

A. In HPMS, complete the table below:

Attest 'yes' or 'no' to the following qualification by clicking on the appropriate response in HPMS:	Yes	No
HPMS		
1. Applicant uses HPMS to communicate with CMS in support of the application process, formulary submission process, bid submission process, ongoing operations of its Medicare-Medicaid plan, and reporting and oversight activities. Medicare-Medicaid plan sponsors are required to secure access to HPMS in order to carry out these functions.		
Enrollment & Payment		
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 Systems link.		
Data Exchange		
3. Applicant has reviewed, understands, and complies with all requirements related to data exchange between sponsors and CMS, including those contained in 42 CFR §§422.504(b) and (l),		

423.505(c) and (k).		
4. 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, and discrepancy records.		
5. In accordance with 42 CFR §422.310, the Applicant provides CMS with encounter data for each item and service provided to its enrollees.		

3.17. Health Insurance Portability and Accountability Act of 1996 (HIPAA), Health Information Technology for Economic and Clinical Health Act (HITECH Act), 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:

Attest 'yes' or 'no' to the following qualification by clicking on the appropriate response in HPMS:	**Yes**	**No**
1. Applicant has reviewed, understands, and complies with all applicable standards, implementation specifications, and requirements in the Standards for Privacy of Individually Identifiable Health Information, and Security Standards, Standards for Electronic Transactions, and the Standard Unique Identifier for Health Care Providers under 45 CFR Parts 160, 162, and 164.		
2. Applicant transmits payment and remittance advice consistent with the HIPAA-adopted ACS X12N 835, Version 5010: Health Care Claim Payment and Remittance Advice Implementation Guide ("835").		
3. 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.		

3.18. 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:

Attest 'yes' or 'no' to the following qualification by clicking on the appropriate response in HPMS:	Yes	No
1. Applicant does not use an enrollee's Social Security Number (SSN) or Medicare ID Number on the enrollee's identification card.		

3.19. Record Retention 42 CFR §§422.504(d) and (i), 423.505(d) and (i)

A. 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. The applicant maintains, and requires its first tier, downstream, and related entities to maintain, books, records, documents, and other evidence of accounting procedures and practices consistent with 42 CFR §§422.504(d) and (i) and 423.505(d) and (i).		

3.20. Prescription Drug Event (PDE) Records; 42 CFR Part 423 Subpart G; CMS issued guidance 04/27/06, 06/23/06, 12/17/10, 03/01/11, 03/04/11, 04/28/11, 05/16/11, 02/04/13

Attest 'yes' or 'no' to the following qualification by clicking on the appropriate response in HPMS:	Yes	No
1. Applicant has reviewed, understands, and complies with CMS requirements and guidance related to submission of PDE data, including 42 CFR Part 423 Subpart G, the 2008 Regional Prescription Drug Event Data Participant Training Guide and Technical Assistance Resource Guide (www.csscoperations.com/new/pdic/pdd-training/pdd-training.html) and related guidance.		
2. Applicant meets all data submission deadlines.		
3. Applicant pays all Plan-to-Plan payables on time.		

3.21. Claims Processing; 42 CFR §§ 422.520, 423.120(c)(4), 42 CFR §423.466; CMS issued guidance 04/26/06, 01/13/10, and 03/29/10

A. In HPMS, complete the table below:

Attest 'yes' or 'no' to the following qualification by clicking on the appropriate response in HPMS:	Yes	No
Applicant has reviewed, understands, and complies with all requirements related to processing of electronic and paper claims contained in 42 CFR §§422.520, 423.120(c)(4), 423.466, & 423.520 and all related CMS guidance.		

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

A. 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 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 on contracting with approved CAHPS survey vendors.		

Upload in HPMS MMP Supporting Files Contracting/Experience/History, in a .pdf format, the following certification:

4. MEDICARE-MEDICAID PLAN 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 three-way contract with CMS and my respective State, I will abide by the requirements contained in Sections 3 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 that preclude full compliance by January 1 of the upcoming contract year with the requirements stated here in this application as well as the requirements of 42 CFR Parts 422 and 423.
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 capitated financial alignment contract with CMS and the respective State.
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. My organization will comply with such

guidance, as applicable, should it be approved for a capitated financial alignment contract.

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

5. APPENDICES

APPENDIX I --Organization Background and Structure

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

1. 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.)

2. 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 §§ 422.506(a)(5), 422.508(d), 422.510(e)(2), 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.

3. Parent Organization Information

Name of Parent Organization

Date Parent Organization established

4. 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 (e.g., marketing, compliance, pharmacy network/contracting, and claims adjudication). Do not provide the internal structure of the parent organization.

APPENDIX II -- Crosswalks of Prescription Drug Benefit Requirements in Part D-Related First Tier, Downstream and Related Entity Contracts

INSTRUCTIONS: Applicants must complete and upload in HPMS the following chart for each contract/administrative services agreement submitted under Section 3.2.1F. Applicants must identify where specifically (i.e., the pdf page number) in each contract/administrative services agreement the following elements are found.

Requirement	**Location in Subcontract by Page number and Section**
The parties to the contract. If the Applicant is not a party to the contract, it must be identified as an entity that will benefit from the services described in the contract.	
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)	
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).	
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 Medicare-Medicaid plan sponsor. 42 CFR §423.505(i)(3)(iii)	
The payment the first tier, downstream, or related entity will receive for performance under the contract, if applicable.	
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).	

Are signed by a representative of each party with legal authority to bind the entity.	
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)	
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.	
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 Medicare-Medicaid plan 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	
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)	
Language ensuring that if the Applicant, upon becoming a Medicare-Medicaid plan 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 Medicare-Medicaid plan 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)	
Language specifying that the Applicant, upon becoming a Medicare-Medicaid plan sponsor, will monitor the performance of the first tier, downstream, or related entity on an ongoing basis. 42 CFR §423.505(i)(4)(iii)	
Language that the Medicare-Medicaid plan 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)	
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)	
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 Medicare-Medicaid plan sponsor for the prescription drug pricing standard of reimbursement. 42 CFR §423.505(i)(3)(viii)(B)	
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)	
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 Medicare-Medicaid plan 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)	
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 42 CFR 423.514(d) and (e).	

APPENDIX III – Crosswalk for Retail Pharmacy Access Contracts

INSTRUCTIONS: Applicants must complete and upload in HPMS the following chart (which contains applicable Section 3.2.1G requirements AND additional requirements specific to Pharmacy Access) for each Retail pharmacy contract template submitted under Section 3.5. 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.	
Requirement	**Citation**
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 3.2.1F of the application has to the Applicant. 42 CFR §423.505(i)(4)(i)	
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)	
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.	
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 Medicare-Medicaid plan 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	
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)	
Language ensuring that if the Applicant, upon becoming a Medicare-Medicaid plan 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 Medicare-Medicaid plan 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)	
Language specifying that the Applicant, upon becoming a Medicare-Medicaid plan sponsor, will monitor the performance of the first tier, downstream, or related entity on an ongoing basis. 42 CFR §423.505(i)(4)(iii)	
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)	
For those contracts that use a prescription drug pricing standard for reimbursement, a provision indicating the source used by the Medicare-Medicaid plan sponsor for the prescription drug pricing standard of reimbursement. 42 CFR §423.505(i)(3)(viii)(B)	
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)	
Language requiring the network pharmacy to submit claims to the Medicare-Medicaid plan 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)	
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.	
Provisions governing providing Medicare-Medicaid plan sponsor enrollees access to negotiated prices as defined in 42 CFR 423.100. 42 CFR §423.104(g)	
Provisions regarding charging/applying the correct cost-sharing amount. 42 CFR §423.104	

Provisions governing informing the Medicare-Medicaid plan sponsor 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 3.2.1G requirements AND additional requirements specific to Pharmacy Access) for each Mail Order pharmacy contract template submitted under Section 3.5. 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.	
Requirement	**Citation**
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 3.2.1F of the application has to the Applicant. 42 CFR §423.505(i)(4)(i)	
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)	
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.	
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 Medicare-Medicaid plan 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	
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)	
Language ensuring that if the Applicant, upon becoming a Medicare-Medicaid plan 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 Medicare-Medicaid plan 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)	
Language specifying that the Applicant, upon becoming a Medicare-Medicaid plan sponsor, will monitor the performance of the first tier, downstream, or related entity on an ongoing basis. 42 CFR §423.505(i)(4)(iii)	
For those contracts that use a prescription drug pricing standard for reimbursement, a provision indicating the source used by the Medicare-Medicaid plan sponsor for the prescription drug pricing standard of reimbursement. 42 CFR §423.505(i)(3)(viii)(B)	
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)	
Language requiring the network pharmacy to submit claims to the Medicare-Medicaid plan 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)	

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.	
Provisions governing providing Medicare-Medicaid plan sponsor enrollees access to negotiated prices as defined in 42 CFR 423.100. 42 CFR §423.104(g)	
Provisions regarding charging/applying the correct cost-sharing amount. 42 CFR §423.104	
Provisions governing informing the Medicare-Medicaid plan sponsor 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 3.2.1G requirements AND additional requirements specific to Pharmacy Access) for each Home Infusion pharmacy contract template submitted under Section 3.5. 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.	
Requirement	**Citation**
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 3.2.1F of the application has to the Applicant. 42 CFR §423.505(i)(4)(i)	
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)	
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.	
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 Medicare-Medicaid plan 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	
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)	
Language ensuring that if the Applicant, upon becoming a	

Medicare-Medicaid plan 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 Medicare-Medicaid plan 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)	
Language specifying that the Applicant, upon becoming a Medicare-Medicaid plan sponsor, will monitor the performance of the first tier, downstream, or related entity on an ongoing basis. 42 CFR §423.505(i)(4)(iii)	
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)	
For those contracts that use a standard for reimbursement, a provision indicating the source used by the Medicare-Medicaid plan sponsor for the standard of reimbursement. 42 CFR §423.505(i)(3)(viii)(B)	
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)	
Language requiring the network pharmacy to submit claims to the Capitated Financial Alignment plan 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)	
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.	
Provisions governing providing Medicare-Medicaid plan sponsor enrollees access to negotiated prices as defined in 42 CFR	

423.100. 42 CFR §423.104(g)	
Provisions regarding charging/applying the correct cost-sharing amount. 42 CFR §423.104	
Provisions governing informing the Medicare-Medicaid plan sponsor 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	
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)	
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 3.2.1G requirements AND additional requirements specific to Pharmacy Access) for each Long-Term Care pharmacy contract template submitted under Section 3.5. 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.	
Requirement	**Citation**
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 3.2.1F of the application has to the Applicant. 42 CFR §423.505(i)(4)(i)	
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)	
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	
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 Medicare-Medicaid plan 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	

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)	
Language ensuring that if the Applicant, upon becoming a Medicare-Medicaid plan 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 Medicare-Medicaid plan 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)	
Language specifying that the Applicant, upon becoming a Medicare-Medicaid plan sponsor , will monitor the performance of the first tier, downstream, or related entity on an ongoing basis. 42 CFR §423.505(i)(4)(iii)	
For those contracts that use a standard for reimbursement, a provision indicating the source used by the Medicare-Medicaid plan sponsor for the standard of reimbursement. 42 CFR §423.505(i)(3)(viii)(B)	
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)	
Language requiring the network pharmacy to submit claims to the Medicare-Medicaid plan 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)	
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.	
Provisions governing providing Part D enrollees access to negotiated prices as defined in 42 CFR §423.100. 42 CFR §423.104(g)	
Provisions regarding charging/applying the correct cost-sharing amount. 42 CFR §423.104	

Provisions governing informing the Medicare-Medicaid plan sponsor 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 Medicare-Medicaid plan 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 3.2.1G requirements AND additional requirements specific to Pharmacy Access) for each I/T/U pharmacy contract template submitted under Section 3.5. 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.

Requirement	Citation
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 3.2.1F of the application has to the Applicant. 42 CFR §423.505(i)(4)(i)	
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)	
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.	
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 Medicare-Medicaid plan 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	
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)	

Language ensuring that if the Applicant, upon becoming a Medicare-Medicaid plan 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 Medicare-Medicaid plan 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)	
Language specifying that the Applicant, upon becoming a Medicare-Medicaid plan sponsor, will monitor the performance of the first tier, downstream, or related entity on an ongoing basis. 42 CFR §423.505(i)(4)(iii)	
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)	
For those contracts that use a standard for reimbursement, a provision indicating the source used by the Medicare-Medicaid plan sponsor for the standard of reimbursement. 42 CFR §423.505(i)(3)(viii)(B)	
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)	
Language requiring the network pharmacy to submit claims to the Medicare-Medicaid plan 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)	

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.		
Provisions governing providing Medicare-Medicaid plan sponsor enrollees access to negotiated prices as defined in 42 CFR 423.100. 42 CFR §423.104(g)		
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 Medicare-Medicaid plan sponsor Applicant/Sponsor and PBM submission of P&T Committee membership, and the accountability that each Medicare-Medicaid plan sponsor Applicant/Sponsor holds regarding the integrity of the P&T Committee whose membership is submitted either directly by the Medicare-Medicaid plan sponsor Applicant/Sponsor or by the applicant/sponsor's PBM. This appendix also instructs Medicare-Medicaid plan sponsor 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).

1. P&T Committee Member Disclosure to CMS

As provided in the regulation at 42 CFR §423.120 (b)(1), a Medicare-Medicaid plan 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 Medicare-Medicaid plan sponsor or Plan and pharmaceutical manufacturers.

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

2. Instructions to Plans and PBMs

A. If the Medicare-Medicaid plan sponsor 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 Medicare-Medicaid plan sponsor Applicant) then the Applicant must (1) complete the attached Certification in HPMS MMP Supporting Files Contracting/Experience/History, and (2) forward the attached P&T Committee Member Disclosure form to the sub-contracted PBM and direct the PBM to submit the form to CMS by February 25, 2014. The PBM should email the P&T Committee

Member Disclosure form to the following email box: PartD_Applications@cms.hhs.gov.

B. In the event of any future changes to the membership of the Medicare-Medicaid plan sponsor 's P&T Committee or the PBM's P&T Committee, Medicare-Medicaid plan sponsors must (or in the case of a confidential agreement the Medicare-Medicaid plan sponsor) assure that the PBM will notify the appropriate CMS contract management team member (to be assigned at a future date) and make the correct changes in HPMS on the Contract Management/MMP Data page within 30 days of the effective date of such change.

3. PHARMACY AND THERAPEUTICS COMMITTEE MEMBER DISCLOSURE

PBM must email the following form to PartD_Applications@cms.hhs.gov by February 25, 2014.

Name of Medicare-Medicaid plan sponsor or PBM:
_____
If Medicare-Medicaid plan sponsor, provide Medicare-Medicaid plan sponsor 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 Medicare-Medicaid plan sponsor.

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 MEDICARE-MEDICAID PLAN 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.

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 Medicare-Medicaid Plan 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 specifically (i.e., the .pdf page number) where in its compliance plan the following elements are located.	
Compliance Plan Elements	**Page, paragraph where element located**
A. Applicant's legal entity name	
B. Explicit statement indicating that the compliance plan applies to Medicare Part D, Medicare Advantage and the Capitated Financial Alignment Model.	
C. Written policies, procedures, and standards of conduct must include the following seven components in §§ 42 CFR 422.503(b)(4)(vi)(A) and 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.	
D. Measures that prevent, detect, and correct fraud, waste, and abuse (42 CFR §§ 422.503(b)(4)(vi) and 423.504(b)(4)(vi))	
E. Measures that prevent, detect, and correct noncompliance	

with CMS' program requirements (42 CFR §§ 422.503(b)(4)(vi) and 423.504(b)(4)(vi))	
F. 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 in §§ 42 CFR 422.503(b)(4)(vi)(B) and 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 Applicant, parent organization or corporate affiliate. The compliance officer may not be an employee of the 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 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 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.	
G. 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 in §§ 42 CFR 422.503(b)(4)(vi)(C) and 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.	
H. Establishment and implementation of effective lines of communication, ensuring confidentiality, as described in §§	

42 CFR 422.503(b)(4)(vi)(D) and 423.504(b) (4)(vi)(D):	
1. The compliance officer, members of the compliance committee, the Applicant's employees, managers and governing body.	
2. The 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.	
I. . Well-publicize disciplinary standards and implementation of procedures, which encourage good faith participation in the compliance program by all affected individuals. These standards must include the following policies per §§ 42 CFR 422.503(b)(4)(vi)(E) and 423.504(b) (4)(vi)(E):	
1. 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.	
J. . 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 Applicant, including first tier entities', compliance with CMS requirements and the overall effectiveness of the compliance program. §§ 42 CFR 422.503(b)(4)(vi)(F) and 423.504(b) (4)(vi)(F)	
K. . 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 per §§42 CFR 422.503(b)(4)(vi)(G) and 423.504(b) (4)(vi)(G):	

1. If the 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 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 Applicant should have procedures to voluntarily self-report potential fraud or misconduct related to the Financial Alignment program to CMS or its designee.	

APPENDIX XI – CMS State Certification Form

INSTRUCTIONS

(Medicare-Medicaid Plan State Certification Form)

General:

This form is required to be submitted with all Medicare-Medicaid plan sponsor applications. The Applicant is required to complete the items above the line (items 1 and 2), then forward the document to the appropriate State Agency Official who should complete those items below the line (items 3-6). 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 Medicare-Medicaid plan 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 Medicare-Medicaid plan 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 Medicare-Medicaid plan application will be based upon the organization's entire application that was submitted to CMS, including documentation of appropriate licensure.

Items 1 and 2 (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 Medicare-Medicaid plan 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 Medicare-Medicaid plan.

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 3 - 6 (to be completed by State Official):

3. List the reviewer's pertinent information in the event CMS needs to communicate with the individual conducting the review at the State level.
4. List the requested information regarding other State departments/agencies required to review requests for licensure.
5. 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.

6. 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.

MEDICARE-MEDICAID PLAN

STATE CERTIFICATION REQUEST

Applicants should complete items 1and 2.

1. Applicant Information (Organization that has applied for Medicare-Medicaid plan 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:

   Requested Service Area:

   _____

I certify that _____'s application to CMS is for the type of Medicare-Medicaid plan(s) and the service area(s) indicated above in questions 1and 2.

_____

Applicant

_____ _____

Date CEO/CFO Signature

_____

Title

(An appropriate State official must complete items 3-6.)

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 Medicare-Medicaid plans.

3. State official reviewing State Certification Request:

   Reviewer's Name: _____

   State Oversight/Compliance Officer: _____

   Agency Name: _____

   Address: _____

   Address: _____

   City/State: _____

   Telephone: _____

   E-Mail Address: _____

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

   Agency: _____

   Contact Person: _____

   Address: _____

   City/State: _____

   Telephone: _____

   E-Mail Address: _____

5. 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.

_____

6. 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 Medicare-Medicaid HMO product. The State is not being asked to verify plan eligibility for the Medicare-Medicaid 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 XII -- 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 contract/agreement template that will be used for the Applicant's first tier, downstream and related entity providers. Applicant should only provide the contract/agreement template that will be used in the future contracting with Medical Providers, Medical Group Providers, Hospital Providers, and Facility Providers.

Instructions:

1. Provide in HPMS, using a PDF format, a separate matrix for each county or partial county only if unique provider contract/agreement templates will be used for different counties.
2. At the top of each column enter the name of the medical provider/facility contract/arrangement template.
3. Designate if the medical provider/facility template is for a first tier contracted provider with a "(1)" next to the medical provider/facility name.
4. Designate downstream contract templates with a "(DS)".
5. For each provider contract/arrangement template, in the row listing each requirement, provide the page number where the provision that meets the regulatory requirement can be found in each of the contracts/agreements 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 Contract Required Provision Matrix for MMPs

CONTRACT #: _____

COUNTY: _____ STATE: _____

IPA/Group/Provider Name **Identify if first tier with a (1) next to name; Identify if downstream with a (DS) next to name.**					
CMS REGULATIONS – 42 CFR §422•	**Section/Page**	**Section/Page**	**Section/Page**	**Section/Page**	**Section/Page**
All Medical Provider Contracts (Medical Provider, Medical Group Provider, Hospital Provider, Facility Provider)					
<u>Right to Audit and Records Retention</u> 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 Applicant 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)					

IPA/Group/Provider Name **Identify if first tier with a (1) next to name; Identify if downstream with a (DS) next to name.**					
CMS REGULATIONS – 42 CFR §422•	**Section/Page**	**Section/Page**	**Section/Page**	**Section/Page**	**Section/Page**
<u>Confidentiality and Enrollee Record Accuracy</u> Comply with the confidentiality and enrollee record accuracy requirements, including : (1) abiding by all Federal and State laws regarding confidentiality and disclosure of medical records, or other health and enrollment information, (2) ensuring that medical information is released in accordance with applicable Federal or State law, or pursuant to court orders or subpoenas, (3) maintaining the records and information in an accurate and timely manner, and (4) ensuring timely access by enrollees to the records and information that pertain to them. §422.118 and §422.504(a)13					
<u>Hold Harmless</u> Prohibited from holding any enrollee liable for payment of any fees that are the legal obligation of the Applicant. §422.504(g)(1)(i);§422.504(i)(3)(i)					
<u>Hold Harmless for Medicare-Medicaid Plans</u> For all enrollees eligible for both Medicare and Medicaid, enrollees will not be held liable for Medicare Part A and B cost sharing. Specifically, Medicare Parts A and B services must be provided at zero cost-sharing as part of the integrated package of benefits.					

IPA/Group/Provider Name **Identify if first tier with a (1) next to name; Identify if downstream with a (DS) next to name.**					
CMS REGULATIONS – 42 CFR §422•	**Section/Page**	**Section/Page**	**Section/Page**	**Section/Page**	**Section/Page**
March 29, 2012 CMS Issued Guidance					
Consistent and Comply with Applicant's Contractual Obligations Any services or other activity performed are consistent and comply with the Applicant's contractual obligations. §422.504(i)(3)(iii)					
Prompt Payment The Applicant is obligated to pay contracted medical providers under the terms of the contract between the Applicant and the medical provider. The contract must contain a prompt payment provision, the terms of which are developed and agreed to by both the Applicant and the relevant medical provider. §422.520(b)					
Cultural Considerations Written arrangements must include a provision that services are provided in a culturally competent manner to all enrollees, including those with limited English proficiency or reading skills, and diverse					

IPA/Group/Provider Name **Identify if first tier with a (1) next to name; Identify if downstream with a (DS) next to name.**					
CMS REGULATIONS – 42 CFR §422•	**Section/Page**	**Section/Page**	**Section/Page**	**Section/Page**	**Section/Page**
cultural and ethnic backgrounds. §422.112(a)(8)					
Delegated Activities – Selection of Providers If the Applicant delegates a selection of providers, written arrangements must state that the Applicant retains the right to approve, 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 Applicant determines that such parties have not performed satisfactorily. §422.504(i)(4)(ii)					

IPA/Group/Provider Name **Identify if first tier with a (1) next to name; Identify if downstream with a (DS) next to name.**					
CMS REGULATIONS – 42 CFR §422•	**Section/Page**	**Section/Page**	**Section/Page**	**Section/Page**	**Section/Page**
Delegated Activities – Monitoring Agreement provides that the performance of the parties is monitored by the Applicant 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 Applicant OR the credentialing process will be reviewed and approved by the Applicant and the Applicant must audit the credentialing process on an ongoing basis. §422.504(i)(4)(iv)					
Compliance with Applicable Medicare Laws and Regulations Must comply with all applicable Medicare laws, regulations, and CMS instructions. §422.504(i)(4)(v)					
Effective Date of Contract (e.g., January 1, 2014-December 31, 2014, or automatic renewal provision)					

IPA/Group/Provider Name **Identify if first tier with a (1) next to name; Identify if downstream with a (DS) next to name.**					
CMS REGULATIONS – 42 CFR §422•	**Section/Page**	**Section/Page**	**Section/Page**	**Section/Page**	**Section/Page**
Scope of Contract (incorporate Medicare-Medicaid population)					

Appendix XIII – Medical Benefit Administrative/ Management Delegated Contracting Matrix for MMPs

(For contracts and/or agreements that directly relate to Applicant's core functions under its contract with CMS – see Medicare Medical Benefit First Tier, Downstream and Related Entities Function Chart (Section 3.2.1C) of the Capitated Financial Alignment Application)

Instructions for Medical Benefit Administrative/Management Delegated Contracting Matrix

Applicants must complete this matrix to indicate (by Section/Page) on each fully executed administrative contract complies with the required Medicare provisions as listed in the Matrix. Applicants are only required to upload the executed administrative contracts and corresponding matrix for the following functions:

- Administrative/Management Staffing
- Claims Administration, Processing and/or Adjudication
- Utilization and/or Quality Improvement Operations
- Part C Call Center Operations
- Health Risk Assessments

Instructions:

1. Enter the name of the administrative contractor with which the Applicant has a fully executed agreement for the specified core functions.
2. Enter the section and/or page number within each column on which that fully executed agreement includes the required Medicare provision.

Medical Benefit Administrative/ Management Delegated Contracting Matrix for MMPs

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 Applicant 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 of Records** Providers and suppliers agree to safeguard beneficiary privacy and confidentiality 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 Applicant. §422.504(g)(1)(i); §422.504(i)(3)(i)					

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: Compliance with Applicant's contractual obligations A provision requiring that any services performed will be consistent and comply with the Applicant's contractual obligations with CMS and the State. §422.504(i)(3)(iii)					
Delegated Activities: Selection of Providers If the Applicant delegates the selection of providers, written arrangements must state the Applicant retains the right to approve, 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					

NAME OF CONTRACTOR (FIRST TIER, DOWNSTREAM and RELATED ENTITY)					
CMS REGULATIONS – 42 CFR §422*	**Section/Page**	**Section/Page**	**Section/Page**	**Section/Page**	**Section/Page**
reporting requirements or specifies other remedies in instances when CMS or the Applicant 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 Applicant on an ongoing basis. §422.504(i)(3)(ii); §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 Applicant OR the credentialing process will be reviewed and approved by the Applicant; and the Applicant 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					

NAME OF CONTRACTOR (FIRST TIER, DOWNSTREAM and RELATED ENTITY)					
CMS REGULATIONS – 42 CFR §422*	**Section/Page**	**Section/Page**	**Section/Page**	**Section/Page**	**Section/Page**
CMS instructions. §422.504(i)(4)(v)					
<u>Scope of Contract</u> Must incorporate the Medicare-Medicaid population. Contracts that are limited in scope to D-SNP products are not broad enough in scope.					
Dated and Signed					

*In addition to the CFR citations provided above, the following contract provisions are required in agreements between Applicants and provider and suppliers of health care as stated in Chapter 11, section 100.4 of the Medicare Managed Care Manual.

******This provision is not required in administrative agreements where the first tier, downstream or related entity does perform a function that directly interacts with beneficiaries.

Appendix XIV – MMP Model of Care Matrix Upload Document

Please complete and upload this document into HPMS per HPMS MMP Application User Guide instructions.

Applicant's Contract Name (as provided in HPMS)	Insert Contract Name Here
Applicant's CMS Contract Number	Insert Contract Number Here

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	**Document Page Number/Section**
1. Description of the MMP Population: The identification and comprehensive description of the MMP-specific population is an integral component of the MOC because all of the other elements depend on the firm foundation of a comprehensive population description. It must provide an overview that fully addresses the full continuum of care of current and potential MMP beneficiaries, including end-of-life needs and considerations, if relevant to the target population served by the MMP. The description of the MMP population must include, but not be limited to, the following:	
• Clear documentation of how the health plan staff determines or will determine, verify, and track eligibility of MMP beneficiaries.	
• A detailed profile of the medical, social, cognitive, environmental, living conditions, and co-morbidities associated with the MMP population in the plan's geographic service area.	
• Identification and description of the health conditions impacting MMP beneficiaries, including specific information about other characteristics that affect health such as, population demographics (e.g. average age, gender, ethnicity, and potential health disparities associated with specific groups such as: language barriers, deficits in health literacy, poor socioeconomic status, cultural beliefs/barriers, caregiver considerations, other).	
• Define unique characteristics for the MMP population served, including the unique health needs for beneficiaries enrolled in an MMP. Include limitations and barriers that pose potential challenges for these MMP enrollees.	
A. Sub-Population: Most Vulnerable Beneficiaries You must include a complete description of the specially-tailored services for beneficiaries considered especially vulnerable using specific terms and details (e.g., members with multiple hospital admissions within three months, "medication spending above $4,000"). Other information specific to the description of the most vulnerable beneficiaries must include, but not be limited to, the following:	
• A description of the internal health plan procedures for identifying the most vulnerable beneficiaries within the MMP.	

• A description of the relationship between the demographic characteristics of the most vulnerable beneficiaries with their unique clinical requirements. Explain in detail how the average age, gender, ethnicity, language barriers, deficits in health literacy, poor socioeconomic status and other factor(s) affect the health outcomes of the most vulnerable beneficiaries.	
• The identification and description of the established partnerships with community organizations that assist in identifying resources for the most vulnerable beneficiaries, including the process that is used to support continuity of community partnerships and facilitate access to community services by the most vulnerable beneficiaries and/or their caregiver(s).	
2. Care Coordination: Care coordination helps ensure that MMP beneficiaries' healthcare needs, preferences for health services and information sharing across healthcare staff and facilities are met over time. Care coordination maximizes the use of effective, efficient, safe, and high-quality patient services that ultimately lead to improved healthcare outcomes, including services furnished outside the MMP's provider network. The following MOC sub-elements are essential components to consider in the development of a comprehensive care coordination program; no sub-element must be interpreted as being of greater importance than any other. All five sub-elements below, taken together, must comprehensively address the MMPs' care coordination activities.	
A. MMP Staff Structure Fully define the MMP staff roles and responsibilities across all health plan functions that directly or indirectly affect the care coordination of beneficiaries enrolled in the MMP. This includes, but is not limited to, identification and detailed explanation of:	
• Specific employed and/or contracted staff responsible for performing administrative functions, such as: enrollment and eligibility verification, claims verification and processing, other.	
• Employed and/or contracted staff that perform clinical functions, such as: direct beneficiary care and education on self-management techniques, care coordination, pharmacy consultation, behavioral health counseling, other.	
• Employed and/or contracted staff that performs administrative and clinical oversight functions, such as: license and competency verification, data analyses to ensure appropriate and timely healthcare services, utilization review, ensuring that providers use appropriate clinical practice guidelines and integrate care transitions protocols.	
• Provide a copy of the MMP's organizational chart that shows how staff responsibilities identified in the MOC are coordinated with job titles. If applicable, include a description of any instances when a change to staff title/position or level of accountability was required to accommodate operational changes in the MMP.	
• Identify the MMP contingency plan(s) used to ensure ongoing continuity of critical staff functions.	
• Describe how the MMP conducts initial and annual MOC training for its employed and contracted staff, which may include, but not be limited to, printed instructional materials, face-to-face training, web-based instruction, and audio/video-conferencing.	
• Describe how the MMP documents and maintains training records as evidence to ensure MOC training provided to its employed and contracted staff was completed. For example, documentation may include, but is not limited to: copies of dated attendee lists, results of MOC competency testing, web-based attendance confirmation, and electronic training records.	

• Explain any challenges associated with the completion of MOC training for MMP employed and contracted staff and describe what specific actions the MMP will take when the required MOC training has not been completed or has been found to be deficient in some way.	
B. Health Risk Assessment Tool (HRAT) The quality and content of the HRAT should identify the medical, functional, cognitive, psychosocial and mental health needs of each MMP beneficiary. The content of, and methods used to conduct the HRAT have a direct effect on the development of the Individualized Care Plan and ongoing coordination of Interdisciplinary Care Team activities; therefore, it is imperative that the MOC include the following**:**	
• A clear and detailed description of the policies and procedures for completing the HRAT including:	
○ Description of how the HRAT is used to develop and update, in a timely manner, the Individualized Care Plan (MOC Element 2C) for each beneficiary and how the HRAT information is disseminated to and used by the Interdisciplinary Care Team (MOC Element 2D).	
○ Detailed explanation for how the initial HRAT and annual reassessment are conducted for each beneficiary.	
○ Detailed plan and rationale for reviewing, analyzing, and stratifying (if applicable) the results of the HRAT, including the mechanisms to ensure communication of that information to the Interdisciplinary Care Team, provider network, beneficiaries and/or their caregiver(s), as well as other MMP personnel that may be involved with overseeing the MMP beneficiary's plan of care. If stratified results are used, include a detailed description of how the MMP uses the stratified results to improve the care coordination process.	
C. Individualized Care Plan (ICP)	
• The ICP components must include, but are not limited to: beneficiary self-management goals and objectives; the beneficiary's personal healthcare preferences; description of services specifically tailored to the beneficiary's needs; roles of the beneficiaries' caregiver(s); and identification of goals met or not met.	
○ When the beneficiary's goals are not met, provide a detailed description of the process employed to reassess the current ICP and determine appropriate alternative actions.	
• Explain the process and which MMP personnel are responsible for the development of the ICP, how the beneficiary and/or his/her caregiver(s) or representative(s) is involved in its development and how often the ICP is reviewed and modified as the beneficiary's healthcare needs change.	
• Describe how the ICP is documented and updated as well as, where the documentation is maintained to ensure accessibility to the ICT, provider network, beneficiary and/or caregiver(s).	
• Explain how updates and/or modifications to the ICP are communicated to the beneficiary and/or their caregiver(s), the ICT, applicable network providers, other MMP personnel and other stakeholders as necessary.	
D. Interdisciplinary Care Team (ICT)	

• Provide a detailed and comprehensive description of the composition of the ICT; include how the MMP determines ICT membership and a description of the roles and responsibilities of each member. Specify how the expertise and capabilities of the ICT members align with the identified clinical and social needs of the MMP beneficiaries, and how the ICT members contribute to improving the health status of MMP beneficiaries.	
○ Explain how the MMP facilitates the participation of beneficiaries and their caregivers as members of the ICT.	
○ Describe how the beneficiary's HRAT (MOC Element 2B) and ICP (MOC Element 2C) are used to determine the composition of the ICT, including those cases where additional team members are needed to meet the unique needs of the individual beneficiary.	
○ Explain how the ICT uses healthcare outcomes to evaluate established processes to manage changes and/or adjustments to the beneficiary's health care needs on a continuous basis.	
• Identify and explain the use of clinical managers, case managers or others who play critical roles in ensuring an effective interdisciplinary care process is being conducted.	
• Provide a clear and comprehensive description of the MMP's communication plan that ensures exchanges of beneficiary information is occurring regularly within the ICT, including not be limited to, the following:	
○ Clear evidence of an established communication plan that is overseen by MMP personnel who are knowledgeable and connected to multiple facets of the MMP MOC. Explain how the MMP maintains effective and ongoing communication between MMP personnel, the ICT, beneficiaries, caregiver(s), community organizations and other stakeholders.	
○ The types of evidence used to verify that communications have taken place, e.g., written ICT meeting minutes, documentation in the ICP, other.	
○ How communication is conducted with beneficiaries who have hearing impairments, language barriers and/or cognitive deficiencies.	
E. Care Transitions Protocols	
• Explain how care transitions protocols are used to maintain continuity of care for MMP beneficiaries. Provide details and specify the process and rationale for connecting the beneficiary to the appropriate provider(s).	
• Describe which personnel (e.g., case manager) are responsible for coordinating the care transition process and ensuring that follow-up services and appointments are scheduled and performed as defined in MOC Element 2A.	
• Explain how the MMP ensures elements of the beneficiary's ICP are transferred between healthcare settings when the beneficiary experiences an applicable transition in care. This must include the steps that need to take place before, during and after a transition in care has occurred.	
• Describe, in detail, the process for ensuring the MMP beneficiary and/or caregiver(s) have access to and can adequately utilize the beneficiaries' personal health information to facilitate communication between the MMP beneficiary and/or their caregiver(s) with healthcare providers in other healthcare settings and/or health specialists outside their primary care network.	

• Describe how the beneficiary and/or caregiver(s) will be educated about indicators that his/her condition has improved or worsened and how they will demonstrate their understanding of those indicators and appropriate self-management activities.	
• Describe how the beneficiary and/or caregiver(s) are informed about who their point of contact is throughout the transition process.	
3. MMP Provider Network: The MMP Provider Network is a network of healthcare providers who are contracted to provide health care services to MMP beneficiaries. Each MMP is responsible for ensuring their MOC identifies, fully describes, and implements the following for its MMP Provider Network:	
A. Specialized Expertise	
• Provide a complete and detailed description of the specialized expertise available to MMP beneficiaries in the MMP provider network that corresponds to the MMP population identified in MOC Element 1.	
• Explain how the MMP oversees its provider network facilities and ensures its providers are actively licensed and competent (e.g., confirmation of applicable board certification) to provide specialized healthcare services to MMP beneficiaries. Specialized expertise may include, but is not limited to: internal medicine, endocrinologists, cardiologists, oncologists,, mental health specialists, other.	
• Describe how providers collaborate with the ICT (MOC Element 2D) and the beneficiary, contribute to the ICP (MOC Element 2C) and ensure the delivery of necessary specialized services. For example, describe: how providers communicate MMP beneficiaries' care needs to the ICT and other stakeholders; how specialized services are delivered to the MMP beneficiary in a timely and effective way; and how reports regarding services rendered are shared with the ICT and how relevant information is incorporated into the ICP.	
B. Use of Clinical Practice Guidelines & Care Transitions Protocols	
• Explain the processes for ensuring that network providers utilize appropriate clinical practice guidelines and nationally-recognized protocols. This may include, but is not limited to: use of electronic databases, web technology, and manual medical record review to ensure appropriate documentation.	
• Define any challenges encountered with overseeing patients with complex healthcare needs where clinical practice guidelines and nationally-recognized protocols may need to be modified to fit the unique needs of vulnerable MMP beneficiaries. Provide details regarding how these decisions are made, incorporated into the ICP (MOC Element 2C), communicated with the ICT (MOC Element 2D) and acted upon.	
• Explain how MMP providers ensure care transitions protocols are being used to maintain continuity of care for the MMP beneficiary as outlined in MOC Element 2E.	
C. MOC Training for the Provider Network	
• Explain, in detail, how the MMP conducts initial and annual MOC training for network providers and out-of-network providers seen by beneficiaries on a routine basis. This could include, but not be limited to: printed instructional materials, face-to-face training, web-based instruction, audio/video-conferencing, and availability of instructional materials via the MMP plan's website.	

• Describe how the MMP documents and maintains training records as evidence of MOC training for their network providers. Documentation may include, but is not limited to: copies of dated attendee lists, results of MOC competency testing, web-based attendance confirmation, electronic training records, and physician attestation of MOC training.	
• Explain any challenges associated with the completion of MOC training for network providers and describe what specific actions the MMP Plan will take when the required MOC training has not been completed or is found to be deficient in some way.	
4. MOC Quality Measurement & Performance Improvement: The goals of performance improvement and quality measurement are to improve the MMP's ability to deliver healthcare services and benefits to its MMP beneficiaries in a high-quality manner. Achievement of those goals may result from increased organizational effectiveness and efficiency by incorporating quality measurement and performance improvement concepts used to drive organizational change. The leadership, managers and governing body of a MMP organization must have a comprehensive quality improvement program in place to measure its current level of performance and determine if organizational systems and processes must be modified based on performance results.	
A. MOC Quality Performance Improvement Plan Explain, in detail, the quality performance improvement plan and how it ensures that appropriate services are being delivered to MMP beneficiaries. The quality performance improvement plan must be designed to detect whether the overall MOC structure effectively accommodates beneficiaries' unique healthcare needs. The description must include, but is not limited to, the following:	
• The complete process, by which the MMP continuously collects, analyzes, evaluates and reports on quality performance based on the MOC by using specified data sources, performance and outcome measures.	
• Details regarding how the MMP leadership, management groups and other MMP personnel and stakeholders are involved with the internal quality performance process.	
• Details regarding how the MMP-specific measurable goals and health outcomes objectives are integrated in the overall performance improvement plan (MOC Element 4B).	
B. Measureable Goals & Health Outcomes for the MOC Identify and clearly define the MMP's measureable goals and health outcomes and describe how identified measureable goals and health outcomes are communicated throughout the MMP organization. Responses should include but not be limited to, the following:	
• Specific goals for improving access and affordability of the healthcare needs outlined for the MMP population described in MOC Element 1.	
• Improvements made in coordination of care and appropriate delivery of services through the direct alignment of the HRAT, ICP, and ICT.	
• Enhancing care transitions across all healthcare settings and providers for MMP beneficiaries.	
• Ensuring appropriate utilization of services for preventive health and chronic conditions.	
• Identify the specific beneficiary health outcomes measures that will be used to measure overall MMP population health outcomes, including the specific data source(s) that will be used.	

• Describe, in detail, how the MMP establishes methods to assess and track the MOC's impact on the MMP beneficiaries' health outcomes.	
• Describe, in detail, the processes and procedures the MMP will use to determine if the health outcomes goals are met or not met.	
• Explain the specific steps the MMP will take if goals are not met in the expected time frame.	
C. Measuring Patient Experience of Care (MMP Member Satisfaction)	
• Describe the specific MMP survey(s) used and the rationale for selection of that particular tool(s) to measure MMP beneficiary satisfaction.	
• Explain how the results of MMP member satisfaction surveys are integrated into the overall MOC performance improvement plan, including specific steps to be taken by the MMP to address issues identified in response to survey results.	
D. Ongoing Performance Improvement Evaluation of the MOC	
• Explain, in detail, how the MMP will use the results of the quality performance indicators and measures to support ongoing improvement of the MOC, including how quality will be continuously assessed and evaluated.	
• Describe the MMP's ability to improve, on a timely basis, mechanisms for interpreting and responding to lessons learned through the MOC performance evaluation process.	
• Describe how the performance improvement evaluation of the MOC will be documented and shared with key stakeholders.	
E. Dissemination of MMP Quality Performance related to the MOC	
• Explain, in detail, how the MMP communicates its quality improvement performance results and other pertinent information to its multiple stakeholders, which may include, but not be limited to: MMP leadership, MMP management groups, MMP boards of directors, MMP personnel & staff, MMP provider networks, MMP beneficiaries and caregivers, the general public, and regulatory agencies on a routine basis.	
• This description must include, but is not limited to, the scheduled frequency of communications and the methods for ad hoc communication with the various stakeholders, such as: a webpage for announcements; printed newsletters; bulletins; and other announcement mechanisms.	
• Identify the individual(s) responsible for communicating performance updates in a timely manner as described in MOC Element 2A.	
NOTE TO APPLICANT: The following rows will capture any additional MOC elements required by the state in which your Medicare-Medicaid 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 elements cms will review.	

Additional Element #1		
Additional Element #2		
Additional Element #3		

Additional Element #4		
Additional Element #5		
Please complete and upload this document into HPMS, in the MMP Supporting Files Model of Care Upload section.		

Appendix XV – 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 MMP 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 Medicare-Medicaid 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 Medicare-Medicaid 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.