**Medicare Part D Application for New PACE Organizations**

**2025 Contract Year**

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Expiration: TBD

# 1 GENERAL INFORMATION

## 1.1 Background

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

PACE organizations have a longstanding history of providing statutorily required prescription drugs to all participants. Prior to Part D, prescription drugs were included as a portion of the Medicaid capitation rate. However, the MMA mandates that State Medicaid programs may no longer cover Part D drugs on behalf of dual eligible beneficiaries. PACE organizations may elect to offer a Part D plan in a similar manner as MA-PD local plans in order to account for this shift in payer source for prescription drugs.

This chapter of the PACE provider application serves as the Medicare Part D application.

NOTE: CMS reserves the right to amend or cancel this solicitation at any time. CMS also reserves the right to revise the Medicare Prescription Drug Benefit program implementation schedule, including the solicitation and bidding process timelines.

## 1.2 Summary of PACE Organization's Roles and Responsibilities

Each PACE organization should have the ability to:

- Submit a formulary each year for CMS approval (as applicable).
- Submit a Part D bid each year for CMS approval.
- Administer the Part D benefit.
- Provide all required prescription drug services as outlined in the PACE statute and regulation.
- Operate quality assurance, drug utilization review, and medication therapy management programs in accordance with existing PACE requirements.
- Protect the privacy of beneficiaries and beneficiary-specific health information.
- Develop and/or maintain systems to support enrollment, provide claims-based data to CMS, accept CMS payment, and support e-prescribing.
- Provide necessary data to CMS to support payment, oversight, and quality improvement activities and otherwise cooperate with CMS oversight responsibilities.
- Ensure the integrity of the Medicare Trust Fund by eliminating fraud, abuse, and waste within its organization.

## 1.3 Summary Instructions for Part D Formularies (42 CFR § 423.120)

Applicants that meet one or more of the definitive criteria for formularies described later in this document will be required to submit their Part D formulary in the HPMS Formulary Submission module prior to the Part D bid and formulary deadline the first Monday in June. Formularies must be submitted by PACE applicants and organizations when using any of the following:

- Step therapy, or
- Prior authorizations, or
- Cost sharing tiers, or
- Quantity limitations, or
- Steerage to preferred drugs.

## 1.4 Summary Instructions for Part D Bids (42 CFR § 423.265)

Each PACE applicant must submit to CMS, via HPMS, two Part D bids; one for enrollees dually eligible for Medicare and Medicaid (dual eligible) and one for Medicare-only enrollees. Applicants using this solicitation must apply to offer full risk Part D plans.

The applicant's bid will represent the expected monthly cost to be incurred by the applicant for qualified prescription drug coverage in the plan's service area for a Part D-eligible beneficiary on a standardized basis. The costs represented in each bid should be those for which the applicant would be responsible. The bid will require the separate identification, calculation, and reporting of costs assumed to be reimbursed by CMS through reinsurance. CMS requires that the bid represent a uniform benefit package among all beneficiaries enrolled in the plan. The benefit packages submitted must be cross walked appropriately from the formulary (as applicable). Pursuant to 42 CFR § 423.505(k)(4), the chief executive officer (CEO), chief financial officer (CFO), or an individual delegated with the authority to sign on behalf of one of these officers, and who reports directly to such officer, must certify (based on best knowledge, information, and belief) that the information in the bid submission is accurate, complete, and truthful, and fully conforms to the requirements in 42 CFR § 423.265 of the regulations (except 42 CFR § 423.265(b), the applicability of which is discussed below). In addition, the pricing component of the bid must be certified by a qualified actuary.

PACE organizations must submit annual Part D bids and formularies (as applicable) and receive CMS approval of the Part D bids and formularies (when applicable) prior to providing or continuing to provide Part D benefits. Any PACE organization that wishes to either continue receiving Part D payment or begin receiving Part D payment in January of a given year, must submit their Part D bids no later than the first Monday in June of the year prior. The June bid submission deadline (42 CFR § 423.265(b)) has been waived for newly forming PACE organizations pending the development of a methodology for accepting mid-year bids.

In order to prepare plan bids, applicants will use HPMS to define their plan structures and associated plan service areas and then download the Plan Benefit Package (PBP) and Bid Pricing Tool (BPT) software. For each plan being offered, applicants will use the PBP software to describe the detailed structure of their Part D benefit and the BPT software to define their bid pricing information. The formulary (as applicable) must

accurately crosswalk to the PBP.

Once the PBP and BPT software has been completed for each plan being offered, applicants will upload their bids to HPMS.

### 1.4.1 CMS Review of Part D Bids

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

CMS is also required to make certain that bids and plan designs meet statutory and regulatory requirements. We will conduct an actuarial analysis to determine whether the proposed benefit meets the standard of providing qualified prescription drug coverage.

### 1.4.2 Overview of Part D Bid Negotiation

CMS evaluates the reasonableness of bids submitted by PACE Part D sponsors by means of an actuarial valuation analysis. This requires evaluating assumptions regarding the expected distribution of costs, including average utilization and cost by drug coverage tier. CMS could test these assumptions for reasonableness through actuarial analysis and comparison to industry standards and other comparable bids. Bid negotiation could take the form of negotiating changes upward or downward in the utilization and cost per script assumptions underlying the bid's actuarial basis. We could exercise our authority to deny a bid if we do not believe that the bid and its underlying drug prices reflect market rates.

## 1.5 Standard Contract with PACE Part D Sponsors

Successful applicants will be deemed qualified to enter into a PACE program agreement that includes Part D coverage. Under this agreement the PACE Part D sponsor will be authorized to operate the Medicare Part D benefit for all eligible PACE participants. Only after the qualified applicant and CMS have reached agreement on the applicant's bid submissions will the applicant be asked to execute its PACE program agreement.

## 1.6 General Enrollment Processing

CMS has developed a system to review an individual's eligibility for the Part D benefit. For individuals applying for enrollment in a Part D plan, CMS reviews an individual's status as a Medicare beneficiary. CMS tracks enrollments and ensures that the beneficiary does not enroll in more than one plan. Also, CMS tracks low-income subsidy status and auto-enrollments of full-benefit dual eligible individuals into Part D plans and facilitated enrollments for other low-income Medicare beneficiaries. Finally, CMS tracks disenrollments from Part D plans and will deny new enrollments during any given year unless the enrollment occurs during an allowable enrollment period. For

additional information regarding enrollment processing, refer to the http://www.cms.gov website.

## 1.7 Eligibility for the Low-Income Subsidy Program

Low-income Medicare beneficiaries receive full or partial subsidies of premiums and reductions in cost sharing under the Part D benefit. Certain groups of Medicare beneficiaries are automatically eligible for the low-income subsidy program. These beneficiaries include Medicare beneficiaries who are full-benefit dual eligible individuals (eligible for full benefits under Medicaid); Medicare beneficiaries who are recipients of Supplemental Security Income benefits; and participants in Medicare Savings Programs as Qualified Medicare Beneficiaries (QMBs), Specified Low-Income Medicare Beneficiaries (SLMBs), and Qualifying Individuals (QIs). Beneficiaries who are low-income and who do not fall into one of the automatic subsidy eligibility groups apply for a low-income subsidy and have their eligibility determined by either the state in which they reside or the Social Security Administration (SSA). CMS has developed a database to track individuals who are automatically deemed subsidy-eligible or who are determined subsidy-eligible by states or SSA, and communicates the names and eligibility category of those individuals to Part D sponsors as part of the enrollment files from the enrollment processing system described below. For additional information regarding the low-income subsidy program, refer to the www.cms.gov/ website.

## 1.8 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 § 5.42(d) and by *Executive Order 12,600 Predisclosure notification for confidential commercial information* to give the submitter notice before the information is disclosed. CMS will use the following to determine whether commercial or financial information provided by an applicant is "confidential" under Exemption 4:

1. Does the submitter customarily keep the information private or closely-held? (This inquiry may in appropriate contexts be determined from industry practices concerning the information.)
2. Did the government provide an express or implied assurance of confidentiality when the information was shared with the government?
3. Were there express or implied indications at the time the information was submitted that the government would publicly disclose the information?

Consistent with our approach under the Medicare Advantage program, we would not release information under the Medicare Part D program that would be considered proprietary in nature.

## 1.9 Payment to PACE Part D Sponsors

Payments will be wired to the organization’s account on the first day of each month (or

the last business day of the prior month if the first day of the month is not a business day). The monthly payment will include premiums that SSA or other agencies are deducting from beneficiary Social Security payments or other payments as well as those premiums CMS is paying on behalf of low-income individuals. Estimated monthly reinsurance subsidies, low-income subsidies, and gap discount amounts are also included.

## 1.10 Applicability of the National Provider Identifier (NPI) to PACE Organizations

The Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) mandated the adoption of standard unique identifiers for health care providers, as well as the adoption of standard unique identifiers for health plans. The purpose of these provisions is to improve the efficiency and effectiveness of the electronic transmission of health information. The NPI has been adopted as the standard unique identifier for health care providers. The National Plan and Provider Enumeration System (NPPES) is the entity that assigns these unique identifiers.

For purposes of HIPAA, PACE organizations may be defined as both health plans and health care providers. Any health care provider, as that term is defined for purposes of HIPAA that transmits any health information in electronic form in connection with one of the standard transactions, including electronically billing any health plan (including Medicare), must obtain an NPI. Health care providers are defined at 45 CFR § 160.103 as “a provider of services (as defined in section 1861 (u) of the Act, 42 USC 1395x (u)), a provider of medical or health services (as defined in section 1861(s) of the Act, 42 USC 1395x(s)), and any other person or organization who furnishes, bills, or is paid for health care in the normal course of business.”

Although PACE organizations may meet the definition or a health care provider, as described above, only those that transmit health information in electronic form in connection with one of the standard transactions, including billing any health plan electronically must obtain an NPI. We note that in some instances, PACE organizations may elect to provide Medicare services to a beneficiary prior to the beneficiary’s effective date of PACE enrollment. These services may be billable under Medicare Fee-For-Service. To the extent a PACE organization that is a HIPAA health care provider elects to bill Medicare electronically for these non-PACE services, an NPI would be needed.

In addition, consistent with HIPAA requirements, as health plans, all PACE organizations (regardless of whether the NPI requirements apply to them as health care providers) are required to accept and recognize the NPI as the health care provider identifier in standard transactions that are submitted to them from health care providers or other health plans.

# 2 GENERAL INSTRUCTIONS

The following section provides instructions for completing this chapter of the application. The actual application forms are included under Section 3.

Note: Nothing in this chapter of the PACE Provider Application is intended to supersede the regulations at 42 CFR Part 423 or Part 460. Failure to reference a regulatory requirement in this application does not affect the applicability of such requirement, and PACE organizations are required to comply with all applicable requirements of the regulations in Part 423 or Part 460 of 42 CFR.

## 2.1 Summary Instructions and Technical Support

This application is to be completed by those newly forming PACE organizations that intend to provide the Part D benefit to eligible participants beginning in 2025. **Applicants must use the 2025 solicitation. CMS will not accept or review in any way those submissions using prior versions of the application.**

Applicants must follow the instructions contained in the PACE Initial Application at https://www.cms.gov/Medicare/Health-Plans/pace/Overview.html to submit a Notice of Intent to Apply and initiate the application process. The Part D PACE application must be completed in HPMS. **Applicants should not rely on their understanding of prior years' applications and review standards in determining whether they are complying with application requirements. If they are uncertain about how to interpret application instructions and requirements, they should ask CMS for guidance.**

For technical assistance in the completion of this application, please send an email to the DMAO portal at: https://dmao.lmi.org and click on the "PACE" tab.

In many instances applicants are directed to affirm that they will meet particular requirements by indicating "Yes" next to a statement of a particular Part D program requirement. By providing such attestation, an applicant is committing its organization to complying with the relevant requirements as of the date your contract is signed, unless an alternative date is noted.

Additional supporting documentation is notated in the following manner throughout the application and is to be submitted as follows:

- Forms: documents supplied by CMS that are contained at the end of this application. They are to be completed by the applicant and uploaded in HPMS as part of the application.
- Legal documents such as subcontracts should be provided as an upload in the Contracting section of the HPMS application.

CMS will check the Part D application for completeness after its receipt. We will notify applicants of any deficiencies and afford them the opportunity to amend their Part D applications. CMS also does not evaluate or issue a notice of determination described in § 423.503(c) when an organization submits a substantially incomplete application. An application is substantially incomplete "when the submission as of the deadline for applications established by CMS is missing content or responsive materials for one or more sections of the application form required by CMS." 42 CFR § 423.503(a)(4)(ii).

CMS may verify a sponsor's compliance with qualifications it attests it will meet, through on-site facility visits as well as through other program monitoring techniques.

Failure to meet the requirements attested to in the applicant's response to this solicitation and failure to operate its Part D plan(s) consistent with the requirements of the applicable statutes, regulations, and the Part D contract may disqualify it from participation in the Part D program.

An individual with legal authority to bind the applicant shall sign and submit the certification.

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

## 2.2 Application Acceptance and Submission Timeframe

PACE Applications are reviewed on a quarterly basis in accordance with the timeline in the PACE application.

## 2.3 Part D Waivers

CMS is authorized to grant waivers of Part D program requirements where such a requirement conflicts with or duplicates a PACE requirement, or where granting such a waiver would improve the PACE organization's coordination of PACE and Part D benefits. The following waivers are in effect for all PACE organizations.

**Summary of Medicare Part D Regulatory Requirements Waived for PACE Organizations**

| Part D Regulation | Regulatory Requirement(s) Description |
|---|---|
| 423.44 | Involuntary disenrollment |
| 423.48 | Information about Part D |
| 423.104(g)(1) | Access to negotiated prices |
| 423.112 | Establishment of PDP service areas |
| 423.120(a) | Access to covered Part D drugs |
| 423.120(c) | Use of standardized technology |
| 423.124 | Out-of-network access to covered Part D drugs at out-of-network pharmacies |
| 423.128 | Dissemination of Part D plan information |
| 423.132 | Public disclosure of pharmaceutical prices for equivalent drugs |

| | |
|---|---|
| 423.136 | Privacy, confidentiality, and accuracy of enrollee records |

| Part D Regulation | Regulatory Requirement(s)<br>Description |
|---|---|
| 423.153(a)-423.153(d)<br>**Note: Organizations are required to abide by 423.153(f).** | Drug utilization management, quality assurance, and medication therapy management programs (MTMPs) |
| 423.156 | Consumer satisfaction surveys |
| 423.159(c), 423.160(a) | Electronic prescribing |
| 423.162 | Quality Improvement organization activities |
| 423.265(b)<br>***Note: Automatic waiver applies to new or potential organizations that are not operational by the June deadline.***<br>***Those organizations with effective program agreements must submit a Part D waiver request in the event they are unable to meet the June deadline.*** | Part D bid submission deadline |
| 423.401(a)(1) | Licensure |
| 423.420 | Solvency standards for non-licensed entities |
| 423.462 | Medicare secondary payer procedures |
| 423.464(c) | Coordination of benefits and user fees |
| 423.464(f)(2) and 423.464(f)(4) | Coordination with other prescription drug coverage |
| 423.502(b)(1)(i-ii) | Documentation of State licensure or Federal waiver |
| 423.504(b)(2-3), 423.504(b)(4)(i-v) and (vi)(A-E)<br>***Note: Organizations are required to abide by 423.504(b)(4)(vi)(F-H), 423.504(b)(5), 423.504(c)-(e)*** | Conditions necessary to contract as a Part D plan sponsor |

| Part D Regulation | Regulatory Requirement(s)<br>Description |
|---|---|
| 423.505(a-c) and 423.505(e-i)<br>***Note: Organizations are required to abide by 423.505(d and j)*** | Contract provisions |
| 423.505(k)(6)<br>***Note: Organizations are required to abide by 423.505(k)(1-5)*** | Certification for purposes of price compare |
| 423.506(a)-(b)<br>***Note: Organizations are required to abide by 423.506(c)-(e)*** | Effective date and term of contract |
| 423.512 – 423.514 | Contracting terms |
| 423.551-423.552 | Change of ownership or leasing of facilities during term of contract |
| 423.560-423.638 | Grievances, coverage determinations, and appeals |
| 423.2262 | Approval of marketing materials and enrollment forms |
| N/A | A PDP sponsor is required to be a nongovernmental entity |

### 2.3.1 Applicant Requests for Additional Waivers

CMS may grant additional waivers upon a PACE organization's request, provided that the waivers may be justified because the Part D requirement is duplicative of or conflicting with PACE requirements, or the waiver will improve the coordination of PACE and Part D benefits. Any waiver granted by CMS will apply to all similarly situated PACE organizations.

PACE organizations that identify the need for additional Part D waivers should submit a waiver request in conjunction with the PACE application. Please use the naming convention "waiver request" and include as separate document in the PACE application zip file. The Part D waiver request package must include:

1. Information identifying the submitted document(s) as a waiver request;
2. The regulatory provision to be waived;
3. Specific reason(s) for requesting the waiver;

4. Policies and procedures put into place by the PACE organization to ensure participant care will not be compromised by the waiver, if applicable;
5. Point of contact for waiver; and,
6. PACE Waiver Crosswalk (Attachment A) indicating that the PACE organization has provided all necessary information, if applicable.

Finally, the PACE organization should also copy their State Administering Agency on the request.

Determinations will be coordinated between Part D and PACE policy staff and issued to applicants following a comprehensive review of the request in a similar manner as PACE BIPA 903 waivers are evaluated in accordance with 42 CFR § 460.26(b) and 42 CFR § 460.28 of the PACE regulation.

# 3 APPLICATION FORMS

## 3.1 Management and Operations

### 3.1.1 Management and Operations

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

| **Applicant must attest 'yes' to be approved for a Part D contract. Attest 'yes' or 'no' to qualifications by clicking on the appropriate response in HPMS:** | **Yes** | **No** |
|---|---|---|
| Applicant has not filed for or been placed under bankruptcy proceedings. An organization that has filed for or is currently under bankruptcy is deemed to have failed to comply with the requirements of the Part D program pursuant to 42 CFR § 423.503(b)(1)(i)(C). | | |

### 3.1.2 Upload organizational background and structure information.

Submit this information by downloading the appropriate template found in HPMS that mimics the Appendix entitled, Organization Background and Structure. Also upload into HPMS proof of your organization's incorporation, such as articles of incorporation or a certificate of good standing from your state of incorporation. 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)

### 3.1.3 Subcontractor (first tier, downstream, and related entities) Function Chart

A Part D sponsor may meet program requirements by delegating the performance of certain required functions to entities with which it contracts directly, referred to in the Part D regulations (§ 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 Part D sponsor. A related entity may be either a first tier or downstream entity.

Where an applicant has elected to use subcontractors to meet Part D requirements, it must demonstrate that it has binding contracts in place that reflect these relationships. These 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 HPMS the first tier and downstream entities with which it has contracted to perform the listed Part D functions. The chart below is provided to assist applicants in identifying the information that must be provided in HPMS.

**Note concerning parent and subsidiary relationships:** In establishing its subcontracting arrangements, an applicant must clearly demonstrate that it has elected to delegate certain Part D 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 Part D 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.

In HPMS, on the Contract & Management/Part D Information/Part D Data Page, provide names of the first tier, downstream and related entities you will use to carry out each of the functions listed in this chart and whether the first tier, downstream and related entities are off-shore. Organizations applying for an SAE should ensure that the information in HPMS is up to date for the current contract year.

(Indicate with "name of Applicant's Organization" where applicant will perform those functions).

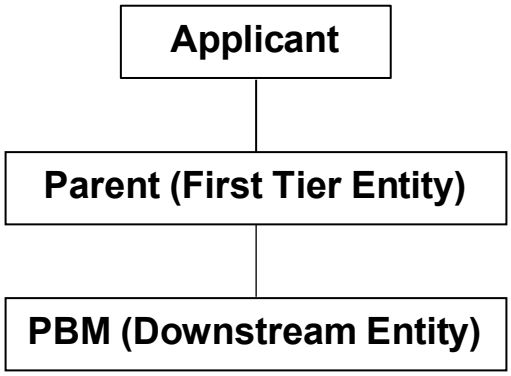
| Function | First tier, Downstream and Related entities | Off-Shore yes/no |
|---|---|---|
| A pharmacy benefit program that performs adjudication and processing of pharmacy claims at the point of sale. | | |

| Function | First tier, Downstream and Related entities | Off-Shore yes/no |
|---|---|---|
| A pharmacy benefit program that performs negotiation with prescription drug manufacturers and others for rebates, discounts, or other price concessions on prescription drugs. | | |
| A pharmacy benefit program that performs administration and tracking of enrollees' drug benefits in real time, including TrOOP balance processing. | | |
| A pharmacy benefit program that performs coordination with other drug benefit programs, including, for example, Medicaid, state pharmaceutical assistance programs, or other insurance. | | |
| A pharmacy benefit program that develops and maintains a pharmacy network. | | |
| A pharmacy benefit program that operates an enrollee grievance and appeals process | | |
| A pharmacy benefit program that performs customer service functionality, that includes serving seniors and persons with a disability. | | |
| A pharmacy benefit program that performs pharmacy technical assistance service functionality. | | |
| A pharmacy benefit program that maintains a pharmaceutical and therapeutic committee. | | |
| A pharmacy benefit program that performs enrollment processing. | | |

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

### 3.1.4 First Tier, Downstream, and Related Entity Relationship Chart

Provide a chart showing the relationship between the applicant and each first tier, downstream, and related entity identified in Section 3.2.1. This chart must include the names of all entities in the contracting chain between the applicant and the entity performing the identified function. An example of a chart is provided below for reference.




### 3.1.5 Requirements in Contracts/Administrative Services Agreements

Except for SAE applicants, 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 Sections 3.2.2 (**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. Unless otherwise indicated, each and every contract must:

1. Clearly identify the parties to the contract (or letter of agreement). If the applicant is not a direct party to the contract (e.g., if one of the contracting entities is entering into the contract on the applicant's behalf), **the applicant must be identified as an entity that will benefit from the services described in the contract.**
2. Describe the functions to be performed by the first tier, downstream or related entity, and the reporting requirements the first tier, downstream, or related entity has to the applicant. 42 CFR § 423.505(i)(4)(i)
3. Contain language clearly indicating that the first tier, downstream, or related entity has agreed to participate in your Medicare Prescription Drug Benefit program (except for a network pharmacy if the existing contract would allow participation in this program).
4. Contain flow-down clauses requiring that any services or other activity they perform in accordance with the contract be consistent and comply with the applicant's contractual obligations as a Part D sponsor. 42 CFR § 423.505(i)(3)(iii)
5. Describe the payment 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. Be signed by a representative of each party with legal authority to bind the entity.
7. Contain language obligating the first tier, downstream, or related entity to abide by all applicable Federal laws and regulations and CMS instructions. 42 CFR
8. § 423.505(i)(4)(iv)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.
9. Contain language ensuring that the first tier, downstream, or related entity will make its books and other records available in accordance with 42 CFR § 423.505(e)(2) and 42 CFR § 423.505(i)(2). Generally stated, these regulations give HHS, the Comptroller General, or their designees the right to audit, evaluate and inspect any books, contracts, records, including medical records and documentation involving transactions related to CMS' contract with the Part D sponsor and that these rights continue for a period of 10 years from the final date of the contract period or the date of audit completion, whichever is later. 42 CFR § 423.505(e)(2) and (i)(2)
10. Contain language that the first tier, downstream, or related entity will ensure that beneficiaries are not held liable for fees that are the responsibility of the Part D sponsor. 42 CFR § 423.505(i)(3)(i)
11. Contain language that delegated activities or reporting responsibilities may be revoked if CMS or the Part D sponsor determines the first tier, downstream, or related entity has not performed satisfactorily. The contract/administrative services agreement may include remedies in lieu of revocation to address this requirement. 42 CFR § 423.505(i)(4)(ii)
12. Contain language specifying that the applicant, upon becoming a Part D sponsor, will monitor the performance of the first tier, downstream, or related entity on an ongoing basis. **The contract must explicitly provide that the sponsor itself will perform ongoing monitoring. Language indicating that the sponsor has the right to monitor is not sufficient; the contract must affirmatively state that the sponsor will monitor the entity on an ongoing basis.** 42 CFR§ 423.505(i)(4)(iii)
13. If the first tier, downstream, or related entity will establish the pharmacy network or select pharmacies to be included in the network, contain language that the Part D sponsor retains the right to approve, suspend, or terminate any arrangement with a pharmacy. 42 CFR § 423.505(i)(5)
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 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
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 if a prescription drug pricing standard is used for reimbursement, identify the source used by the Part D sponsor for the standard of reimbursement. 42 CFR §§ 423.505(b)(21) and 423.505(i)(3)(vii)

16. 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)
17. If the first tier, downstream, or related entity will establish the pharmacy network or select pharmacies to be included in the network and a prescription drug pricing standard is used for reimbursement, contain a provision that updates to such a prescription drug pricing standard occur not less frequently than once every 7 days beginning with an initial update on January 1 of each year, to accurately reflect the market price of acquiring the drug. 42 CFR §§ 423.505(b)(21) and (i)(3)(vii)
18. If the first tier, downstream, or related entity will establish the pharmacy network or select pharmacies to be included in the network, contain language requiring the network pharmacies to submit claims to the Part D sponsor or first tier, downstream or related entity whenever the membership ID card is presented or on file at the pharmacy unless the enrollee expressly requests that a particular claim not be submitted. 42 CFR § 423.120(c)(3)

Each complete contract must meet all of the above requirements when read on its own. PLEASE NOTE: The "Medicare Advantage Contract Amendment" (referenced in the "Release of the Medicare Advantage Contract Amendment" HPMS memo dated October 5, 2012) is outdated and also does not fulfill the above Part D contracting requirements.

**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.**

### A. Crosswalk of Requirements in Contracts/Administrative Services Agreements

INSTRUCTIONS: Applicants must complete and upload in HPMS the following chart for each contract/administrative services agreement submitted under Section 3.1.1D. Applicants must identify where specifically (i.e., the pdf page number) in each contract/administrative services agreement the following elements are found.

| Requirement | Citation |
|---|---|
| The parties to the contract. If the Applicant is not a party to the contract, it must be identified as an entity that will benefit from the services described in the contract. | |
| The functions to be performed by the first tier, downstream, or related entity. Describe the reporting requirements the first tier, downstream, or related entity identified in Section 3.1.1C of the application has to the Applicant. 42 CFR § 423.505(i)(4)(i) | |

| | |
|---|---|
| Language clearly indicating that the first tier, downstream, or related entity has agreed to participate in your Medicare Prescription Drug Benefit program (except for a network pharmacy if the existing contract would allow participation in this program). | |

| Requirement | Citation |
|---|---|
| Contains flow-down clauses requiring the first tier, downstream, or related entity's activities to be consistent and comply with the Applicant's contractual obligations as a Part D sponsor. 42 CFR § 423.505(i)(3)(iii) | |
| The payment 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.** | |
| 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 423.505(i)(2). Generally stated these regulations give HHS, the Comptroller General, or their designees the right to audit, evaluate and inspect any books, contracts, records, including medical records and documentation involving transactions related to CMS' contract with the Part D sponsor and that these rights continue for a period of 10 years from the final date of the contract period or the date of audit completion, whichever is later. 42 CFR § 423.505 | |
| 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 Part D sponsor, delegates an activity or responsibility to the first tier, downstream, or related entity, that such activity or responsibility may be revoked if CMS or the Part D sponsor determines the first tier, downstream, or related entity has not performed satisfactorily. Note: The contract/administrative services agreement may include remedies in lieu of revocation to address this requirement. 42 CFR § 423.505(i)(4)(ii) | |
| Language specifying that the Applicant, upon becoming a Part D sponsor, will monitor the performance of the first tier, downstream, or related entity on an ongoing basis. 42 CFR § 423.505(i)(4)(iii) | |
| **Requirement** | **Citation** |

| | |
|---|---|
| Language that the Part D sponsor retains the right to approve, suspend, or terminate any arrangement with a pharmacy if the first tier, downstream, or related entity will establish the pharmacy network or select pharmacies to be included in the network. 42 CFR § 423.505(i)(5) | |
| 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 Part D sponsor for the prescription drug pricing standard of reimbursement. 42 CFR § 423.505(b)(21) and 423.505(i)(3)(vii) | |
| 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) | |
| 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(b)(21) and 423.505(i)(3)(vii) | |
| If the first tier, downstream, or related entity will establish the pharmacy network or select pharmacies to be included in the network, language requiring the network pharmacies to submit claims to the Part D sponsor or first tier, downstream or related entity whenever the membership ID card is presented or on file at the pharmacy unless the enrollee expressly requests that a particular claim not be submitted. 42 CFR § 423.120(c)(3) | |

### 3.1.6 Requirements for Long-Term Care Pharmacy Access Contracts 42 CFR § 423.120(a)(5); Prescription Drug Benefit Manual, Chapter 5

**INSTRUCTIONS**: Applicants must complete and upload in HPMS the following chart (which contains applicable requirements from above AND additional requirements specific to Pharmacy Access) for each long-term care pharmacy contract template submitted. Applicants must identify where specifically (i.e., section numbers, page numbers, paragraph numbers, etc.) in each contract template the following elements are found. [E.g., Medicare Part D Long-Term Care Pharmacy Addendum, page 14, section

3.2, paragraph 2.]

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 3.1.1C 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 423.505(i)(2). Generally stated these regulations give HHS, the Comptroller General, or their designees the right to audit, evaluate and inspect any books, contracts, records, including medical records and documentation involving transactions related to CMS' contract with the Part D sponsor and that these rights continue for a period of 10 years from the final date of the contract period or the date of audit completion, whichever is later. 42 CFR § 423.505 | |
| 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 Part D sponsor, delegates an activity or responsibility to the first tier, downstream, or related entity, that such activity or responsibility may be revoked if CMS or the Part D sponsor determines the first tier, downstream, or related entity has not performed satisfactorily. Note: The contract may include remedies in lieu of revocation to address this requirement. 42 CFR § 423.505(i)(4)(ii) | |
| Language specifying that the Applicant, upon becoming a Part D sponsor, will monitor the performance of the first tier, downstream, or related entity on an ongoing basis. 42 CFR § 423.505(i)(4)(iii) | |
| For those contracts that use a standard for reimbursement, a provision indicating the source used by the Part D sponsor for the standard of reimbursement. 42 CFR § 423.505(b)(21) and 423.505(i)(3)(vii) | |
| If 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) | |
| 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(b)(21) and 423.505(i)(3)(vii) | |
| Language requiring the network pharmacy to submit claims to the Part D sponsor or first tier, downstream or related entity whenever the membership ID card is presented or on file at the pharmacy unless the enrollee expressly requests that a particular claim not be submitted. 42 CFR 423.120(c)(3) | |
| Provisions governing submitting claims to a real-time claims adjudication system. 42 CFR §§ 423.505(j) and 423.505(b)(17)<br>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 Part D enrollee at the point of sale (or at the point of delivery for mail order drugs) of the lowest-priced, generically equivalent drug, if one exists for the beneficiary's prescription, as well as any associated differential in price. 42 CFR § 423.132 | |
| Provide that long-term care pharmacies must have not less than 30 days, nor more than 90 days, to submit to the Part D Sponsor claims for reimbursement under the plan. 42 CFR § 423.505(b)(20) | |
| Provisions requiring that long-term care pharmacies dispense drugs and report information as required by 42 CFR § 423.154. | |

## 3.2 HPMS Part D Contacts

**A. In HPMS, on the Contract Management/Contact Information/Contact Data Page provide the name/title, mailing address, phone number, fax number, and email address for the following Applicant contacts.**

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

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

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

| Applicant must attest 'yes' to the following qualification to be approved for a Part D contract. Attest 'yes' or 'no' to the following qualification by clicking on the appropriate response in HPMS: | Yes | No |
|---|---|---|
| Applicant agrees that CMS may release contact information to States, State Pharmaceutical Assistance Programs (SPAPs), providers, Part D sponsors, and others who need the contact information for legitimate purposes. | | |

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

In HPMS, complete the table below:

| **Applicant must attest 'yes' or 'no' to the following qualification to be approved for a Part D contract. Attest 'yes' or 'no' to the following qualification by clicking on the appropriate response in HPMS:** | **Yes** | **No** |
|---|---|---|
| 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 Inspector General or by the General Services Administration exclusion lists. Please note that this includes any member of its board of directors, and any key management or executive staff or any major stockholder. Additionally, given Medicare payment may not be made for items or services furnished by an excluded provider or entity, applicant should follow the guidance provided in the January 13, 2010 HPMS memo entitled Claims for Drugs Prescribed or Dispensed by Excluded Providers. | | |

## 3.4 Health Information Technology 42 CFR § 423.159; Prescription Drug Benefit Manual, Chapter 7; P.L. 111-5 (2009)

In HPMS, complete the table below:

| **Applicant must attest 'yes' or 'no' to the following qualification to be approved for a Part D contract. Attest 'yes' or 'no' to the following qualification by clicking on the appropriate response in HPMS:** | **YES** | **NO** | **Requesting Waiver?** |
|---|---|---|---|
| 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. | | | |

## 3.5 Enrollment and Eligibility 42 CFR § 423.30; Prescription Drug Benefit Manual, Chapters 3, 4, and 13; Plan Communications User Guide

In HPMS, complete the table below:

| **Applicant must attest 'yes' or 'no' to the following qualification to be approved for a Part D contract. Attest 'yes' or 'no' to the following qualification by clicking on the appropriate response in HPMS:** | **YES** | **NO** | **Requesting Waiver?** |
|---|---|---|---|
| Applicant has reviewed, understands, and complies with requirements related to enrollment, disenrollment, and eligibility contained in 42 CFR § 423.30, Chapters 3, 4, and 13 of the Prescription Drug Benefit Manual, the Plan Communications User Guide, and all related enrollment and disenrollment guidance and technical specifications. | | | |
| Applicant has reviewed, understands, and complies with CMS operational guidance on Creditable Coverage and the Late Enrollment Penalty, including the Best Available Evidence requirements contained in 42 CFR § 423.800(d). | | | |

## 3.6 Complaints Tracking 42 CFR § 423.505(b)(22); Prescription Drug Benefit Manual, Chapter 7

In HPMS, complete the table below:

| **Applicant must attest 'yes' or 'no' to the following qualification to be approved for a Part D contract. Attest 'yes' or 'no' to the following qualification by clicking on the appropriate response in HPMS:** | **YES** | **NO** | **Requesting Waiver?** |
|---|---|---|---|
| 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. | | | |

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

In HPMS, complete the table below:

| **Applicant must attest 'yes' or 'no' to the following qualification to be approved for a Part D contract. Attest 'yes' or 'no' to the following qualification by clicking on the appropriate response in HPMS:** | **YES** | **NO** | **Requesting Waiver?** |
|---|---|---|---|
| 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 related guidance. | | | |

## 3.8 Tracking True Out-of-Pocket Costs (TrOOP) Social Security Act § 1860D-2(b)(4); 42 CFR Part 423 Subpart J; Prescription Drug Benefit Manual, Chapters 13 and Chapter 14

In HPMS, complete the table below:

| **Applicant must attest 'yes' or 'no' to the following qualification to be approved for a Part D contract. Attest 'yes' or 'no' to the following qualification by clicking on the appropriate response in HPMS:** | **YES** | **NO** | **Requesting Waiver?** |
|---|---|---|---|
| Applicant has reviewed, understands, and complies with requirements for tracking each enrollee's true out of pocket (TrOOP) costs contained in section 1860D-2(b)(4) of the Act, 42 CFR Part 423 subpart J, Chapters 13 and 14 of the Prescription Drug Benefit Manual, and all related guidance. | | | |

NOTE: For information regarding the TrOOP facilitator, Applicant may link to **https://medifacd.mckesson.com/ /**

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

In HPMS, complete the table below:

| **Applicant must attest 'yes' or 'no' to the following qualification to be approved for a Part D contract. Attest 'yes' or 'no' to the following qualification by clicking on the appropriate response in HPMS:** | **YES** | **NO** | **Requesting Waiver?** |
|---|---|---|---|
| Applicant has reviewed, understands, and complies with all Medicare Secondary Payer (MSP) requirements, including those contained in 42 CFR § 423.462, Chapter 14 of the Prescription Drug Benefit Manual, and related guidance. | | | |
| Applicant adheres to MSP laws and any other Federal and State laws in establishing payers of last resort. | | | |
| Applicant follows the Rules for Coordination of Benefits adopted in the most current National Association of Insurance Commissioner Coordination of Benefits Model Regulation. | | | |

## 3.10 Data Exchange between PACE Organizations and CMS 42 CFR § 423.505(c) and (k)

In HPMS, complete the table below:

| **Applicant must attest 'yes' or 'no' to the following qualification to be approved for a Part D contract. Attest 'yes' or 'no' to the following qualification by clicking on the appropriate response in HPMS:** | **YES** | **NO** | **Requesting Waiver?** |
|---|---|---|---|
| Applicant uses HPMS to communicate with CMS in support of the application process, formulary submission process, bid submission process, ongoing operations of the Part D program, and reporting and oversight activities. Part D sponsors are required to secure access to HPMS in order to carry out these functions. | | | |

| | | | |
|---|---|---|---|
| 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 Help Desk webpage, https://www.cms.gov/mapd-helpdesk in the Access to CMS Systems and Identity Management (IDM) System link. | | | |
| Applicant has reviewed, understands, and complies with all requirements related to data exchange between sponsors and CMS, including those contained in 42 CFR § 423.505(c) & (k). | | | |
| 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, , discrepancy records, and premium payment data. | | | |

## 3.11 Health Insurance Portability and Accountability Act of 1996 (HIPAA), Health Information Technology for Economic and Clinical Health Act (HITECH Act), and Related CMS Requirements 45 CFR Parts 160, 162, and 164

In HPMS, complete the table below:

| **Applicant must attest 'yes' or 'no' to the following qualification to be approved for a Part D contract. 'yes' or 'no' to the following qualification by clicking on the appropriate response in HPMS:** | **YES** | **NO** | **Requesting Waiver?** |
|---|---|---|---|
| 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 Health Identifier for Health Care Providers under 45 CFR Parts 160, 162, and 164. | | | |
| 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"). | | | |

| | | | |
|---|---|---|---|
| Applicant has reviewed, understands, and complies with the Offshore Subcontractor requirements, and as applicable, submits the Offshore Subcontract Information and Attestation via HPMS for each offshore subcontractor (first tier, downstream and related entities) (including downstream offshore subcontractors' first tier, downstream and related entities) that receive, process, transfer, handle, store, or access Medicare beneficiary protected health information (PHI) by the last Friday in September for the upcoming contract year. | | | |

## 3.12 Prohibition on Use of Social Security Number (SSN) or Medicare Beneficiary Identifier Number on Enrollee ID Cards Prescription Drug Benefit Manual, Chapter 2

In HPMS, complete the table below:

| **Applicant must attest 'yes' or 'no' to the following qualification to be approved for a Part D contract. Attest 'yes' or 'no' to the following qualification by clicking on the appropriate response in HPMS:** | **YES** | **NO** | **Requesting Waiver?** |
|---|---|---|---|
| Applicant does not use an enrollee's Social Security Number (SSN) or Medicare Beneficiary Identifier number on the enrollee's identification card. | | | |

## 3.13 Prescription Drug Event (PDE) Records 42 CFR Part 423 Subpart G

In HPMS, complete the table below:

| **Applicant must attest 'yes' or 'no' to the following qualification to be approved for a Part D contract. Attest 'yes' or 'no' to the following qualification by clicking on the appropriate response in HPMS:** | **YES** | **NO** | **Requesting Waiver?** |
|---|---|---|---|
| Applicant has reviewed, understands, and complies with CMS requirements and guidance related to submission of prescription drug event (PDE) data, including 42 CFR Part 423 Subpart G, the Prescription Drug Program (Part D) resources, instructions, and trainings, such as the *2011 PDE Participant Guide* and *Key Changes to Medicare Part D in 2025: An Overview for PACE Organizations April 16, 2024* on the website www.csscoperations.com/. | | | |
| Applicant meets all data submission deadlines. | | | |
| Applicant pays all Plan-to-Plan payables on time. | | | |
| Applicant complies with Medicare Part D Manufacturer Discount Program requirements. | | | |

## 3.14 Claims Processing 42 CFR § 423.120(c)(4); 42 CFR § 423.466

In HPMS, complete the table below:

| **Applicant must attest 'yes' or 'no' to the following qualification to be approved for a Part D contract. Attest 'yes' or 'no' to the following qualification by clicking on the appropriate response in HPMS:** | **YES** | **NO** | **Requesting Waiver?** |
|---|---|---|---|
| Applicant has reviewed, understands, and complies with all requirements related to processing of electronic and paper claims contained in 42 CFR §§ 423.120(c)(4), 423.466, & 423.520 and all related CMS guidance. | | | |

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

In HPMS, complete the table below:

| **Applicant must attest 'yes' or 'no' to the following qualification to be approved for a Part D contract. Attest 'yes' or 'no' to the following qualification by clicking on the appropriate response in HPMS:** | **YES** | **NO** | **Requesting Waiver?** |
|---|---|---|---|
| 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 § 423.505(d). | | | |

## 3.16 Formulary Submission Requirements

### 3.16.1 Applicability of Formulary Submission Requirements

For purposes of formulary submission and review, the following paragraphs describe the definition of a formulary.

- **Cost sharing tiers**: Any coverage list that utilizes more than one cost sharing tier with differential co-pay or coinsurance, is considered a formulary.
- **Prior authorization**: Any coverage list that contains one or more drugs that must undergo prior authorization before dispensing is considered a formulary. If in the normal course of clinical practice, the prescribing physician uses FDA-approved indications and use criteria to determine appropriateness of therapy, this is not considered prior authorization.
- **Step therapy**: Any coverage list that contains one or more drugs that are part of a step therapy management program is considered a formulary. This includes any program that requires a certain drug to be used first, before a different drug can be dispensed. Step therapy can apply to certain drug classes or among brand and generic drug combinations.

- **Quantity limitations**: Any coverage list that contains one or more drugs with quantity limits is considered a formulary. Quantity limits are often used in cases where FDA-approved prescribing instructions state that only a certain number of doses should be used in a certain time period.
- **Steerage**: Any coverage list that contains one or more drugs that are considered preferred or drugs that are steered towards is considered a formulary. Common prescribing patterns are not considered steerage as long as there are no adverse consequences to physicians or patients if a particular drug is not chosen.

If a PACE organizationattested 'yes' to any of the five criteria referenced above, then their drug coverage list constitutes a formulary per 42 CFR § 423.4 and needs to be submitted to CMS for review and approval.

Only those applicants that have a coverage list absent any of the items listed above must adhere to formulary requirements specified in 42 CFR § 423.120(b) and complete the application sections that follow.

### 3.16.2 Formulary/Pharmacy and Therapeutics (P&T) Committee

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

| **Applicant must attest 'yes' or 'no' to the following qualification to be approved for a Part D contract. Attest 'yes' or 'no' to the following qualification by clicking on the appropriate response in HPMS:** | **YES** | **NO** | **NA** |
|---|---|---|---|
| 1. Applicant will submit a formulary to CMS for the Part D benefit by the CMS specified dates. 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. | | | [redacted] |
| 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 Applicant's formulary submission upon 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 Applicant's bid(s) and contracting with Applicant for the following benefit year. | | | [redacted] |

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

| **Applicant must attest 'yes' or 'no' to the following qualification to be approved for a Part D contract. Attest 'yes' or 'no' to the following qualification by clicking on the appropriate response in HPMS:** | **YES** | **NO** | **NA** |
|---|---|---|---|
| 1.Applicant is using the P&T Committee of its PBM for purposes of the Part D benefit. | | | |
| 2.If answered yes to B1, Applicant's PBM is operating under a confidentiality agreement for purposes of the P&T Committee (meaning Applicant has no knowledge of the membership of the PBM's P&T Committee). (If not applicable, check "NO.") Note: If answer is YES, then Applicant must complete P&T Committee Certification Statement and PBM must complete the P&T Committee Member List located in Appendix XVI entitled *Applicant Submission of P&T Committee Member List and Certification Statement*. | | | |
| 3.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.<br><br>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. | | | |

**C. If Applicant is intending for its Part D benefit to include use of a formulary, then the members of the P&T committee must be provided either directly by Applicant or by Applicant's PBM. The membership of the P&T committee must be comprised as described in Appendix I . If Applicant is providing names of P&T committee directly, then provide the membership in HPMS' Contract Management/Part D Data page. If the PBM operates under a confidentiality agreement (where 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.**

**Upload in HPMS, in a .pdf format, the following certification:**

# 4 CERTIFICATION

I,_____, attest to the following:
(NAME & TITLE)

1. I have read the contents of the completed application and the information contained herein is true, correct, and complete. If I become aware that any information in this application is not true, correct, or complete, I agree to notify the Centers for Medicare & Medicaid Services (CMS) immediately and in writing.
2. I authorize CMS to verify the information contained herein. I agree to notify CMS in writing of any changes that may jeopardize my ability to meet the qualifications stated in this application prior to such change or within 30 days of the effective date of such change. I understand that such a change may result in termination of the approval.
3. I agree that if my organization meets the minimum qualifications and is Medicare-approved, and my organization enters into a Part D contract with CMS, I will abide by the requirements contained in Section 3.0 of this Application and provide the services outlined in my application.
4. I agree that CMS may inspect any and all information necessary including inspecting of the premises of the Applicant's organization or plan to ensure compliance with stated Federal requirements including specific provisions for which I have attested. I further agree to immediately notify CMS if despite these attestations I become aware of circumstances which preclude full compliance by January 1 of the upcoming contract year with the requirements stated here in this application as well as in part 423 of 42 CFR.
5. I understand that in accordance with 18 U.S.C. § 1001, any omission, misrepresentation or falsification of any information contained in this application or contained in any communication supplying information to CMS to complete or clarify this application may be punishable by criminal, civil, or other administrative actions including revocation of approval, fines, and/or imprisonment under Federal law.
6. I further certify that I am an authorized representative, officer, chief executive officer, or general partner of the business organization that is applying for qualification to enter into a Part D contract with CMS.
7. I acknowledge that I am aware that there is operational policy guidance relevant to this application that is posted on the CMS website and that it is continually updated. My organization will comply with such guidance should it be approved for a Part D contract.

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

# 5 APPENDICES

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

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

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

As provided in the regulation at 42 CFR § 423.120(b)(1), a Part D Sponsor's P&T Committee list must contain a majority of members who are practicing physicians and/or pharmacists, include at least one practicing physician and one practicing pharmacist who are experts regarding care of the elderly or disabled individuals, and includes at least one practicing physician and one practicing pharmacist who are independent and free of conflict relative to the Part D Sponsor or Plan and pharmaceutical manufacturers.

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

## II. Instructions to Plans and PBMs

**A.** If the Part D Applicant sub-contracts with a PBM for its P&T Committee and operates under a Confidentiality Agreement (such that its members are not disclosed to the Part D Applicant) then the Applicant must (1) complete the attached Certification in HPMS, and (2) forward the attached P&T Committee Member Disclosure form to the sub-contracted PBM and direct the PBM to submit the form to CMS by 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 Part D Sponsor's P&T Committee or the PBM's P&T Committee, Part D Sponsors must assure that the PBM will notify the appropriate CMS account manager (to be assigned at a future date) and make the

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

**III.** PHARMACY AND THERAPEUTICS COMMITTEE MEMBER DISCLOSURE

PBM must email the following form to PartD_Applications@cms.hhs.gov by the application due date.

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

**A.** Complete the table below.

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

| **Full Name of Member**<br><br>**Start Date and End Date** | **Practicing Physician** | **Practicing Pharmacist** | **Elderly/ Disabled Expert** | **Free of Conflict of Interest With Your Organization?** | **Free of Conflict of Interest With Pharmaceutical Manufacturers?** |
|---|---|---|---|---|---|
| | | | | | |
| | | | | | |
| | | | | | |

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

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

| Organization Name | Type of Application | Contract Number(s) |
|---|---|---|
| | | |
| | | |
| | | |
| | | |

Applicant must upload in HPMS:

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

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

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

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

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

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

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

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

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

Part D Applicant's Contract Number: _____

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

## APPENDIX II- 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.

_____
(Day/Month/Year)

For New PDP applicants, Number of Covered Lives for Whom Organization Provided Health Insurance and/or Prescription Drug Coverage in 2023 and 2024:

_____

### C. Management of Legal Entity

Identify the staff (name and title) 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, 2022.

### D. Parent Organization Information

Name of Parent Organization: _____

Date Parent Organization established: _____

Note to applicants - If parent organization is the same as the legal entity name, complete this section and provide an explanation.

## 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.