2024 CAPITATED FINANCIAL ALIGNMENT MODEL APPLICATION

Initial Medicare-Medicaid Plan and Expansion of Existing Contracts

1. GENERAL INFORMATION

1.1. Purpose of Application

The Centers for Medicare & Medicaid Services (CMS) is accepting applications from qualified entities to enter into contracts with the CMS and applicable States to offer integrated Medicare and Medicaid services to dual eligible beneficiaries. This application must be used for all organizations seeking to offer new Medicare-Medicaid Plans or seeking to expand the service area of existing contracts in applicable demonstrations under the Medicare-Medicaid Financial Alignment Initiative. Please submit your application according to the process described in Section 2.0.

1.2. Background

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 Alignment Initiative. Through this Initiative, CMS created two approaches to align financing between the Medicare and Medicaid programs while preserving or enhancing the quality of care furnished to dual eligible beneficiaries. 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 enter into a three-way contract through which the Medicare-Medicaid Plan (MMP) receives 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 enter into an agreement by which the State is 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 dual eligible beneficiaries.

MMPs will receive a blended capitated rate for the full continuum of benefits provided to dual eligible beneficiaries 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.

New organizations seeking to become MMPs in existing demonstrations will be selected through a joint process with the States and CMS. This application incorporates the CMS Medicare criteria for prescription drug coverage and Medicare A and B services. This application is only for entities seeking to operate a new MMP in applicable demonstrations or existing MMPs seeking to add existing demonstration counties into its service area. Organizations that currently operate an MMP and are not seeking to expand its service area for 2024 do not need to complete this application.

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1.4. Schedule

Note: This schedule follows, to the extent applicable, the same dates as used by Medicare Advantage and Part D.

APPLICATION REVIEW PROCESS	
Date	**Milestone**
November 10, 2022	Recommended date by which Applicants should submit their Notice of Intent to Apply Form to CMS to ensure access to Health Plan Management System (HPMS) by the date applications are released.
December 6, 2022	CMS User ID form due to CMS
January 2023	Final Application posted by CMS and available in HPMS
January 27, 2023	Deadline for NOIA form submission to CMS
February 15, 2023	Applications due
February 2023	CMS releases guidance concerning updates to Parent Organization designations in HPMS
March 2023	Parent Organization Update requests from sponsors due to CMS (instructional memo to be released in February 2023)
April 2023	Release of the 2024 Plan Benefit Package (PBP) online training module

April 2023	Release of the 2024 Plan Creation Module, PBP software in HPMS
April 2023	Release of the CY 2024 Medication Therapy Management Program (MTMP) submission module in HPMS
May 2023	MTMP submissions due
May 2023	Release of HPMS Part D formulary submission module for CY 2024
Late-May 2023	CMS sends contract eligibility determinations to Applicants, based on review of application.
May 2023	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 5, 2023	Submission of proposed PBPs due to CMS
June 5, 2023	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-June 2023	Kick-off call for Readiness Review process Start the Readiness Review desk review
Mid-July 2023	Readiness Review site visit
Early August 2023	CMS releases the 2024 Part D national average bid amount.
August 2023	MTMP reviews completed.
September 2023	CMS mails the CY 2024 *Medicare & You* handbook to Medicare beneficiaries.
September 2023	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 2024.
September 2023	Three-way contracts among selected plans, States, and CMS must be finalized and signed for a January 1 start date.
September 2023	Readiness Review determinations issued
October 2023	CY 2024 marketing activity begins for Medicare Advantage and Part D. Demonstration marketing will be specific to State MOUs.
October 2023	Medicare Plan Finder on www.medicare.gov goes live for CY 2024
October 15, 2023	2024 Annual Coordinated Election Period begins.
December 7, 2023	2024 Annual Coordinated Election Period ends.
January 1, 2024	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.

1.5. Summary of Application Approval, Plan Benefit Package Review, Readiness Review and Contracting Processes

There are four distinct phases to the overall review to determine whether CMS and the State will enter into a contract with an Applicant.

The first phase is the application review process. CMS will review all applications submitted on or by February 15, 2023 to determine whether the Applicant meets the Medicare qualifications we have established to begin the readiness review phase. Interested organizations will concurrently go through a competitive selective contracting process with a participating demonstration state.

The second phase has two steps – the formulary upload and bid upload which both begin in May 2023. The formulary review entails determining that the proposed formulary (if one is used):

- Has at least two drugs in every therapeutic category and class (unless special circumstances exist that would allow only one drug);
- Does not substantially discourage enrollment by certain types of Part D eligible individuals;

- Includes adequate coverage of the types of drugs most commonly needed by Part D enrollees;
- Includes all drugs in certain classes and categories as established by the Secretary; and
- Includes an appropriate transition policy.

CMS will contact Applicants if any issues are identified during the formulary review to provide an opportunity for applicants to make any necessary corrections prior to the PBP submission date. The second step involves the PBP review with Applicants and the respective demonstration states.

The third phase is contracting. Applicants judged qualified to meet the Medicare criteria that have also been selected by the State will be offered a three-way contract, the effectuation of which is contingent on the fourth phase.

The fourth phase is the readiness review. Applicants judged qualified to meet the Medicare criteria that have also been selected by the State will go through a readiness review process. The readiness review will further validate policies and procedures unique to the demonstration, have a site visit, submit contracted provider networks for Medicaid and Medicare covered services, and go through a pre-enrollment validation that will assess call center scripts and staffing. Applicants will not be eligible to market or enroll until a readiness determination has been provided by CMS and the State.

2. INSTRUCTIONS

2.1. Overview

This application is to be completed by those organizations that intend to offer a new Medicare-Medicaid Plan (MMP) or add coverage to an existing MMP during 2024.

2.2. Technical Assistance

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

Marla Rothouse by email at Marla.Rothouse@cms.hhs.gov, or by phone at 410-786-8063.

As stated in section 2.4.1, Applicants must contact the HPMS Help Desk if they are experiencing technical difficulties uploading or completing any part of this solicitation within HPMS prior to the submission deadline. Applicants requesting technical assistance with uploading or completing any part of the online HPMS application after the published CMS application deadline will not be granted technical assistance, nor the opportunity to complete their application submission.

2.3. Health Plan Management System (HPMS) Data Entry

Organizations that submit a Notice of Intent to Apply form for an initial application are assigned a pending contract number (H number) to use throughout the application and subsequent operational processes. Applicants seeking to expand coverage under an existing contract use the associated contract ID.

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.

2.4. Instructions and Format of Application

Applications may be submitted until February 15, 2023. Applicants must use the 2024 capitated financial alignment application. CMS will not accept or review any submissions using other Medicare applications (e.g., MA and Part D applications or earlier MMP applications).

2.4.1. 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.

Upon completion of the HPMS online application, organizations are required to click 'Final Submit,' which time and date stamps the completion of the application. No additional work on the application may be done after the Applicant clicks 'Final Submit.' 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.

2.4.2. 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.

2.4.3. Application Review Standard

CMS will check the application for completeness shortly after its receipt. Consistent with the rulemaking conducted in April 2011, CMS does not "review application that are submitted after the established deadline." 76 FR 21527 (April 15, 2011). CMS does not consider an application to be submitted when the materials submitted by the deadline are "so lacking in required information or correct detail as to fail to constitute a valid, timely submission." 76 FR 21527 (April 15, 2011). Some examples of invalid submissions include but are not limited to the following:

- Applicants that fail to upload executed administrative agreements or contract templates
- Applicants that upload contract crosswalks or matrices instead of contracts
- Applicants that fail to upload any pharmacy network lists

CMS will notify any organizations that are determined to have provided invalid submissions that they fail to meet the application deadline.

In accordance with 42 CFR §§ 422.502, 423.502, and 423.503, Applicants must demonstrate that they meet all (not "substantially all") program requirements to qualify as a MMP sponsor in the proposed service area.

2.4.4. 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 "Confirmation History" link on the My Application page in HPMS. 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 the start of marketing or enrollment by the selected plan for the demonstration.

CMS will not review applications received after 8:00 P.M. Eastern Daylight Time on February 15, 2023. CMS will lock access to application fields within HPMS as of that time. Applicants must complete the 2024 application in order to be considered to offer a plan under the capitated financial alignment in 2024.

2.4.5. 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.

2.4.6. Withdrawal of an Application

In those instances, in which an organization seeks to withdraw its submission of a pending application or reduce the service area of a pending application prior to the execution of the three-way 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, https://dmao.lmi.org (click on the MA Applications tab) and PartD_Applications@cms.hhs.gov and the subject line of the email should read "Pending application withdrawal or reduction to pending service area." The withdrawal will be considered effective as of the date of the email.

2.4.7. Technical Support

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

CMS provides two user manuals to assist applicants with the technical requirements of submitting the Part D application through the Health Plan Management System[1] (HPMS). The *Basic Contract Management User's Manual* provides information on completing and maintaining basic information required in Contract Management. The *My Application User 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.

2.4.8. References

References to CMS guidance is provided throughout the application. Links to specific manual chapters are included in the application to further assist Applicants.

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[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.

Applicants can also link to the Medicare Managed Care Manual table of contents at Medicare Managed Care Manual and the Prescription Drug Benefit Manual table of contents at Prescription Drug Benefit Manual. 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 Financial Alignment Initiative Guidance. Applicants should also familiarize themselves with the CMS Advance Notice that can be found at CMS Advance Notices.

Applicants should further familiarize themselves with the applicable three-way contracts that are currently in effect for the respective demonstration. The current three-way contracts can be found within each State link at the following website: Capitated Model State Demonstrations.

Note, that absence of any CMS issued guidance in this application does not preclude the applicability of such requirements.

2.5. 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 2023. 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.

Interested organizations will also submit a plan benefit package that details the Medicare, Medicaid and supplemental benefits they will offer for CY 2024. 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, state-specific 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.

2.6. System Access and Data Transmissions with CMS

2.6.1. 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.

Applicants and other interested parties, whom do not have access to HPMS, can stay abreast of current HPMS memos and guidance by subscribing to available listservs. Subscribers to the CMS Plan or Industry listservs receive memos and guidance regarding Medicare Advantage, Part D prescription drug, and Medicare-Medicaid Plan programs.

If you do not have access to HPMS but would like to receive CMS guidance and memos, simply request to be added to one of the following listservs:

- PLAN listserv: Choose this listserv to get HPMS guidance and memos if you are a user that works for an MA or Part D organization but your role in the company does not require HPMS access.
- INDUSTRY listserv: Choose this listserv if you are an industry user that is not associated with any existing MA or Part D organization, but work with MA and Part D in some capacity (e.g., consultants, PBMs, doctors, pharmacists, etc.).

Please email your request directly to Sara Walters at Sara.Walters@cms.hhs.gov. Please indicate in the email which listserv you wish you join. If you wish to join the PLAN listserv please provide the contract number(s) you are associated with.

2.6.2. 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, https://www.cms.gov/Research-Statistics-Data-and-Systems/CMS-Information-Technology/mapdhelpdesk/index.html, 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/Research-Statistics-Data-and-

[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.

Systems/CMS-Information-Technology/mapdhelpdesk/Plan-Reference-Guide-for-CMS-Part-C-D-Systems.html.

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 https://www.cms.gov/Research-Statistics-Data-and-Systems/CMS-Information-Technology/mapdhelpdesk/Plan_Communications_User_Guide.html). The MAPD Help Desk also provides additional system and technical information at https://www.cms.gov/Research-Statistics-Data-and-Systems/CMS-Information-Technology/mapdhelpdesk/index.html.

2.6.3. 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:

- Copy of a voided check or a letter from bank confirming the routing and account information
- W-9 Form

The completed Payment Information Form and supporting documentation must be emailed to DPO_PAYMENT_ADMINISTRATOR@cms.hhs.gov by the date the completed applications are due to CMS. The subject line of the email should be "Payment Information Form for [insert contract number]", and the Applicant should specify the effective date (month and year) in the body of the email.

If the Applicant has questions about this form, please contact Louise Matthews at (410) 786-6903.

2.7. Pharmacy Access

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

enrollees. 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.

2.7.1. 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 2023 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 2024. If the Applicant's retail pharmacy network is segmented (i.e., the Applicant has developed multiple networks for use in the same service area), the Applicant must submit the most restrictive (or, least accessible) network based on its executed contracts for 2023.

CMS conducts the review of retail pharmacy access based on the service area that the Applicant has provided in HPMS by February 15, 2023. The access review is automated. 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.

2.7.2. Home Infusion Pharmacy Access

Applicants must demonstrate that their contracted pharmacy network provides adequate access to home infusion pharmacies in accordance with 42 CFR §423.120(a)(4). In order to demonstrate adequate access to home infusion pharmacies, Applicants must provide a list of all contracted home infusion pharmacies (see section 3.5.4). CMS uses this pharmacy listing to compare Applicants' home infusion pharmacy network against existing Part D sponsors in the same service area to ensure that Applicants have contracted with an adequate number of home infusion pharmacies. The adequate number of home infusion pharmacies is developed based on data provided by all Part D sponsors through the annual Part D Reporting Requirements. A reference file entitled "*Adequate Access to Home Infusion Pharmacies*" is provided on the CMS website, http://www.cms.gov/PrescriptionDrugCovContra/04_RxContracting_ApplicationGuidance.html.

2.7.3. Long-Term Care Pharmacy Access

Applicants must demonstrate that their contracted pharmacy network provides convenient access to long-term care pharmacies in accordance with 42 CFR §423.120(a)(5). 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. To assist applicants with preparing their LTC pharmacy network, CMS provides the LTC Facilities List on the CMS website, http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxContracting_ApplicationGuidance.html.

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

Applicants must demonstrate that they have offered standard contracts to all I/T/U pharmacies residing within the Applicants' service areas in accordance with 42 CFR §423.120(a)(6). 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 ITU Pharmacies Reference File is located on the CMS website,

http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxContracting_ApplicationGuidance.html.

2.8. Health Service Delivery (HSD) Tables Instructions

Service area expansion Applicants are required to demonstrate Medicare network adequacy of the pending counties through the submission of HSD Tables for the Medicare medical services at the time of the application submission. Initial Applicants will complete the Medicare network submission as part of the readiness review process.

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 https://www.cms.gov/medicare-medicaid-coordination/medicare-and-medicaid-coordination/medicare-medicaid-coordination-office/financialalignmentinitiative/mmpinformationandguidance/informationandguidanceforplans 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.

SAE Applicants who do not believe that CMS default values for a given provider type in a given county are not in line with local patterns of care may seek an exception, in which case the Applicant will submit required information to support the exception(s) request.

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. Service Area Expansion Applicants

Current Medicare-Medicaid Plans seeking to expand the service area within an existing demonstration must complete the following sections of this application:

- Section 3.1
- Sections 3.2.1A.1, 3.2.1.A.4, 3.2.1.C, and 3.2.1.F
- Section 3.2.2
- Section 3.2.3.A
- Section 3.4.B
- Section 3.5.1.B
- Sections 3.5.3.A and B
- Section 3.5.4.A
- Section 3.5.5.B
- Sections 3.5.6. A and B
- Section 3.23
- Section 4

2.12. 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 capitated financial alignment demonstrations 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 three-way contract for the applicable demonstration, 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 My Application Module. Applicants should refer to the Contract Management – My Application User Guide for further instructions.

3.1. Service Area/Regions

References: *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/My Application>Contract Service Area/Service Area Data page, enter the state and county information for the area the Applicant proposes to serve.

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. Applicants seeking to serve a partial county must enter all service area information in HPMS by the application submission deadline. Organizations requesting partial county service areas for the first time (initial or SAE applicants) and organizations expanding a current partial county (SAE applicants) by one or more zip codes (when the resulting service area will continue to be a partial county) must submit their Partial County Justifications with their applications. Applicants cannot introduce a partial county request after the initial application submission. In other words, applicants cannot reduce a full-county request to a partial county request during the application review period. Similarly, applicants cannot expand a partial county request to a full-county request during the application review period.

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 and MMP Facility Table for SAE applicants and the pharmacy lists (initial and SAE applicants) that are provided as part of this application.

3.2. Applicant Experience, Contracts, Licensure and Financial Stability

3.2.1. Management and Operations

References: *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)*

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. Applicant attests that the organization is incorporated and recognized by the state of incorporation as of the initial application submission deadline.			
2. 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 continuous effect since January 1, 2022 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".) (For all Applicants) 42 CFR §§ 422.502(b)(2) and 423.503(b)(2)			

Attest 'yes,' 'no,' or 'NA' to the following qualification by clicking on the appropriate response in HPMS:	Yes	No	NA
3. The Applicant, its parent organization, a subsidiary of its parent organization, or its contracted first tier, downstream, or related entities have, in combination, at least one full year of experience within the past two years performing each of the following functions: - Authorization, adjudication, and processing of prescription drug claims at the point of sale. - Administration and tracking of enrollees' drug benefits in real time, including automated coordination of benefits with other payers. - Operation of an enrollee appeals and grievance process. (Not applicable for SAE Applicants) 42 CFR §423.504(b)(8)			
4. 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. (Not applicable for SAE Applicants)			
5. 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. (For all Applicants) 42 CFR §§ 422.504(i) and 423.505(i)			

Attest 'yes,' 'no,' or 'NA' to the following qualification by clicking on the appropriate response in HPMS:	Yes	No	NA
6. 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 (b), or whose contract CMS terminated pursuant to 42 CFR §422.510 or §423.509, 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, 2021. "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. (Not applicable for SAE Applicants)			

Attest 'yes,' 'no,' or 'NA' to the following qualification by clicking on the appropriate response in HPMS:	Yes	No	NA
7. Applicant has not had a contract terminated by CMS pursuant to 42 CFR §§ 422.510 and 423.509 since January 1, 2020 and does not have any covered persons who also served as covered persons for an entity whose contract was terminated by CMS pursuant to 42 CFR §§ 422.510 and 423.509 since January 1, 2020. "Covered persons", as defined at 42 CFR §§ 422.502(b)(4) and 423.503(b)(4) 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. (Not applicable for SAE applicants)			
8. Applicant has not filed for or been placed under bankruptcy proceedings. An organization that has filed or is currently under bankruptcy is deemed to have failed to comply with the requirements pursuant to 42 CFR §§ 422.502(b)(1)(i)(C) and 423.503(b)(1)(i)(C). (applicable for all Applicants)			

B. Except for SAE Applicants, 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. You must demonstrate that your organization was incorporated and recognized by the state of incorporation as of the date the application was due. (Not applicable for SAE Applicants)

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 Start Page>MMP Information>MMP Data,

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. Organizations applying for an SAE should ensure that the information in HPMS is up-to-date for the current contract year.

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 applicable requirements. CMS will not consider any other types of materials, including articles of incorporation, organizational charts, or lists of board members or senior executives, which the Applicant might believe demonstrate that the parent is authorized to contract on the applicant's behalf.

(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		

Function	First tier, Downstream and Related entities	Off-Shore yes/no
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. Except for SAE Applicants, 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 provisions enumerated in the Appendix entitled "CMS Medical Benefit Administrative/Management Delegated Contracting Crosswalk Template", as described below, as well as the additional provisions included in the applicable three-way contract Relationship with First Tier, Downstream, and Related Entities required provisions appendix located at https://www.cms.gov/medicare-medicaid-coordination/medicare-and-medicaid-coordination/medicare-medicaid-coordination-office/financialalignmentinitiative/mmpinformationandguidance/informationandguidanceforplans.

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. Contain language that indicates payment terms have been agreed upon with the first tier, downstream or related entity for performance under the contract if applicable (note: actual payment terms may be redacted)
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 obligating the first tier, downstream, or related entity to abide by State and Federal confidentiality and disclosure laws related to medical records, or other health and enrollment information. 42 CFR § 422.504(a)(13). (Note: this provision is not required in administrative agreements where the first tier, downstream, or related entity does not perform a function that directly interacts with beneficiaries)
11. Contain language ensuring that the first tier, downstream, or related entity will make its books and other records available in accordance with 42 CFR § 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)

12. Contain language that the first tier, downstream, or related entity will ensure that beneficiaries are not held liable for fees that are the responsibility of the Applicant. 42 CFR § 422.504(i)(3)(i)
13. 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)
14. 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)
15. 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)
16. 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. Except for SAE Applicants, upload in HPMS, MMP Supporting Files Medical Benefit Administrative Contracting, electronic lists of the contract/administrative service agreement/intercompany agreement citations demonstrating that the requirements of Section 3.2.1D 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 Medical Benefit Requirements of Administrative/Management Delegated Contracting Entities*. If the Applicant fails to upload crosswalks for executed agreements and contract templates, CMS cannot guarantee that the Applicant will receive notice of any deficiencies in the contracting documents as part of this courtesy review.

F. 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 Start Page>MMP Information>MMP Data, 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. Organizations applying for an SAE should ensure that the information in HPMS is up-to-date for the current contract year.

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 applicable requirements. CMS will not consider any other types of materials, including articles of incorporation, organizational charts, or lists of board members or senior executives, which the Applicant might believe demonstrate that the parent is authorized to contract on the applicant's behalf.

(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.		

Function	First tier, Downstream and Related entities	Off-Shore yes/no
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.		
Data Validation Contractor	**For this item, applicant may list the organization as "TBD".**	

Function	First tier, Downstream and Related entities	Off-Shore yes/no
Data Validation Pre-Assessment Consultant	**For this item, applicant may list the organization as "TBD".**	

G. Except for SAE Applicants, prepare and upload into HPMS a chart showing the relationship between the Applicant and each First Tier, Downstream, and Related Entity identified in section 3.2.1 F. This chart must include the names of all entities in the contracting chain between the Applicant and the entity performing the identified function.

H. Except for SAE Applicants, 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 word-searchable .pdf format) with each first tier, downstream or related entity identified in Section 3.2.1F (EXCEPT for the Data Validation Contractor and Data Validation Pre-Assessment Consultant) and with any first tier, downstream, or related entity that contracts with any of the identified entities on the applicant's behalf. As noted above, this requirement applies even if an entity contracting on the Applicant's behalf is the Applicant's parent organization or a subsidiary of the Applicant's parent organization.

All contracts must include the provisions enumerated in the Appendix entitled "Crosswalks of Prescription Drug Benefit Requirements in Part D-Related First Tier, Downstream, and Related Entity Contracts" as also described below, as well as the additional provisions identified in the applicable three-way contract Relationship with First Tier, Downstream, and Related Entities required provisions appendix located at https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/InformationandGuidanceforPlans.html.

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 any services or other activity they perform in accordance with the contract 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 parties have agreed that the first tier, downstream, or related entity will receive for performance under the contract. Applicants may not redact this information.
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 delegated activities or reporting responsibilities 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 the source for any prescription drug pricing standard is not publicly available, a provision for disclosing all individual drug prices to be updated to the applicable pharmacies in advance of their use for reimbursement of claims. 42 CFR § 423.505(i)(3)(vii).
18. 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)
19. 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)
20. 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.

DO NOT UPLOAD a contract for the Data Validation Contractor or the Data Validation Pre-Assessment Consultant. It is not required and will not be reviewed.

I. Except for SAE Applicants, 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

References: *42 CFR §§ 422.400, 422.402; Medicare Managed Care Manual, Chapter 10 (**http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R7MCM.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 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.		

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

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. If an SAE Applicant is adding counties to an already approved MMP service area in a state, then only the CMS_MMP State Certification Form for that state needs to be uploaded. The MMP State Certification Form must be current and must clearly identify the requested service area. Forms related to prior years' application will not be accepted.

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

References: *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 by at least maintaining a positive net worth (Total Assets exceed Total Liabilities) in accordance with 42 CFR § 422.504(a)(14).		

B. Initial Applicants only: In HPMS MMP Supporting Files Fiscal Soundness section, upload:

1. The most recent audited annual financial statements that are available for the legal entity (Applicant); and
2. The most recent quarterly financial statements available for the legal entity (Applicant). Financial statements must include, at a minimum, a balance sheet, income statement, and statement of cash flows. CMS reserves the right to request additional information, such as financial projections, as it sees fit to determine if the Applicant is maintaining a fiscally sound operation. In addition, CMS will verify that the Applicant meets State financial solvency requirements as documented on the CMS State Certification Form (uploaded under State Licensure).

Note: If the Applicant was not in business in previous years, 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 organization, it must submit the parent's most recent audited annual financial statements and the most recent Quarterly NAIC Health Blank or other form of quarterly financial statements if the Quarterly Health Blank is not required by your state.

If the Applicant is exempt from submitting audited annual financial statements to the State for the previous year, and it does not have audited financial statements, it must electronically upload its most recent unaudited financial statements and documentation of its exemption status from the State.

C. SAE Applicants only: CMS will confirm the attestation response by reviewing the most recent audited annual financial statements submitted by the MMP through the Fiscal Soundness Module in HPMS. If the most recent audited annual financial statements in the HPMS Fiscal Soundness Module do not demonstrate that the Applicant is maintaining a fiscally sound operation by at least maintaining a positive net worth, the Applicant must demonstrate that it is meeting fiscal soundness requirements and upload in HPMS MMP Supporting Files Fiscal Soundness section, either:

1. The final audited annual financial statements for the most recent fiscal year end, demonstrating the organization is maintaining a fiscally sound

operation by at least maintaining a positive net worth (Total Assets exceed Total Liabilities) in accordance with 42 CFR § 422.504(a)(14); or

2. The most recent quarterly or annual financial statements and include an opinion (such as a letter, not a full audit) from the Applicant's independent auditor confirming the organization is currently meeting CMS' fiscal soundness requirement by at least maintaining a positive net worth (Total Assets exceed Total Liabilities) in accordance with 42 CFR § 422.504(a)(14).

3.2.4. Program Integrity and Compliance Program

References: *2 CFR Part 376; 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)

(Not applicable to SAE Applicants)

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 June 29, 2011 HPMS memo entitled *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) 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 Medicare-Medicaid Plan 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

References: *42 CFR § 422.503(b)(4)(ii); HPMS Basic Contract Management Manual and Contact Definitions*

(Not applicable to SAE Applicants)

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 Applicant contacts listed in HPMS:

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.

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

(Not applicable to SAE Applicants)

3.3.1. Formulary/Pharmacy and Therapeutics (P&T) Committee

References: *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 (https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.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 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.		

Attest 'yes' or 'no' to the following qualification by clicking on the appropriate response in HPMS:	Yes	No
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 3.3.1.A.5 (the attestation above), 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/MMP 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

References: *42 CFR §§ 422.100-102; Medicare Managed Care Manual, Chapter 4 (http://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/index.html)*

(Not applicable to SAE Applicants)

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

References: *42 CFR 423.153(b); Prescription Drug Benefit Manual, Chapter 6 (https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf) Prescription Drug Benefit Manual, Chapter 7 (https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Chapter7.pdf)*

(Not applicable to SAE Applicants)

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 utilization management requirements in 42 CFR § 423.153(b), Chapters 6 and 7 of the Prescription Drug Benefit Manual and related CMS guidance.		

3.3.4. Quality Assurance and Patient Safety

References: *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)*

(Not Applicable to SAE Applicants)

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 (QI) Program in		

Attest 'yes' or 'no' to the following qualification by clicking on the appropriate response in HPMS:	Yes	No
42 CFR § 422.152, Chapter 5 of the Medicare Managed Care Manual, and all related guidance, including but not limited to the following: • Applicant has an ongoing QI Program that can be expected to have a favorable effect on health outcomes and enrollee satisfaction; • Applicant agrees to provide CMS with all documents pertaining to the QI Program upon request; • Applicant conducts a formal evaluation at least annually, on the impact and effectiveness of the MMP's overall QI Program.		
2. Applicant has reviewed, understands, and complies with requirements related to quality assurance and patient safety in section 1860D-4(c)(3) of the Social Security 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.		

3.3.5. Medication Therapy Management

References: *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)*

(Not Applicable to SAE Applicants)

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 Social Security 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. 42 CFR §423.153(d)(6) This description is not due at the time of this application.		

3.3.6. Electronic Prescription Program and Health Information Technology Standards

References: *42 CFR § 423.159; Prescription Drug Benefit Manual, Chapter 7 (http://www.cms.gov/PrescriptionDrugCovContra/Downloads/Chapter7.pdf); P.L. 111-5 (2009)*

(Not Applicable to SAE Applicants)

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

References: *42 CFR §§ 422.112, 114, and 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.		
3. Applicant has reviewed, understands, and complies with requirements related to covered services contained in the applicable three-way contract posted located at https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/InformationandGuidanceforPlans.html		

B. For SAE Applicants Only, using the instructions provided in the appendix titled "MMP Health Service Delivery Instructions, upload the following completed HSD tables for your medical provider/facility network for the pending counties only. Specifically, download the Microsoft Excel worksheet templates from HPMS that is located at: HPMS Home Page>Monitoring>Network Management>Select Contract Number>Documentation>Templates (Download Templates)

- CMS MMP Provider Table
- CMS MMP Facility Table

The HSD submission may be based on your contracted network to provide Medicare services for your organization. Applicants must upload the completed HSD tables in the HPMS Network Management Module. Select CMS Ad Hoc Event titled CY2022 MMP SAE Application. NOTE: Initial MMP Applicants will submit the Medicare medical portion of its network during the readiness review process.

3.5. Pharmacy Access

References: *42 CFR § 423.120(a); Prescription Drug Benefit Manual, Chapter 5 (https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/MemoPDBManualChapter5_093011.pdf)*

(Not applicable for SAE Applicants)

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.		

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

References: *42 CFR § 423.120(a); 42 CFR § 423.859(c); Prescription Drug Benefit Manual, Chapter 5 (https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/MemoPDBManualChapter5_093011.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 template from HPMS that is located specifically on the Pharmacy Upload page, complete the worksheet and upload the finished document back into HPMS.

3.5.2. Out of Network Access

References*: 42 CFR § 423.124; Prescription Drug Benefit Manual, Chapter 5 (https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/MemoPDBManualChapter5_093011.pdf)*

(Not Applicable to SAE Applicants)

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

References: *42 CFR § 423.120(a)(10); Prescription Drug Benefit Manual, Chapter 5 (https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/MemoPDBManualChapter5_093011.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 template from HPMS that is located on the Pharmacy Upload page, complete the worksheet and upload the finished document back into HPMS.

3.5.4. Home Infusion Pharmacy

References: *42 CFR § 423.120(a)(4); Prescription Drug Benefit Manual, Chapter 5 (https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/MemoPDBManualChapter5_093011.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

References*: 42 CFR § 423.120(a)(5); Prescription Drug Benefit Manual, Chapter 5 (https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/MemoPDBManualChapter5_093011.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 standard contracting terms and conditions to all long-term care pharmacies in its service area.		
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		

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

***References**: 42 CFR § 423.120(a)(6); Prescription Drug Benefit Manual, Chapter 5 (https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/MemoPDBManualChapter5_093011.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 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:	Yes	No	N/A
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). The Applicant's list must be submitted using

the Microsoft Excel template provided by CMS on the HPMS Pharmacy Upload page, and must include all I/T/U pharmacies residing in any and all states within its service area.

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

3.6. Enrollment and Eligibility

***References**: 42 CFR 423.30; 42 CFR 422 Subpart B; Medicare Managed Care Manual, Chapter 2 (https://www.cms.gov/Medicare/Eligibility-and-Enrollment/MedicareMangCareEligEnrol/Downloads/CY_2017_MA_Enrollment_and_Disenrollment_Guidance_06-03-2016.pdf); Prescription Drug Benefit Manual, Chapter 3, 4, and 13 (https://www.cms.gov/regulations-and-guidance/guidance/transmittals/downloads/chapter13.pdf); Plan Communications User Guide; Medicare-Medicaid Plan Enrollment and Disenrollment Guidance (https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/MMPFinalEnrollGuidance.pdf)*

(Not Applicable to SAE Applicants)

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, 42 CFR § 423. 30, Chapter 2 of the Medicare Managed Care Manual, Chapters 3,4, and 13 of the Medicare Prescription Drug Benefit Manual, the Plan Communications User Guide, and the national MMP enrollment/disenrollment guidance and technical specifications.		

3.7. Complaints Tracking

***References:** 42 CFR 423.505(b)(22); Prescription Drug Benefit Manual, Chapter 7 (http://www.cms.gov/PrescriptionDrugCovContra/Downloads/Chapter7.pdf)*

(Not Applicable to SAE Applicants)

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 42 CFR §423.505(b)(22), Chapter 7 of the Prescription Drug Benefit Manual, and all related guidance.		

3.8. Medicare Plan Finder

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

(Not Applicable to SAE Applicants)

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 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

***References**: 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)*

(Not applicable to SAE Applicants)

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 13 of the Medicare Managed Care Manual, Chapter 18 of the Prescription Drug Benefit Manual, and all related guidance.		

3.10. Coverage Determinations (including Exceptions) and Appeals

References: *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*

(Not applicable to SAE Applicants)

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

References: *42 CFR Part 423 Subpart J; Prescription Drug Benefit Manual, Chapter 14 (https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Chapter-14-Coordination-of-Benefits-v09-17-2018.pdf)*

(Not applicable to SAE Applicants)

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)

References*: Social Security Act § 1860 D-2(b)(4); 42 CFR Part 423 Subpart J; Prescription Drug Benefit Manual, Chapters 13 and 14 (https://www.cms.gov/Medicare/Prescription-Drug-*

Coverage/PrescriptionDrugCovContra/Downloads/Chapter-13-Premium-and-Cost-Sharing-Subsidies-for-Low-Income-Individuals-v09-14-2018.pdf)

(https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Chapter-14-Coordination-of-Benefits-v09-17-2018.pdf)

(Not applicable to SAE Applicants)

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 Social Security 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/

3.13. Medicare Secondary Payer

References: *42 CFR §§ 422.108 and 423.462; Prescription Drug Benefit Manual, Chapter 14 (http://www.cms.gov/PrescriptionDrugCovContra/Downloads/Chapter14.pdf)*

(Not applicable to SAE Applicants)

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 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.		

3.14. Marketing/Beneficiary Communications

References: *42 CFR §§ 422.2260-2276, 423.128, and 423.505; Medicare Communications and Marketing Guidelines; Marketing Guidance and Model Materials for Medicare-Medicaid Plans (https://www.cms.gov/medicare-medicaid-*

coordination/medicare-and-medicaid-coordination/medicare-medicaid-coordination-office/financialalignmentinitiative/mmpinformationandguidance/mmpmarketinginformationandresources)

(Not applicable to SAE Applicants).

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 §§ 422.111, 422.2260 – 422.2276, 42 CFR §§ 423.128 & 423.505, the Medicare Communications and Marketing Guidelines, and Demonstration-specific Marketing Guidance and Model Materials for Medicare-Medicaid Plans.		

3.15. Reporting Requirements

References: *Social Security Act § 1150A; 42 CFR §§ 422.516 and 423.514; Annual Part C, Part D, and MMP Reporting Requirements*

(Not applicable to SAE Applicants)

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 Social Security Act.		

3.16. Data Exchange between Medicare-Medicaid Plan Sponsor and CMS

References: *42 CFR §§ 422.310, 422.504(b) and (l), 423.322, and 423.505(c) and (k)*

(Not applicable to SAE Applicants)

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 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.		
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, https://www.cms.gov/Research-Statistics-Data-and-Systems/CMS-Information-Technology/mapdhelpdesk/index.html, in the Plan Reference Guide for CMS Part C/D Systems link.		
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

***References**: 45 CFR Parts 160, 162, and 164*

(Not applicable to SAE Applicants)

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").		

3.18. Prohibition on Use of SSN or Medicare Beneficiary Identifier Number on Enrollee ID Cards

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

(Not applicable to SAE Applicants)

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 Beneficiary Identifier number on the enrollee's identification card.		

3.19. Record Retention

References: *42 CFR §§ 422.504(d) and (i), 423.505(d)*

(Not applicable to SAE Applicants)

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. 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)		

3.20. Prescription Drug Event (PDE) Records

References: *42 CFR Part 423 Subpart G; Regional Prescription Drug Event Data Participant Training Guide and Technical Assistance Resource Guide*

(Not Applicable to SAE Applicants)

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 CMS requirements and guidance related to submission of PDE data, including 42 CFR Part 423 Subpart G, the Regional Prescription Drug Event Data Participant Training Guide and Technical Assistance Resource Guides under the link USERGROUP/technical assistance (www.csscoperations.com/) and related guidance.		
2. Applicant meets all data submission deadlines.		
3. Applicant complies with Medicare Coverage Gap Discount Program requirements.		

3.21. Claims Processing

References: *42 CFR §§ 422.520, 423.120(c)(4), 423.466*

(Not applicable to SAE Applicants)

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 processing of electronic and paper claims contained in 42 CFR §§ 422.504(c), 422.520(a), 422.566(a), 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

References: *42 CFR § 423.156*

(Not applicable to SAE Applicants)

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.		

3.23. Staffing

(Not applicable to Initial Applicants)

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 to maintain staffing for care coordination, including staff whose responsibility it is to conduct initial health risk assessments, at a level that is appropriate based on projected enrollment. Such levels shall include any staffing ratios that are specified in applicable three-way contracts.		
2. Applicant agrees to increase staff as necessary for call center customer service representatives.		

B. Complete and submit the Appendix titled: Staffing Template to CMS. Applicants must download the template from HPMS that is located at: HPMS Home Page>Contract Management>Basic Contract Management>Select Contract Number>Submit Application Data>MMP (Download Templates), complete and upload the finished document back into HPMS in the MMP Supporting Files page.

Note: Initial Applicants will have the staffing assessed as part of the readiness review process.

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 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.

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

5. APPENDICES

Appendix I --Organization Background and Structure

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

A. Legal Entity Background

Date Legal Entity Established: _____

State of Incorporation

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

B. Experience of Legal Entity

Date Organization, Its Parent Organization, or a Subsidiary of the Parent Organization Began Offering Health Insurance or Health Benefits Coverage _____

Date Organization, Its Parent Organization, or a Subsidiary of the Parent Organization Began Actively Managing Prescription Drug Benefits for an Organization that Offers Health Insurance or Health Benefits Coverage, Including:

(a) Authorization, adjudication, and processing of prescription drug claims at the point of sale;
(b) Administration and tracking of enrollees' drug benefits in real time, including automated coordination of benefits with other payers; and
(c) Operation of an enrollee appeals and grievance process.

_____

Date

C. Management of Legal Entity

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

Identify all owners or members of the board of directors/ trustees that were also owners or members of a board of directors/trustees of an organization that terminated or nonrenewed its Part C or Part D contract since January 1, 2020.

D. Parent Organization Information

Name of Parent Organization

Date Parent Organization established

E. Organizational Charts (may be uploaded as separate documents)

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.

Provide a chart of the relationships between the Applicant and its first tier, downstream, and related entities.

F. Proof of Incorporation

Upload proof of incorporation, such as articles of incorporation or a certificate of good standing from the state in which the Applicant is organized.

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
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.	
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. Applicants may not redact this information.	
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	

Requirement	Location in Subcontract by Page number and Section
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	

Requirement	Location in Subcontract by Page number and Section
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)	

Requirement	Location in Subcontract by Page number and Section
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	

Requirement	Citation
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)	

Requirement	Citation
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	

Requirement	Citation
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	

Requirement	Citation
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)	

Requirement	Citation
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 §4 23.505(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.	

Requirement	Citation
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. 42 CFR § 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. 42 CFR § 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)	

Requirement	Citation
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)	

Requirement	Citation
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.	

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)	

Requirement	Citation
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.	

Requirement	Citation
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 Number	Description	Citation
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 Number	Description	Citation
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 the application due date. 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 17, 2021.

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.

Full Name of Member Start Date and End Date	Practicing Physician	Practicing Pharmacist	Elderly/Disabled Expert	Free pf Any Conflict of Interest With Your Organization?	Free of Any Conflict of Interest With Pharmaceutical Manufacturers?

B. Complete the table below if a PBM submitting on behalf of Medicare-Medicaid Plan sponsor.

PR OVIDE 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 MEDICARE-MEDICAID PLAN APPLICANTS/SPONSORS USING A PHARMACY BENEFIT MANAGER'S PHARMACY& THERAPEUTICS COMMITTEE UNDER A CONFIDENTIALITY AGREEMENT

I, attest, on behalf of [INSERT LEGAL NAME OF MEDICARE-MEDICAID PLAN APPLICANT] ("Applicant"), to the following:

I certify that APPLICANT has entered into a contract with [INSERT 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 Addendum

Note: All Medicare-Medicaid Plan Sponsors will be required to use the attached 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 required elements 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))	

Compliance Plan Elements	Page, paragraph where element located
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):	[redacted]
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 must include the following components in §§ 42 CFR 422.503(b)(4)(vi)(C) and 423.504(b) (4)(vi)(C):	[redacted]
1. Training and education must occur at least annually and must be part of the orientation for new employees, including the chief executive and senior administrators or managers; and governing body members.	

Compliance Plan Elements	Page, paragraph where element located
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. The lines of communication (e.g, free telephone hotlines) must be accessible to all, including first tier, downstream, and related entities.	
4. Include 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 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)	

Compliance Plan Elements	Page, paragraph where element located
K. Establish and implement procedures and a system for promptly 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 a potential violation of item 1, above.	
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 1-3), then forward the document to the appropriate State Agency Official who should complete those items below the line (items 4-7). After completion, the State Agency Official should return this document to the Applicant organization for submission to CMS as part of its application for a 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.
3. Enter the National Association of Insurance Commissioners (NAIC) number if there is one.

New Federal Preemption Authority – The Medicare Modernization Act amended section 1856(b)(3) of the SSA to significantly broaden the scope of Federal preemption of State laws governing plans serving Medicare beneficiaries. Current law provides that the provisions of Title XVIII of the SSA supersede State laws or regulations, other than laws relating to licensure or plan solvency, with respect to MA plans.

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

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

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

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

MEDICARE-MEDICAID PLAN
STATE CERTIFICATION REQUEST

Applicants should complete items 1-3.

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:
   _____

3. National Association of Insurance Commissioner (NAIC) number:
   _____

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 1-3.

_____

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.

4. State official reviewing State Certification Request:

   Reviewer's Name: _____

   State Oversight/Compliance Officer: _____

   Agency Name: _____

   Address: _____

   Address: _____

   City/State: _____

   Telephone: _____

   E-Mail Address: _____

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

   Agency: _____

   Contact Person: _____

   Address: _____

   City/State: _____

   Telephone: _____

   E-Mail Address: _____

6. Financial Solvency:

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

   ● Yes ● No

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

7. State Licensure:

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

   ● Yes ● No

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

State Certification

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

(Check one)

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

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

And

(Check one)

_____ is in compliance with State solvency requirements, or

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

By signing the certification, the State of _____ is certifying that the organization is licensed and/or that the organization is authorized to bear the risk associated with the 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 Benefit Administrative/ Management Delegated Contracting Crosswalk Template

INSTRUCTIONS: Applicants must complete this template to indicate (by Section/Page) for each fully executed administrative/management contract that the contracts comply with the required Medicare provisions as listed in the crosswalk. Applicants are only required to upload the executed administrative contracts and corresponding templates 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

Requirement	Location in Subcontract by Page number and Section
1. 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.	
2. The delegated activities and reporting responsibilities to be performed by the first tier, downstream, or related entity. 42 CFR § 422.504(i)(4)(i)	
3. Language clearly indicating that the first tier, downstream, or related entity has agreed to participate in your Medicare-Medicaid Plan product (except for a network pharmacy if the existing contract would allow participation in this program).	
4. Contain flow-down clauses requiring that the first tier, downstream, or related entity's activities be consistent and comply with the Applicant's contractual obligations as a Medicare-Medicaid Plan sponsor. 42 CFR § 422.504(i)(3)(iii)	
5. Language that indicates payment terms have been agreed upon with the first tier, downstream or related entity for performance under the contract if applicable (note: actual payment terms may be redacted).	
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	

Requirement	Location in Subcontract by Page number and Section
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. Are signed by a representative of each party with legal authority to bind the entity.	
8. 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. 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. Language obligating the first tier, downstream, or related entity to abide by State and Federal confidentiality and disclosure laws related to medical records, or other health and enrollment information. 42 CFR § 422.504(a)(13). (Note: this provision is not required in administrative agreements where the first tier, downstream, or related entity does not perform a function that directly interacts with beneficiaries)	
11. 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(i)(2)(iv) and 42 CFR 422.504(i)(2)(i). Generally stated these regulations give HHS, the Comptroller General, or their designees the right to audit, evaluate and inspect any books, contracts, computer or other electronic systems, 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	

Requirement	Location in Subcontract by Page number and Section
contract period or the date of audit completion, whichever is later. 42 CFR § 422.504	
12. 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 § 422.504(i)(3)(i) (Note: this provision is not required in administrative agreements where the first tier, downstream, or related entity does not perform a function that directly interacts with beneficiaries)	
13. 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 § 422.504(i)(4)(ii)	
14. 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 § 422.504(i)(4)(iii)	
15. Language specifying that if the first tier, downstream, or related entity is delegated credentialing that 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. 42 CFR § 422.504(i)(4)(iv)	
16. Language that the Medicare-Medicaid Plan sponsor retains the right to approve, suspend, or terminate any arrangement with a provider if the first tier, downstream, or related entity will establish the provider network or select providers to be included in the network. 42 CFR § 422.504(i)(5)	

Appendix XIII – 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.

Appendix XIV – MMP Health Service Delivery Instructions

(SAE Applicants Only)

General Instructions and Guidance

On June 2, 2020, CMS codified network adequacy rules at 42 CFR § 422.116 that address policies on maximum time and distance standards in rural areas, telehealth, and Certificate of Need (CON) laws. The standards identified at 422.116 define how CMS quantifies prevailing community patterns of health care delivery for each provider and facility specialty type in a service area. These regulatory provisions are applicable to how CMS will assess network adequacy for Medicare-Medicaid Plans (MMPs). The purpose of this document is to provide additional information and instructions for MMP Service Area Expansion Applicants.

MMP Service Area Expansion Applicants should include all contracted providers within and outside of the pending service area that will be available to serve the county's beneficiaries (even if those providers/facilities may be outside of the time and distance standards). Applicants need to upload the completed health service delivery (HSD) tables, in the HPMS Network Management Module. Select CMS Ad Hoc Event titled CY2024 MMP SAE Application. After your organization submits the required MMP health service delivery (HSD) tables, CMS-generated Automated Criteria Check (ACC) reports will be created showing the provider and facility types that are meeting or failing to meet the MMP access standards. Based on those results, your organization may submit exception(s) requests based on the process described below.

Applicants are required to only submit HSD tables for the **pending service area** reflected in the CMS Health Plan Management System (HPMS).

SPECIALTY CODES

CMS has created specific specialty codes for each of the physician/provider and facility types. Applicants should use the codes when completing HSD tables (MMP Provider and MMP Facility tables).

Specialty Codes for the MMP Provider Table

HSD Specialty Code	HSD Specialty Name	Medicare Specialty Codes Indicated
S03	Primary Care	General Practice (001), Family Practice (002), Internal Medicine

HSD Specialty Code	HSD Specialty Name	Medicare Specialty Codes Indicated
		(003), Geriatrics (004), Primary Care – Physician Assistants (005), Primary Care – Nurse Practitioners (006)
007	Allergy and Immunology	Allergy/Immunology (03)
008	Cardiology	Cardiology (06)
010	Chiropractor	Chiropractor (35)
011	Dermatology	Dermatology (07)
012	Endocrinology	Endocrinology (46)
013	ENT/Otolaryngology	Otolaryngology (04)
014	Gastroenterology	Gastroenterology (10)
015	General Surgery	General Surgery (02)
016	Gynecology, OB/GYN	Obstetrics & Gynecology (16)
017	Infectious Diseases	Infectious Disease (44)
018	Nephrology	Nephrology (39)
019	Neurology	Neurology (13)
020	Neurosurgery	Neurosurgery (14)
021	Oncology-Medical, Surgical	Hematology (82), Hematology-Oncology (83), Surgical Oncology (91), Gynecological Oncology (98)
022	Oncology-Radiation/Radiation Oncology	Radiation Oncology (92)
023	Ophthalmology	Ophthalmology (18)
025	Orthopedic Surgery	Orthopedic Surgery (20), Hand Surgery (40)

HSD Specialty Code	HSD Specialty Name	Medicare Specialty Codes Indicated
026	Physiatry, Rehabilitative Medicine	Physical Medicine and Rehabilitation (25)
027	Plastic Surgery	Plastic and Reconstructive Surgery (24)
028	Podiatry	Podiatry (48)
029	Psychiatry	Psychiatry (26)
030	Pulmonology	Pulmonary Disease (29)
031	Rheumatology	Rheumatology (66)
033	Urology	Urology (34)
034	Vascular Surgery	Vascular Surgery (77)
035	Cardiothoracic Surgery	Thoracic Surgery (33), Cardiac Surgery (78)

Description of MMP Provider Types

The following section contains information related to MMP Provider specialty types in order to assist the Applicant with the accurate submission of the MMP Provider HSD Table.

MMP Provider Table – Select Provider Specialty Types

Primary Care Providers – The following six specialties are reported separately on the MMP Provider Table, and the criteria, as discussed below, are published and reported under “Primary Care Providers (S03):

- General Practice (001)
- Family Practice (002)
- Internal Medicine (003)
- Geriatrics (004)
- Primary Care – Physician Assistants (005)
- Primary Care – Nurse Practitioners (006)

Applicants submit contracted providers using the appropriate individual specialty codes (001 – 006). CMS sums these providers, maps them as a single group, and evaluates

the results of those submissions whose office locations are within the prescribed time and distance standards for the specialty type: Primary Care Providers. These six specialties are also summed and evaluated as a single group against the Minimum Number of Primary Care Providers criteria (note that in order to apply toward the minimum number, a provider has to be within the prescribed time and distance standards, as discussed below). States may require MMPs to include pediatric providers in their tables, However, CMS does not review pediatric providers for purposes of network adequacy determinations. Therefore, physicians and specialists that are pediatric providers should not be included on HSD tables; as they do not routinely provide services to the Medicare-Medicaid population. There are HSD network criteria for the specialty type: Primary Care Providers, and not for the individual specialties. The criteria and the results of the Automated Criteria Check (ACC) are reported under the specialty type: S03.

Primary Care – Physician Assistants (005) – Applicants include submissions under this specialty code **only if** the contracted individual meets the applicable state requirements governing the qualifications for assistants to primary care physicians and is duly certified as a provider of primary care services. In addition, the individuals listed under this specialty code function as the primary care source for the beneficiary/member, not supplement a physician primary care provider's care, in accordance with state law and be practicing in or rendering services to enrollees residing in a state and/or federally designated physician manpower shortage area.

Primary Care – Nurse Practitioners (006) -- Applicants include submissions under this specialty code **only if** the contracted registered professional nurse is currently licensed in the state, meets the state's requirements governing the qualifications of nurse practitioners, and is duly certified as a provider of primary care services. In addition, the individuals listed under this specialty code function as the primary care source for the beneficiary/member, not supplement a physician primary care provider's care, in accordance with state law and be practicing in or rendering services to enrollees residing in a state and/or federally designated physician manpower shortage area.

Geriatrics (004) – Submissions appropriate for this specialty code are internal medicine, family practice, and general practice physicians who have a special knowledge of the aging process and special skills and who focus upon the diagnosis, treatment, and prevention of illnesses pertinent to the elderly.

Physiatry, Rehabilitative Medicine (026) – A physiatrist, or physical medicine and rehabilitation specialist, is a medical doctor trained in the diagnosis and treatment of patients with physical, functionally limiting, and/or painful conditions. These specialists focus upon the maximal restoration of physical function through comprehensive rehabilitation and pain management therapies. Physical Therapists are NOT Physiatry/Rehabilitative Medicine physicians and are not to be included on the MMP Provider tables under this specialty type.

Psychiatry (029) -- Psychiatrists are only licensed physicians and no other type of practitioner.

Cardiothoracic Surgery (035) – Cardiothoracic surgeons provide operative, perioperative, and surgical critical care to patients with acquired and congenital pathologic conditions within the chest. This includes the surgical repair of congenital and acquired conditions of the heart, including the pericardium, coronary arteries, valves, great vessels and myocardium. Cardiologists, including interventional cardiologists, are not cardiothoracic surgeons, and may not be included under this specialty type.

Specialty Codes for the MMP Facility Table

HSD Specialty Code	HSD Specialty Name
040	Acute Inpatient Hospitals
041	Cardiac Surgery Program
042	Cardiac Catheterization Services
043	Critical Care Services-Intensive Care Units (ICU)
045	Surgical Services (Outpatient or ASC)
046	Skilled Nursing Facilities
047	Diagnostic Radiology
048	Mammography
049	Physical Therapy
050	Occupational Therapy
051	Speech Therapy
052	Inpatient Psychiatric Facility Services
057	Outpatient Infusion/Chemotherapy

Description of MMP Medicare Facility Types
The following section contains information related to Medicare Facility specialty types in order to assist Applicants with the accurate submission of the MMP Facility HSD Table.

MMP Facility Table – Select Facility Specialty Types
Contracted facilities/beds need to be Medicare-certified.

Acute Inpatient Hospital (040) – Applicants should submit at least one contracted acute inpatient hospital. MMPs may need to submit more than one acute inpatient hospital in order to satisfy the time/distance criteria. There are Minimum Number criteria for the acute inpatient hospital specialty. Applicants need to demonstrate that their contracted acute inpatient hospitals have at least the minimum number of Medicare-certified hospital beds. The minimum number of Medicare-certified acute inpatient hospital beds, by county of application, can be found on the "Minimum Facility #s" tab of the HSD Reference Table.

Cardiac Surgery Program (041) – A hospital with a cardiac surgery program provides for the surgical repair of problems with the heart, traditionally called open-heart surgeries. Procedures performed in a cardiac surgery hospital program include, but are not limited to: coronary artery bypass graft (CABG), cardiac valve repair and replacement, repair of thoracic aneurysms and heart replacement, and may additionally include minimal access cardiothoracic surgeries.

Inpatient Psychiatric Facility Services (052) – Inpatient Psychiatric Facility Services may include inpatient hospital services furnished to a patient of an inpatient psychiatric facility (IPF). IPFs are certified under Medicare as inpatient psychiatric hospitals and distinct psychiatric units of acute care hospitals and critical access hospitals. The regulations at 42 CFR § 412.402 define an IPF as a hospital that meets the requirements specified in 42 CFR § 412.22 and 42 CFR § 412.23(a), 42 CFR § 482.60, 42 CFR § 482.61, and 42 CFR § 482.62, and units that meet the requirements specified in 42 CFR § 412.22, 42 CFR § 412.25, and 42 CFR § 412.27.

Outpatient Infusion/Chemotherapy (057) – Appropriate submissions for this specialty include freestanding infusion / cancer clinics and hospital outpatient infusion departments. While some physician practices are equipped to provide this type of service within the practice office, Applicants should only list a contracted office-based infusion service if access is made available to all members and is not limited only to those who are patients of the physician practice.

MMP Provider Supply File
The supply file is a cross-sectional database that includes information on providers name, address, national provider identifier, and specialty type and is posted by state and specialty type. The supply file is segmented by state to facilitate development of

networks by service area. Contracts with service areas near a state border may need to review the supply file for multiple states, as network adequacy criteria are not restricted by state or county boundaries. The current MMP provider supply file can be found using the following navigation path: HPMS Home Page>Monitoring>Network Management>Reference Files.

Given the dynamic nature of the market, the file is a resource and may not be a complete depiction of the provider supply available in real-time. MMPs remain responsible for conducting validation of data used to populate HSD tables, including data initially drawn from the MMP provider supply file. MMPs should not rely solely on the MMP provider supply file when establishing networks, as additional providers may be available.

CMS uses the MMP provider supply file when validating information submitted on provider exception requests. Therefore, CMS may update the MMP provider supply file periodically to reflect updated provider information and to capture information associated with exception requests.

Note, that this MMP provider supply file only addresses those specialties that make up the provider HSD table and does not address the specialty types that make up the facility HSD table.

Certificate of Need Credit

CMS' network adequacy requirements also account for Certificate of Need (CON) laws, or other anticompetitive restrictions, as described at 42 CFR § 422.116(d)(6). In a state with CON laws, or other state imposed anti-competitive restrictions that limit the number of providers or facilities in the state or a county in the state, CMS will either award the organization a 10-percentage point credit towards the percentage of beneficiaries residing within published time and distances standards for affected providers and facilities or, when necessary due to utilization or supply patterns, customize the base time and distance standards. CMS conducted extensive analyses to identify all counties and specialties where the CON credit is applicable and created a CON reference file. Networks submitted to the NMM will automatically be reviewed for the CON criteria and receive the credit as applicable. Please note, in accordance with 42 CFR § 422.116(d)(6), the 10% credit will not be applied if the county maximum time and distance standards are customized.

If an organization determines there are additional county/specialty combinations that are not reflected in the CON reference file, they may request an exception related to the CON criteria and provide substantial and credible evidence that a provider or facility type is adversely affected by a CON law. Organizations need to use the current exception request template. Organization should select "other" as the reason for not contracting on the exception request template and include supplemental documentation at the end of the PDF. Organizations can find the MMP Exception template at the

following navigation path: HPMS Home Page>Monitoring>Network Management>Templates

Telehealth Credit

Organizations will receive a 10% credit towards the percentage of beneficiaries that reside within required time and distance standards when they contract with telehealth providers in the following specialties: Dermatology, Psychiatry, Cardiology, Otolaryngology, Neurology, Ophthalmology, Allergy and Immunology, Nephrology, Primary Care, Gynecology/OB/GYN, Endocrinology, and Infectious Diseases.

Detailed technical instructions on reporting telehealth providers during a MMP's network submission are outlined in the HPMS NMM Plan User Guide. Organizations can find the Plan User Guide at the following navigation path: HPMS Home Page>Monitoring>Network Management>Guidance.

HSD Table Instructions

The tables should reflect the Applicant's executed contracted network on the date of submission. CMS considers a contract fully executed when both parties have signed. Applicants should only list providers with whom they have a fully executed updated contract. These contracts should be executed on or prior to the submission deadline. In order for the automated network review tool to appropriately process this information, your organization needs to submit Provider and Facility names and addresses exactly the same way each time they are entered, including spelling, abbreviations, etc. Any errors will result in problems with processing of submitted data and may result in findings of network deficiencies. CMS expects all organizations to fully utilize the functionality in the CMS HPMS Network Management Module (NMM) to conduct organization-initiated checks prior to the February due date to ensure that their HSD tables are accurate and complete. For instructions on the organization-initiated NMM uploads, please refer to HPMS>Monitoring>Network Management>Documentation>User Guide.

The MMP Provider Table Template can be found in HPMS using the following path: HPMS Home Page>Monitoring>Network Management>Documentation >Templates. This table captures information on the specific physicians/providers in the MMP's contracted network. If a provider serves beneficiaries residing in multiple counties in the service area, list the provider multiple times with the appropriate state/county code to account for each county served. Do NOT list contracted providers in the state/county codes where the beneficiary could not reasonably access services and that are outside the pattern of care. Such extraneous listing of providers affects CMS' ability to quickly and efficiently assess provider networks against network criteria. You should ensure that the providers listed have not have opted out of Medicare.

The Applicant is responsible for ensuring contracted providers (physicians and other health care practitioners) meet state and Federal licensing requirements and your credentialing requirements for the specialty type prior to including them on the MMP Provider Table. Verification of credentialing documentation may be requested at any time. Including physicians or other health care practitioners that are not qualified to provide the full range of specialty services listed in the MMP Provider Table will result in inaccurate ACC measurements that may result in your MMP Medicare network submission being found deficient. Explanations for each of the columns in the MMP Provider Table can be found in Appendix B.1.

MMP Facility Table Template

The MMP Facility Table Template can be found in HPMS using the following path: HPMS Home Page>Monitoring>Network Management>Documentation >Templates. Only list the providers that are Medicare certified providers. Please do not list any additional providers or services except those included in the list of facility specialty codes. Additionally, do not list contracted facilities in state/county codes where the Medicare-Medicaid beneficiary could not reasonably access services and that are outside the pattern of care. Such extraneous listing of facilities affects CMS' ability to quickly and efficiently assess facility networks against network criteria.

If a facility offers more than one of the defined services and/or provides services in multiple counties, the facility should be listed multiple times with the appropriate "SSA State/County Code" and "Specialty Code" for each service.

Exception Requests:

As MMPs will submit networks at the time your organization seeks to complete a service area expansion application for the pending counties, and annually for the overall network. Any approved exceptions will be in place until the next annual MMP Medicare network submission. CMS, in collaboration with each respective state, will consider requests for exceptions to the required minimum number of providers and/or maximum time/distance criteria under limited circumstances. Each exception request has to be supported by information and documentation as specified in the exception request template attached to these instructions. If your organization believes that it will not meet the time/distance or minimum number MMP standards based on your contracted network, wants to request an exception(s), and already has additional contracted providers outside of the time and distance to serve beneficiaries, then you should include those other contracted providers on the MMP HSD tables in the MMP SAE application submission.

Exception Process Timing
Following the submission for the MMP SAE application, organizations should review the ACC report. This report identifies the providers and/or facilities passing and failing to meet the MMP Medicare network standards. For those providers and/or facilities that are not meeting the MMP Medicare network standards, your organization may submit an exception request.

Exceptions are only permitted to be requested and uploaded between specific timeframes identified in the initial deficiency notice your organization will receive during the application review process.

Completing the Exception Request Template

MMPs are required to submit distinct exception requests per contract ID, county, and specialty code. Each request should be tailored to the provider/facility type and the specific county using the MMP exception template available in HPMS using the following path: HPMS Home Page>Monitoring>Network Management>Documentation>Templates.

The MMP SAE Applicant Exception Request template provides the basis for any MMP exception requests. The exception request template has been revised and converted into a fillable form to ease in completion and allow for greater accuracy in the submission of information. The form also allows for the inclusion of in-home delivery of services and the use of mobile health clinic.

CMS will not accept exception request submissions using the Medicare Advantage application template or the MMP template from prior annual MMP network submissions.

Justification for Exception:

CMS will consider an organization's justification if:

- A county has an insufficient number of providers or insufficient capacity among existing providers to ensure access and availability to covered services. For example, the organization can submit evidence demonstrating insufficient provider supply (e.g., list of non-contracted provider names/locations and valid reasons for not contracting).
- Geographic features (e.g., mountains, water barriers, large national park) or exceptionally large counties create situations where the local pattern of care in the county justifies less than a complete county because covered services are not available and accessible throughout the entire county. For example, the organization can demonstrate the geographic features or characteristic.

- A provider/facility does not contract with any organizations.
- A provider/facility contracts exclusively with another organization.

CMS will consider these justifications if the organization provides substantial and credible evidence. For example, an organization could submit letters or e-mails to and from the providers' offices demonstrating that the providers were declining to contract with any MMP organization; thus no MMP organizations could be offered in the area in question.

Mobile Health Clinics: Any mobile health clinics that are contracted to provide services to the entire enrollee population within the specified service area. A mobile health clinic may be a specially outfitted truck or van that provides examination rooms, laboratory services, and special medical tests to those who may be in remote areas or who have little to no access to medical facilities, and to patients who do not have the resources to travel for care.

In-Home Medical Services: Applicants can receive consideration in the exceptions process where contracted providers deliver medical services in the beneficiary's home in lieu of an office where the office location may be outside of the established time and or distance standards.

CMS reserves the right to follow up for any additional information that may be need as a result of the exception request review which could include an attestation from the provider outlining their service area/counties, and may also include the number of enrollees served by each provider type (mobile health clinics and in-home service providers) within the designated service areas/counties. CMS will also work with your state of operation to verify laws pertaining to mobile health clinics.

Completing the Exception Request Template*

The exception request template is segmented into the following seven parts:

I. Exception Information
II. Justification for Exception
III. Rationale for why Exception is Necessary
IV. Sources
V. Narrative Text (Optional)
VI. Non-Contracted Providers/Facilities
VII. Mobile Health Clinics, and In-Home Medical Services
VIII. Low Utilization (note: not applicable for MMP SAE Applicants)

Exception Information: This section of the template requires the plan to enter the Contract ID and select from the drop-down list the County name and code and the Specialty name and code for the exception request your organization is seeking.

Justification for Exception: When submitting an exception request in HPMS, the NMM only provides one basis – patterns of care; however, the MMP exception request template requires Applicants to choose from a selection of reasons for the exception. Your organization should select the applicable justification.

Rationale for why Exception is Necessary:

- Questions 1-5 need to be answered Yes or No
- If the response is Yes for Question 3, then Part IV has to be completed.
- If the response is Yes for Question 4, then the table included in Part VI: Non-Contracted Providers/Facilities section has to be completed.
- If the response is Yes for Question 5, then the table included in Part VII: Mobile Health Clinics and In-Home Medical Services section has to be completed

Sources:

Please enter any sources (up to six) you used to identify providers/facilities within or nearby CMS' network adequacy criteria. To enter a source, select an option from the drop-down list, which is comprised of sources commonly used by organizations and CMS. If you have more than six sources, or a source not included on the drop-down list, please describe the additional sources in the Part V: Narrative Text section. The drop-down options for the sources are as follows:

- Physician Compare
- Hospital Compare
- Nursing Home Compare
- Dialysis Compare
- NPI file/NPPES
- MMP Provider Supply File
- Provider of Services (POS) file
- Direct outreach to provider
- Provider website
- State licensing data
- Online mapping tool
- Other (Please describe the other source(s) in the "Part V: Narrative Text" section)

Narrative Text (Optional):

Please use the free text format box in this section to enter any additional text to justify your exception request. This section may also be used to explain "Other" and additional sources from the Part IV: Sources section.

Non-Contracted Providers/Facilities:

Complete the table in this section if your organization answered "Yes" to question 4 in the Part III: Rationale for why Exception is Necessary section. Please include all non-contracted providers/facilities in the table. If the sources of information used (and listed in the table) are proprietary or otherwise not publically available, the Applicant should describe how the information supports the reason for not contracting with a provider/facility and provide evidence of the data source information (e.g., screenshots).

The table is designed to capture most of the non-contracted provider/facility information in a free text format; however, there are drop-down lists to capture the provider state and the reason for the provider not contracting with your organization. The drop-down options to capture the reason for not contracting are as follows:

- Provider is no longer practicing (e.g., deceased, retired, etc.)
- Provider does not provide services at the office/facility address listed in database
- Provider does not provide services in the specialty type listed in the database and for which this exception is being requested
- Provider does not contract with Medicare-Medicaid Plans
- Sanctioned provider on List of Excluded Individuals and Entities
- Provider has opted out of Medicare
- Provider/Facility type better than prevailing Original Medicare pattern of care
- Contract offered to provider/facility but declined/rejected
- Geographic limitations, explain below
- Provider is at capacity and is not accepting new patients
- Other (please enter explanation on the last column of the table)

Mobile Health Clinics and In-Home Medical Services:

Complete the table in this section if your organization answered "Yes" to question 5 in the Part III: Rationale for why Exception is Necessary section. Please include all mobile health clinics and in-home medical services in the table.

The table is designed to capture most of the provider/facility information in a free text format; however, there are drop-down lists to capture the provider state and the provider type. The drop-down options to capture the provider type are as follows:

- Mobile Health Clinic
- In Home Medical Service

In addition to completing the table in this section, your organization should provide justification for utilizing mobile health clinics and in-home medical services. This justification should be provided in a free text format to address the following questions for each provider type:

JUSTIFICATION FOR MOBILE HEALTH CLINICS	JUSTIFICATION FOR IN-HOME MEDICAL SERVICES
a. Explain the medical services provided by the mobile health clinic(s).	a. Explain the medical services provided in the beneficiaries' home?
b. How do beneficiaries access mobile health clinic services?	b. How do beneficiaries access the in-home medical services? Are there any specific requirements for beneficiaries to be able to qualify for in-home visits?
a. Is the mobile health clinic contracted directly with your organization or is the mobile health clinic associated with facility or provider group contracted with your organization?	c. Explain the timeframe for when beneficiaries requests the in-home medical services to when the in-home medical service is provided.
b. Provide the mobile health clinic's fixed schedule that specifies the date(s) and location(s) for services.	d. How does your organization provide access to a provider when an in person visit is

JUSTIFICATION FOR MOBILE HEALTH CLINICS	JUSTIFICATION FOR IN-HOME MEDICAL SERVICES
	deemed necessary following an in-home visit?
c. Provide any additional details for consideration that supports your organization's option to utilize these types of providers over providers in a standard physical building location.	e. Provide any additional details for consideration that support your organization's option to utilize these types of providers over providers in a standard physical building location.

Appendix XIV.1 – MMP Provider Table Column Explanations

A. SSA State/County Code – Enter the SSA State/County code of the county which the listed physician/provider will serve. The state/county code is a five digit number. Please include any leading zeros (e.g., 01010). The state and county codes on the HSD Criteria Reference Table are the codes you should use. Format the cell as "text" to ensure that codes beginning with a "0" appear as five digits.

B. **Name of Physician or Mid-Level Practitioner** – Self-explanatory. Up to 150 characters.

C. **National Provider Identifier (NPI) Number –** The provider's assigned NPI number needs to be included in this column. Enter the provider's individual NPI number whether the provider is part of a medical group or not. The NPI is a ten digit numeric field. Include leading zeros.

D. Specialty – Name of specialty of listed physician/provider. This should be copied directly off of the HSD Criteria Reference Table.

E. **Specialty Code –** Specialty codes are unique codes assigned by CMS to process data. Enter the appropriate specialty code (001-034).

F. **Contract Type –** Enter the type of contract the MMP holds with listed provider. Use "DC" for direct contract between the MMP and the provider and "DS" for downstream (define DS) contract.

- A "DC" – direct contract provider requires the MMP to complete Column K – Medical Group Affiliation with a "DC" and Column L – Employment Status should be marked as "N/A".
- A "DS" – downstream contract is between the first tier entity and other providers (such as individual physicians).
- Where the MMP has a contract with an Independent Practice Association (IPA) with downstream contracts with physicians, MMP needs to complete Column F – Contract Type with a "DS", Column K – Medical Group Affiliation should be completed by entering the IPA Name.

- Where the MMP has a contract with a Medical Group with downstream contracted physicians, the MMP should complete Column F – Contract Type with a “DS”, Column K – Medical Group Affiliation must be completed by entering the name of the Medical Group.
- Where the MMP has a contract with a Medical Group with employed providers, the MMP should complete Column F – Contract Type with a “DS”, Column K – Medical Group Affiliation should be completed by entering the name of the Medical Group.

Provider Service Address Columns- Enter the address (i.e., street, city, state and zip code) of the location at which the provider sees patients. **Do not list P.O. Box, house, apartment, building or suite numbers, or street intersections.**

G. **Provider Service Address: Street Address** – up to 250 characters

H. **Provider Service Address: City** – up to 150 characters

I. **Provider Service Address: State** – 2 characters

J. **Provider Service Address: Zip Code** – up to 10 characters

K. **Medical Group Affiliation –** Provide name of affiliated Medical Group/Individual Practice Association MG/IPA) or if MMP has direct contract with provider enter “DC”.

Appendix XIV.2 – MMP Facility Table Column Explanations

A. SSA State/County Code – Enter the SSA State/County code of the county for which the listed facility will serve. The county code should be a five digit number. Please include any leading zeros (e.g., 01010). The state and county codes on the HSD Criteria Reference Table are the codes that MMP should use. Format the cell as "text" to ensure that codes beginning with a "0" appear as five digits.

B. **Facility or Service Type** – Name of facility/service type of listed facility. This should be copied directly off of the HSD Criteria Reference Table.

C. **Specialty Code** – Specialty codes are unique 3 digit numeric codes assigned by CMS to process data. Enter the Specialty Code that best describes the services offered by each facility or service. Include leading zeros.

D. **National Provider Identifier (NPI) Number** – Enter the provider's assigned NPI number in this column. The NPI is a ten digit numeric field. Include leading zeros.

E. **Number of Staffed, Medicare Certified Beds** – For Acute Inpatient Hospitals (040), Critical Care Services – Intensive Care Units (ICUs) (043), Skilled Nursing Facilities (046), and Inpatient Psychiatric Facility Services (052), your organization needs to enter the number of Medicare certified beds for which it has contracted access for enrollees. This number should not include Neo-Natal Intensive Care Unit (NICU) beds.

F. **Facility Name** – Enter the name of the facility. Field Length is 150 characters.

Provider Service Address Columns- Enter the address (i.e., street, city, state and zip code) from which the provider serves patients. **Do not list P.O. Box, house, apartment, building or suite numbers, or street intersections.** For Home Health and Durable Medical Equipment, indicate the business address where one can contact these vendors.

G. **Provider Service Address: Street Address** – up to 250 characters

H. **Provider Service Address: City** – up to 150 characters

I. **Provider Service Address: State** – 2 characters

J. **Provider Service Address: Zip Code** – up to 10 characters

Appendix XIV.3 – CMS Public Data Source for HSD Exception Request

The following table listed below provides a list of acceptable CMS data sources used for review of HSD Exception Request. **Note:** The Medicare Advantage Provider Supply File is not used as a data source for purposes of the Applicant's Medicare Network Review.

HSD Specialty Type	Data Source
Allergy and Immunology Cardiology Chiropractor Dermatology Endocrinology ENT/Otolaryngology Gastroenterology General Surgery Gynecology, OB/GYN Infectious Diseases Nephrology Neurology Neurosurgery Oncology – Medical, Surgical Oncology – Radiation/Radiation Oncology Ophthalmology Orthopedic Surgery Physiatry, Rehabilitative Medicine Plastic Surgery Podiatry Primary Care Providers Psychiatry Pulmonology Rheumatology Urology	Physician Compare – Data available at: https://data.medicare.gov/data/physician-compare MMP Provider Supply File – Data available at: HPMS>Network Management Module>References
Vascular Surgery Cardiothoracic Surgery	Physician Compare – Data available at: https://data.medicare.gov/data/physician-compare
Acute Inpatient Hospitals Cardiac Surgery Program Cardiac Catheterization Services Critical Care Services – Intensive Care Units (ICU) Surgical Services (Outpatient or ASC) Inpatient Psychiatric Facility Services	Provider of Services – Data available at: https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Provider-of-Services/
Outpatient Dialysis	Dialysis Facility Compare – Data available at: https://data.medicare.gov/data/dialysis-facility-compare
Physical Therapy Speech Therapy Occupational Therapy	Physician Compare – Data available at: https://data.medicare.gov/data/physician-compare and National Plan & Provider Enumeration System

HSD Specialty Type	Data Source
	(NPPES) – Data available at: http://download.cms.gov/nppes/NPI_Files.html
Skilled Nursing Facilities	Nursing Home Compare – Data available at: https://data.medicare.gov/data/nursing-home-compare
Mammography	Hospital Compare – Data available at: https://data.medicare.gov/data/hospital-compare and National Plan & Provider Enumeration System (NPPES) – Data available at: http://download.cms.gov/nppes/NPI_Files.html
Diagnostic Radiology Outpatient Infusion/Chemotherapy	National Plan & Provider Enumeration System (NPPES) – Data available at: http://download.cms.gov/nppes/NPI_Files.html
	and Provider of Services – Data available at: https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Provider-of-Services/

Appendix XV --Staffing Template

Complete and upload in HPMS in the MMP Supporting Files Service Area section, the Staffing Template.

Part I -- Enrollment Assumptions

1. Applicant enrollment assumptions **for pending counties only**:

Date	**Number of Enrollees Expected from pending counties**
Estimated enrollment as of January 1, 2024	
Estimated enrollment as of April 1, 2024	
Estimated enrollment as of July 1, 2024	
Estimated enrollment as of October 1, 2024	

2. In the table below, provide Applicant's enrollment case mix for current counties.

Acuity Level	**Percent of total current enrollment**

3. Does the Applicant anticipate a different case mix for the pending county (ies) from what is reported in #2 above?

_____Yes _____No

4. If the Applicant answered question 3 as 'YES' please provide anticipated case mix in the table below for pending counties.

Acuity Level	Percent of projected enrollment for pending counties

Part II -- Care Management/Care Coordination Staffing

5. In the table below, provide Applicant's existing care management/care coordination ratios.

Acuity Level	Ratio (provide ratios for overall current service area)

6. Will the existing care management/care coordination ratios be maintained for the pending counties?

_____Yes

_____No

7. If Applicant answered question 6 as ‘NO’, provide as part of the zip file with this completed template, a pdf document that indicates the expected care management/care coordination ratio in the pending counties and why it is different than the existing care management/care coordination ratio.

8. Will Applicant delegate any care management/care coordination staffing for the pending counties to a First Tier, Downstream, or Related Entity (FDR)?
_____Yes _____No

9. If ‘Yes’, provide the name of First Tier, Downstream, Related Entity

_____

10. Consistent with the acuity levels provided in Question 5, provide in the table below the Applicant’s expected care management/care coordination staffing **for the pending county(ies) only:**

Date	**Staffing Category by Acuity Level**	**Number of Staff Expected**
January 1, 2024	Acuity Level: _____	# FDR staff: _____ # Applicant staff: _____ # total: _____
	Acuity Level: _____	# FDR staff: _____ # Applicant staff: _____ # total: _____
	Acuity Level: _____	# FDR staff: _____ # Applicant staff: _____ # total: _____
	Acuity Level: _____	# FDR staff: _____ # Applicant staff: _____ # total: _____
	Acuity Level: _____	# FDR staff: _____ # Applicant staff: _____

Date	Staffing Category by Acuity Level	Number of Staff Expected
		# total: _____
April 1, 2024	Acuity Level: _____	# FDR staff: _____ # Applicant staff: _____ # total: _____
	Acuity Level: _____	# FDR staff: _____ # Applicant staff: _____ # total: _____
	Acuity Level: _____	# FDR staff: _____ # Applicant staff: _____ # total: _____
	Acuity Level: _____	# FDR staff: _____ # Applicant staff: _____ # total: _____
	Acuity Level: _____	# FDR staff: _____ # Applicant staff: _____ # total: _____
July 1, 2024	Acuity Level: _____	# FDR staff: _____ # Applicant staff: _____ # total: _____
	Acuity Level: _____	# FDR staff: _____ # Applicant staff: _____ # total: _____
	Acuity Level: _____	# FDR staff: _____ # Applicant staff: _____ # total: _____
	Acuity Level: _____	# FDR staff: _____

Date	Staffing Category by Acuity Level	Number of Staff Expected
		# Applicant staff: _____ # total: _____