Medicare Part D Application for New PACE Organizations
2012 Contract Year

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 1860 D-43 of the Social Security Act (the Act).

1.2 Overview

The Part D benefit constitutes perhaps the most significant change to the Medicare program since its inception in 1965 by recognizing the vital role of prescription drugs in our health care delivery system. However, 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.

1.3 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.

1.4 Health Plan Management System (HPMS)

Completion of the CMS PACE Provider Application and the Part D application (chapter 11) is a significant step towards attaining CMS approval to provide the Part D benefit to eligible PACE participants. In addition, PACE organizations are required to secure access to the CMS Health Plan Management System (HPMS) in order to carry out additional Part D functions including the formulary submission process (as applicable), the bid submission process, ongoing operations of the Part D program, and reporting and oversight activities.

PACE organizations must obtain HPMS user ID's and access to the system only after being assigned a CMS provider number or "H-number". PACE organizations are assigned CMS "H-numbers" upon CMS receipt of the PACE provider application. We note that the PACE provider application is routed to CMS only after it has been reviewed by the SAA. Once your application has arrived and CMS assigns an "H-number, you will be notified by your CMS PACE team lead. At this point, the PACE organizations staff must obtain HPMS user ID's in order to access the system. The HPMS user ID application may be accessed at:
http://www.cms.gov/AccesstoDataApplication/Downloads/Access.pdf

In addition, instructions to PACE organization for completing this form are located at:

http://www.cms.gov/PACE/Downloads/hpmsconn.pdf

Questions concerning HPMS user IDs should be directed to the HPMS Help Desk at helpdesk@hpms@cms.hhs.gov

1.5 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 upload their plan formularies to HPMS using a pre-defined file format and record layout.

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

Each PACE applicant must submit to CMS, via HPMS, two Part D bids; 1 for dual eligible enrollees and 1 for Medicare-only enrollees. Applicants using this solicitation must apply to offer full risk Part D plans.

The applicants 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 CEO, CFO, or an individual delegated with the authority to sign on

behalf of one of these officers, and who reports directly to such officer, must certify (based on best knowledge, information and belief) that the information in the bid submission is accurate, complete, and truthful, and fully conforms to the requirements in section 42 CFR §423.265 of the regulations (except section 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 receive CMS approval of the Part D bids 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.

1.6.1 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.

1.6.2 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.

1.7 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.

1.8 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.

1.9 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 be 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.

1.10 Protection of Confidential Information

Applicants may seek to protect their information from disclosure under the Freedom of Information Act (FOIA) by claiming that FOIA Exemption 4 applies. The Applicant is required to label the information in question "confidential" or "proprietary", and explain

the applicability of the FOIA exemption it is claiming. This designation must be in writing. When there is a request for information that is designated by the Applicant as confidential or that could reasonably be considered exempt under Exemption 4, CMS is required by its FOIA regulation at 45 C.F.R. §5.65(d) and by Executive Order 12,600 to give the submitter notice before the information is disclosed. To decide whether the Applicant's information is protected by Exemption 4, CMS must determine whether the Applicant has shown that— (1) disclosure of the information might to impair the government's ability to obtain necessary information in the future; (2) disclosure of the information would cause substantial harm to the competitive position of the submitter; (3) disclosure would impair other government interests, such as program effectiveness and compliance; or (4) disclosure would impair other private interests, such as an interest in controlling availability of intrinsically valuable records, which are sold in the market. Consistent with our approach under the Medicare Advantage program, we would not release information under the Medicare Part D program that would be considered proprietary in nature.

1.11 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.

1.12 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. We note that an enumeration system applicable to health plans is still in the development stages. However, 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 ISC 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 2013. Applicants projecting PACE provider status by 1/1/2013 may submit the Part D application (chapter 11 of the PACE provider application) up until July 1, 2012. Applicants must use the 2013 solicitation. CMS will not accept or review in any way those submissions using prior version of the application.

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

Jack Healey by email at: jackie.healey@cms.hhs.gov or by phone at 410-786-3683.

2.2 Instructions

Applicants must include the name of the PACE organization in the heading on each page of the Part D application submitted to CMS.

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 returned to CMS as indicated.
- Legal documents such as subcontracts should be provided in hard copy as an attachment to the application. In addition, all subcontracts and other legal documents should be provided on the CD or diskette copies of the application. The CD/diskette identification should include the form number.

CMS will check the Part D application for completeness shortly after its receipt. We will notify Applicants of any deficiencies and afford them the opportunity to amend their Part D applications.

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. CMS reserves the right to request clarifications or corrections to a submitted application. Failure to provide requested clarifications could result in the applicant receiving a notice of intent to deny the application, in which case, the Applicant will then have 10 days to seek to remedy its application.

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

2.3 Format

All responses should be completed in Microsoft Word (in a version that is compatible with Office 2003). Attachments (such as existing contracts) can be submitted in Microsoft Word (in a version that is compatible with Windows 2003) or as a PDF file.

At the time you receive notification from CMS that your provider application has been received from the State, you must submit a cover letter and three (3) hard copies of the Part D application (Chapter 11) and supporting documentation to CMS. In addition, the applicant should simultaneously submit one copy to the State Administrating Agency (SAA).

Centers for Medicare & Medicaid Services (CMS)

Jack Healey

Mail Stop: C4-21-26

Attn: PACE Part D Application

7500 Security Boulevard

Baltimore, Maryland 21244-1850

Each hard copy of the Part D application should include tab indexing identifying all of the major sections of the Part D application. Page size should be 8 ½ by 11 inches. Font size should be 12 point.

One Part D application should be clearly marked, "Original" and contain all original signed certifications requested in the application.

Note: It is important that Applicant provide 2 separate contact persons and applicable contact information for PACE organization Application submission(s). This will help to avoid delays in the processing of an application.

Along with three paper copies of the Part D application each applicant must submit three (3) duplicate CDs or diskettes. This will support the review of the application by different CMS components.

Each CD or diskette must be clearly labeled with the information in the table below:

Applicant's Organization Name
CD or Diskette Number (Copy 1, Copy 2, Copy 3, etc.) **Note: If multiple CDs or diskettes are required to include written application, appendices, attachments and other supporting documentation, label as follows: Copy 1 (1 of 2), Copy 1 (2 of 2), Copy 2 (1 of 2), Copy 2 (2 of 2), etc.**

In order for CMS to receive your application in a timely manner, please note that Federal Express and the US Postal Service possess a CMS security clearance. Applications mailed through carriers that do not have CMS Security Clearance could be delayed due to clearance processing.

Failure to submit a Part D application consistent with these instructions may delay its review by CMS and could result in receipt of a notice of intent to deny.

Bid and formulary (as applicable) submissions are required on an annual basis. Although CMS will not require resubmission of this chapter on an annual basis, we expect to be notified of any changes to responses initially provided.

2.4 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
423.50	Approval of marketing materials and enrollment forms
423.104(g)(1)	Access to negotiated prices
423.112	Establishment of PDP service areas
423.120(a)	Access to covered Part D drugs

Part D Regulation	**Regulatory Requirement(s)** **Description**
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
423.153(a)-423.153(d)	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) ***Note: Automatic waiver applies to new or potential organizations that are not operational by the June deadline.*** ***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

Part D Regulation	**Regulatory Requirement(s)** **Description**
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), and 423.504(d) ***Note: Organizations are required to abide by 423.504(b)(4)(vi)(F-H), 423.504(b)(5), 423.504(c), and 423.504(e)***	Conditions necessary to contract as a Part D plan sponsor
423.505(a-c) and 423.505(e-i) ***Note: Organizations are required to abide by 423.505(d and j)***	Contract provisions
423.505(k)(6) ***Note: Organizations are required to abide by 423.505(k)(1-5)***	Certification for purposes of price compare
423.506(a)-(b) ***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
N/A	A PDP sponsor is required to be a nongovernmental entity

2.4.1 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 must submit a separate Part D waiver request package that includes:

1. The Part D regulation reference;
2. The appropriate waiver criteria (e.g. duplicative, conflicts, improves benefit coordination);
3. A discussion of how the requested waiver meets at least one of the three waiver criteria.

Four copies of these requests should be submitted to the following address:

Centers for Medicare and Medicaid Services (CMS)

Janet Samen

Attn: Part D PACE Waiver Request

Mail Stop: C5-05-27

7500 Security Boulevard

Baltimore, MD 21244-1850

Finally, the PACE Organization should also copy their State Administering Agency on the request as well as their CMS PACE Team Lead.

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 sections 42 CFR §460.26(b) and 42 CFR §460.28 of the PACE regulation.

3 APPLICATION FORMS

Please do not submit the previous pages of this chapter in the printed copy of your application.

3.1 Cover Sheet

CENTERS FOR MEDICARE AND MEDICAID SERVICES MEDICARE PART D APPLICATION PROGRAM OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE)	
NAME OF LEGAL ENTITY TRADE NAME (if different) PARENT ORGANIZATION (if applicable)	MAILING ADDRESS
AREA CODE TELEPHONE NO. EXTENSION	FAX
CEO OR EXECUTIVE DIRECTOR: NAME AND TITLE TELEPHONE NUMBER	MAILING ADDRESS
PRIMARY APPLICANT CONTACT PERSON: NAME TITLE ADDRESS E-MAIL FAX TELEPHONE NUMBER	
SECONDARY APPLICANT CONTACT: NAME TITLE ADDRESS E-MAIL FAX TELEPHONE NUMBER	

3.2 Management and Operations

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

In HPMS, on the Contract and Management/Part D Information/Part D Data Page, provide the names of the first tier, downstream and related entities you will use to carry out each of the functions listed in this chart and whether the first tier, downstream and related entities are off-shore: (Indicate "APPLICANT" where applicant will perform those functions)	**Function**	**<u>Subcontractor(s)</u>** (first tier, downstream and related entities)	**<u>Off-Shore</u>** Yes/No
	A pharmacy benefit program that performs adjudication and processing of pharmacy claims at the point of sale.		
	A pharmacy benefit program that performs negotiation with prescription drug manufacturers and others for rebates, discounts, or other price concessions on prescription drugs		
	A pharmacy benefit program that performs administration and tracking of enrollees' drug benefits in real time, including TrOOP balance processing.		
	A pharmacy benefit program that performs coordination with other drug benefit programs, including, for example, Medicaid, state pharmaceutical assistance programs, or other insurance.		

	A pharmacy benefit program that develops and maintains a pharmacy network.		
	A pharmacy benefit program that operates an enrollee grievance and appeals process		
	A pharmacy benefit program that performs customer service functionality, that includes serving seniors and persons with a disability.		
	A pharmacy benefit program that performs pharmacy technical assistance service functionality.		
	PACE organizations functioning with formularies agree to maintain pharmaceutical and therapeutic committees.		

3.2.2 Requirements in Contracts/Administrative Services Agreements

A. Provide as attachments copies of executed contracts, fully executed letters of agreement, or administrative services agreements with each (first tier, downstream and related entities identified in the above table and with any first tier, downstream, or related entity that contracts with any of the identified entities on the applicant's behalf. All contracts must:

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

3. Contain language clearly indicating that the first tier, downstream, or related entity has agreed to participate in your Medicare Prescription Drug Benefit program (except for a network pharmacy if the existing contract would allow participation in this program).
4. Contain flow-down clauses requiring that their activities be consistent and comply with the Applicant's contractual obligations as a Part D sponsor. 42 CFR §423.505(i)(3)(iii)
5. Describe the payment the first tier, downstream, or related entity will receive for performance under the contract, if applicable.
6. 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 §423.505(i)(4)(iv)
8. 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 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)
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. 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)(viii)(B)
16. 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)
17. If the first tier, downstream, or related entity will establish the pharmacy network or select pharmacies to be included in the network contain language 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)
18. If the first tier, downstream, or related entity will adjudicate and process claims at the point of sale and/or negotiate with prescription drug manufacturers and others for rebates, discounts, or other price concessions on prescription drugs contain language that the first tier, downstream, or related entity will comply with the reporting requirements established in Section 6005 of the Affordable Care Act.

B. 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	**Location in Subcontract by Page number and Section**
1. The parties to the contract	
2. The functions to be performed by the first tier, downstream, or related entity. Describe the reporting requirements the first tier, downstream, or related entity identified in Section 3.1.1C of the application has to the applicant. 42 CFR §423.505(i)(4)(i)	
3. 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. 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)	
5. The payment the first tier, downstream, or related entity will receive for performance under the contract, if applicable.	
6. Are signed by a representative of each party with legal authority to bind the entity.	
7. 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)	
8. 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.	

9. 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	
10. 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)	
11. 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)	
12. 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)	
13. 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)	
14. 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)	

15. Language that if the first tier, downstream, or related entity will establish the pharmacy network or select pharmacies to be included in the network and a prescription drug pricing standard is used for reimbursement,identifies the source used by the Part D sponsor for the prescription drug pricing standard of reimbursement. 42 CFR §423.505(i)(3)(viii)(B)	
16. 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)	
17. 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)	
18. Language that if the first tier, downstream, or related entity will adjudicate and process claims at the point of sale and/or negotiate with prescription drug manufacturers and others for rebates, discounts, or other price concessions on prescription drugs contain language requiring that the first tier, downstream, or related entity will comply with the reporting requirements established in Section 6005 of the Affordable Care Act.	

3.2.3 Requirements for Long Term Care Pharmacy Access Contracts

INSTRUCTIONS: Applicants must complete 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**
1. The functions to be performed by the first tier, downstream, or related entity. Describes the reporting requirements the first tier, downstream, or related entity identified in Section 3.1.1C of the application has to the Applicant. 42 CFR §423.505(i)(4)(i)	
2. Language obligating the first tier, downstream, or related entity to abide by all applicable Federal laws and regulations and CMS instructions. 42 CFR §423.505(i)(4)(iv)	
3. 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.	
4. 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	
5. 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)	

6. 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)	
7. 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)	
8. 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)	
9. For those contracts that use a prescription drug pricing standard for reimbursement, a provision indicating the source used by the Part D sponsor for the prescription drug pricing standard of reimbursement. 42 CFR §423.505(i)(3)(viii)(B)	
10. 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)	
11. 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)	
12. Provisions governing submitting claims to a real-time claims adjudication system. 42 CFR §423.505(j) and §423.505(b)(17) 13. 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.	
14. Provisions governing providing Part D enrollees access to negotiated prices as defined in 42 CFR 423.100. 42 CFR §423.104(g)	
15. Provisions regarding charging/applying the correct cost-sharing amount. 42 CFR §423.104	

16. Provisions governing informing the Part D enrollee at the point of sale (or at the point of delivery for mail order drugs) of the lowest-priced, generically equivalent drug, if one exists for the beneficiary's prescription, as well as any associated differential in price. 42 CFR §423.132	
Elements Specific to Long-Term Care Contracts **Note: CMS Long-Term Care Guidance included in Chapter 5 of the Prescription Drug Benefit Manual contains an updated list of performance and service criteria for contracting with long-term care pharmacies. Applicants should, at a minimum, incorporate these criteria in ALL LTC pharmacy network contracts. Applicant must list the criteria below, and then identify where the elements reside in the contract template(s) submitted.**	
Performance and Service Criteria	**Citation**
Comprehensive Inventory and Inventory Capacity – Network Long Term Care Pharmacies [NLTCPs] must provide a comprehensive inventory of Plan formulary drugs commonly used in the long term care setting. In addition, NLTCPs must provide a secured area for physical storage of drugs, with necessary added security as required by federal and state law for controlled substances. This is not to be interpreted that the pharmacy will have inventory or security measures outside of the normal business setting.	
Pharmacy Operations and Prescription Orders -- NLTCPs must provide services of a dispensing pharmacist to meet the requirements of pharmacy practice for dispensing prescription drugs to LTC residents, including but not limited to the performance of drug utilization review (DUR). In addition, the NLTCP pharmacist must conduct DUR to routinely screen for allergies and drug interactions, to identify potential adverse drug reactions, to identify inappropriate drug usage in the LTC population, and to promote cost effective therapy in the LTC setting. The NLTCP must also be equipped with pharmacy software and systems sufficient to meet the needs of prescription drug ordering and distribution to an LTC facility. Further, the NLTCP must provide written copies of the NLTCP's pharmacy procedures manual and said manual must be available at each LTC facility nurses' unit. NLTCPs are also required to provide ongoing in-service training to assure that LTC facility staff is proficient in the NLTCP's processes for ordering and receiving of medications. NLTCP must be responsible for return and/or disposal of unused medications following discontinuance, transfer, discharge, or death as permitted by State Boards of Pharmacy. Controlled substances and out of date substances must be disposed of within State and Federal guidelines.	

Special Packaging -- NLTCPs must have the capacity to provide specific drugs in Unit of Use Packaging, Bingo Cards, Cassettes, Unit Dose or other special packaging commonly required by LTC facilities. NLTCPs must have access to, or arrangements with, a vendor to furnish supplies and equipment including but not limited to labels, auxiliary labels, and packing machines for furnishing drugs in such special packaging required by the LTC setting.	
IV Medications -- NLTCPs must have the capacity to provide IV medications to the LTC resident as ordered by a qualified medical professional. NLTCPs must have access to specialized facilities for the preparation of IV prescriptions (clean room). Additionally, NLTCPs must have access to or arrangements with a vendor to furnish special equipment and supplies as well as IV trained pharmacists and technicians as required to safely provide IV medications.	
Compounding /Alternative Forms of Drug Composition -- NLTCPs must be capable of providing specialized drug delivery formulations as required for some LTC residents. Specifically, residents unable to swallow or ingest medications through normal routes may require tablets split or crushed or provided in suspensions or gel forms, to facilitate effective drug delivery.	
Pharmacist On-call Service -- NLTCP must provide on-call, 24 hours a day, 7 days a week service with a qualified pharmacist available for handling calls after hours and to provide medication dispensing available for emergencies, holidays and after hours of normal operations.	
Delivery Service -- NLTCP must provide for delivery of medications to the LTC facility up to seven days each week (up to three times per day) and in-between regularly scheduled visits. Emergency delivery service must be available 24 hours a day, 7 days a week. Specific delivery arrangements will be determined through an agreement between the NLTCP and the LTC facility. NLTCPs must provide safe and secure exchange systems for delivery of medication to the LTC facility. In addition, NLTCP must provide medication cassettes, or other standard delivery systems, that may be exchanged on a routine basis for automatic restocking. The NLTCP delivery of medication to carts is a part of routine “dispensing”.	
Emergency Boxes -- NLTCPs must provide “emergency” supply of medications as required by the facility in compliance with State requirements.	

Emergency Log Books -- NLTCP must provide a system for logging and charging medication used from emergency/first dose stock. Further, the pharmacy must maintain a comprehensive record of a resident's medication order and drug administration.	
Miscellaneous Reports, Forms and Prescription Ordering Supplies -- NLTCP must provide reports, forms and prescription ordering supplies necessary for the delivery of quality pharmacy care in the LTC setting. Such reports, forms and prescription ordering supplies may include, but will not necessarily be limited to, provider order forms, monthly management reports to assist the LTC facility in managing orders, medication administration records, treatment administration records, interim order forms for new prescription orders, and boxes/folders for order storage and reconciliation in the facility.	
Provide that long-term care pharmacies must have not less than 30 days, nor more than 90 days, to submit to the Part D Sponsor claims for reimbursement under the plan. 42 CFR § 423.504(b)(20)	
Provisions requiring that long-term care pharmacies dispense drugs and report information as required by 42 CFR §423.154.	

3.3 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. We recognize that due to the many PACE Part D waivers, several of the requested contacts bear no relevance for PACE organizations. However, for systems purposes all sections must be populated. Therefore, in instances where a contact does not apply, please list the Application Contact.

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

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

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

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

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

B. In HPMS, complete the table below:

Applicant must attest 'yes' to each of the following qualifications to be approved for a Part D contract. Attest 'yes' or 'no' to each of the following qualifications by clicking on the appropriate response in HPMS:	Yes	No
1. Applicant agrees that CMS may release contact information to States, SPAPs, providers, Part D sponsors, and others who need the contact information for legitimate purposes.	☐	☐

3.4 Program Integrity and Compliance Program

A. In HPMS, complete the table below:

Applicant must attest 'yes' or 'no' to each of the following qualifications to be approved for a Part D contract. Attest 'yes' or 'no' to each of the following qualifications by clicking on the appropriate response in HPMS:	Yes	No
1. Applicant, applicant staff, and its affiliated companies, subsidiaries or first tier, downstream and related entities, and staff of the first tier, downstream and related entities agree that they are bound by 2 CFR Part 376 and attest that they are not excluded by the Department of Health and Human Services Office of the Inspector General or by the General Services Administration exclusion lists. Please note that this includes any member of its board of directors, and any key management or executive staff or any major stockholder. Additionally, given Medicare payment may not be made for items or services furnished by an excluded provider or entity, applicant should follow the guidance provided in the January 13, 2010 HPMS memo entitled Claims for Drugs Prescribed or Dispensed by Excluded Providers.	☐	☐

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

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

Please be advised that the Applicant is ultimately responsible for the implementation and monitoring of the day-to-day operations of its Part D compliance program. 42 CFR

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

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

Compliance Plan Elements	Page, paragraph here element located
A. Written policies, procedures, and standards of conduct must include the following seven components:	**§ 423.504(b)(4)(vi)(A)**
1. Articulate the applicant's commitment to comply with all applicable Federal and State standards.	
2. Describe compliance expectations as embodied in the standards of conduct.	
3. Describe the implementation and operation of the compliance program.	
4. Provide guidance to employees and others on dealing with potential compliance issues.	
5. Identify how to communicate compliance issues to appropriate compliance personnel.	
6. Describe how potential compliance issues will be investigated and resolved by the applicant.	
7. Include a policy of non-intimidation and non-retaliation for good faith participation in the compliance program, including, but not limited to, reporting potential issues, investigating issues, conducting self-evaluations, audits and remedial actions, and reporting to appropriate officials.	

B. Designation of a compliance officer and a compliance committee who report directly to and are accountable to applicant's chief executive or senior management and include the following three components:	**§ 423.504(b)(4)(vi)(B)**
1. The compliance officer, vested with the day-to-day operations of the compliance program, must be an employee of the MA applicant, parent organization or corporate affiliate. The compliance officer may not be an employee of the MA applicant's first tier, downstream or related entity.	
2. The compliance officer and the compliance committee must periodically report directly to the governing body of the MA applicant on the activities and status of the compliance program, including issues identified, investigated, and resolved by the compliance program.	
3. The governing body of the MA applicant must be knowledgeable about the content and operation of the compliance program and must exercise reasonable oversight with respect to the implementation and effectiveness of the compliance programs.	
C. Establish, implement and provide effective training and education for employees including the chief executive and senior administrators or managers, governing body members, first tier, downstream, and related entities must include the following components:	**§ 423.504(b)(4)(vi)(C)**
1. Training and education must occur at least annually and must be part of the orientation for new employees, new first tier, downstream and related entities, and new appointments to chief executive, senior administrator, or governing body member.	
2. An indication that first tier, downstream, and related entities who have met the fraud, waste, and abuse certification requirements through enrollment into the Medicare program or accreditation as a Durable Medical Equipment, Prosthetics, Orthotics, and supplies (DMEPOS) are deemed to have met the training and educational requirements for fraud, waste, and abuse.	
D. Establishment and implementation of effective lines of communication, ensuring confidentiality, between:	**§ 423.504(b)(4)(vi)(D)**
1. The compliance officer, members of the compliance committee, the MA applicant's employees, managers and governing body.	

2. The MA applicant's first tier, downstream, and related entities.	
3. Such lines of communication must be accessible to all.	
4. Allow compliance issues to be reported, including a method for anonymous and confidential good faith reporting of potential compliance issues, as they are identified.	
E. Well-publicize disciplinary standards and implementation of procedures, which encourage good faith participation in the compliance program by all affected individuals, that are enforced and include the following three policies:	**§ 423.504(b)(4)(vi)(E)**
1. Articulate expectations for reporting compliance issues and assist in their resolution.	
2. Identify non-compliance or unethical behavior.	
3. Provide for timely, consistent, and effective enforcement of the standards when noncompliance or unethical behavior is determined.	
F. Establish and implementation of an effective system for routine monitoring and identification of compliance risks. The system should include: internal monitoring and audits and, as appropriate, external audits, to evaluate the MA applicant, including first tier entities', compliance with CMS requirements and the overall effectiveness of the compliance program.	**§ 423.504(b)(4)(vi)(F)**
G. Establishment and implementation of procedures and a system for 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:	**§ 423.504(b)(4)(vi)(G)**
1. If the MA applicant discovers evidence of misconduct related to payment or delivery of items or services under the contract, it must conduct a timely, reasonable inquiry into that conduct.	
2. The MA applicant must conduct appropriate corrective actions (e.g., repayment of overpayments and disciplinary actions against responsible individuals) in response to the potential violation.	
3. The MA applicant should have procedures to voluntarily self-report potential fraud or misconduct related to the MA program to CMS or its designee.	

3.5 Health Information Technology

Complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PART D CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN:	YES	NO	Requesting Waiver? *Yes or No*
1. Applicant agrees that as it implements, acquires, or upgrades health information technology (HIT) systems, where available, the HIT systems and products meet standards and implementation specifications adopted under section 3004 of the Public Health Services Act as added by section 13101 of the American Recovery and Reinvestment Act of 2009, P.L. 111-5.	☐	☐	☐

3.6 Enrollment and Eligibility

Complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PART D CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN:	YES	NO	Requesting Waiver? *Yes or No*
1. Applicant complies with CMS operational guidance on Creditable Coverage and the Late Enrollment Penalty.	☐	☐	☐
2. For each enrollment request received, Applicant queries the Batch Eligibility Query (BEQ) or the User Interface (UI) prior to the submission of an enrollment transaction to the MARx system to receive: • Verification of Medicare Entitlement and Part D Eligibility, • Periods of enrollment in a Medicare plan that provides prescription drug coverage, • Periods of enrollment in a retiree prescription drug plan whose sponsor receives a retiree drug subsidy from Medicare, and • Information regarding the Low Income Subsidy applicable to each new enrollee.	☐	☐	☐

3. Applicant collects, reviews, and transmits creditable coverage information in accordance with CMS operational guidance and policies.	☐	☐	☐
4. Applicant uses the information provided by CMS, including the Low-Income Subsidy/Part D Premium Report Data File to determine match rates of their information to that of CMS within 72 hours of receipt. Applicant further agrees that their match rate should achieve 95 percent and that non-matches are resolved within 72 hours.	☐	☐	☐
5. Applicant does not disenroll members for failure to pay premiums (or notify them of impending disenrollment) in cases where the individual is considered to be in premium withhold status by CMS as provided in CMS Enrollment and Disenrollment Guidance and Premium Payment policies.	☐	☐	☐
6. Applicant does not disenroll a member or initiate the disenrollment process if the organization has been notified that a State Pharmaceutical Assistance Program (SPAP) or other payer intends to pay the entire Part D premium on behalf of an individual.	☐	☐	☐

3.7 Complaints Tracking

Complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PART D CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN:	**YES**	**NO**	***Requesting Waiver?*** *Yes or No*
1. Applicant resolves 95% of complaints designated as immediate needs complaints via the CMS Complaints Tracking Module within 2 calendar days.	☐	☐	☐
2. Applicant is expected to resolve at least 95% of complaints designated as "urgent" via the CMS Complaints Tracking Module in accordance with CMS issued guidance.	☐	☐	☐
3. Applicant is expected to resolve at least 95% of complaints without an issue level via the CMS Complaints Tracking Module in accordance with CMS issued guidance.	☐	☐	☐

4. Applicant monitors and documents complaint resolutions for complaints attributed to their contracts in the CMS' Complaint Tracking Module in accordance with CMS' Standard Operating Procedures for Part D sponsors.	☐	☐	☐
5. Applicant maintains Standard Operating Procedures that address how its organization will handle and quickly resolve immediate action cases, as well as, outline the steps the organization intends to take to have enrollees call your customer service directly for the prompt resolution of all inquiries.	☐	☐	☐

3.8 Coordination of Benefits

Complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PART D CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN:	**YES**	**NO**	**Requesting Waiver?** ***Yes or No***
1. Applicant complies with Chapter 14 of the Prescription Drug Benefit Manual.	☐	☐	☐
2. Applicant has a system for notifying enrollees when CMS' systems indicate other prescription drug coverage, and requesting enrollees to concur with new/changed information.	☐	☐	☐
3. Applicant permits SPAPs, ADAPs, IHS, and other third party payers to coordinate benefits as required by the regulations in 42 CFR Part 423, Subpart J, and Chapter 14 of the Prescription Drug Benefit Manual. For example, an SPAP may require agreements be signed in order for the state to pay premiums on behalf of a beneficiary. CMS expects Part D sponsors to execute these trading partner agreements within a reasonable timeframe.	☐	☐	☐
4. Applicant does not impose fees on SPAPs or other third-party insurers that are unreasonable and/or unrelated to the cost of coordination of benefits.	☐	☐	☐

5. Applicant coordinates benefits with SPAPs, other entities providing prescription drug coverage, beneficiaries, and others paying on the beneficiaries' behalf for a period not to exceed three years from the date on which the prescription for a covered Part D drug was filled.	☐	☐	☐

3.9 Tracking True Out-of-Pocket Costs (TrOOP)

Complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PART D CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN:	**YES**	**NO**	**Requesting Waiver?** ***Yes or No***
1. Applicant tracks each enrollee's true out of pocket (TrOOP) costs reflecting the amount the enrollee has spent out of pocket during a program year on covered Part D drugs.	☐	☐	☐
2. Applicant accepts data concerning third party payers in a format specified by CMS and uses these data in the Applicant's TrOOP calculation process.	☐	☐	☐
3. In the event of disenrollment, Applicant provides the TrOOP status of the beneficiary as of the effective date of the disenrollment to the beneficiary, if there has been a change in these data since the last report to the beneficiary.	☐	☐	☐
4. Applicant agrees that, when an exception to the ATBT process is required, the Applicant sends TrOOP-related data manually for disenrolling Part D beneficiaries as well as receives these data manually for newly enrolling Part D beneficiaries transferring mid-year from another plan.	☐	☐	☐
5. Applicant treats costs incurred by AIDS Drug Assistance Programs and Indian Health Services in providing prescription drugs toward the annual out-of-pocket threshold.	☐	☐	☐

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

3.10 Medicare Secondary Payer

Complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PART D CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN:	**YES**	**NO**	***Requesting Waiver?*** *Yes or No*
1. Applicant is familiar with rules that determine when other payers are primary or secondary to Medicare as referenced in 42 CFR §423.462.	☐	☐	☐
2. Applicant adheres to MSP laws and any other Federal and State laws in establishing payers of last resort.	☐	☐	☐
3. Applicant follows the Rules for Coordination of Benefits adopted in the most current National Association of Insurance Commissioner Coordination of Benefits Model Regulation.	☐	☐	☐
4. Applicant collects mistaken primary payment from insurers, group health plans, employer sponsors, enrollees and other entities.	☐	☐	☐
5. Applicant agrees that in situations involving workers' compensation, Black Lung, No-Fault, or Liability coverage to make conditional primary payment and recover any mistaken payments, unless the Applicant is already aware that the enrollee has workers' compensation, Black Lung, No-Fault, or Liability coverage and has previously established that a certain drug is being used exclusively to treat a related injury.	☐	☐	☐

3.11 Data Collection and Reporting Requirements

Complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PART D CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN:	**YES**	**NO**	***Requesting Waiver?*** *Yes or No*
REBATE DATA			
1. The Applicant reports direct and indirect remuneration (DIR) dollars for payment reconciliation on an annual basis at the Plan Benefit Package (PBP) level/plan level in the manner specified by CMS. In addition, the Applicant maintains records and documentation to verify the DIR data reported to CMS.	☐	☐	☐

3.12 Data Exchange between PACE Organizations and CMS

Complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PART D CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN:	**YES**	**NO**	***Requesting Waiver?*** *Yes or No*
HPMS			
1. Applicant uses HPMS to communicate with CMS in support of the application process, formulary submission process, bid submission process, ongoing operations of the Part D program, and reporting and oversight activities. Part D sponsors are required to secure access to HPMS in order to carry out these functions.	☐	☐	☐
ENROLLMENT & PAYMENT			
2. Applicant establishes connectivity to CMS as noted in the instructions provided by the MAPD Help Desk at 1-800-927-8069 or via the MAPD HelpDesk webpage, www.cms.gov/mapdhelpdesk, in the Plan Reference Guide for CMS Part C/D system link.	☐	☐	☐
3. Applicant obtains CMS User ID and Password.	☐	☐	☐

4. Applicant submits enrollment, disenrollment and change transactions to communicate membership information to CMS within the timeframes provided by CMS.	☐	☐	☐
5. Applicant reconciles Part D data to CMS enrollment/payment reports received daily, weekly and monthly.	☐	☐	☐
6. Applicant completes the review of monthly reports, including submitting all requests for discrepancy corrections, and submits the CEO Certification of enrollment data for plan payment within 45 days of CMS monthly membership payment report availability.	☐	☐	☐
7. Applicant participates in connectivity testing and other system testing measures as provided to the Applicants prior to contract execution to validate system setup.	☐	☐	☐
8. Applicant has system(s) to process enrollment and payment transactions as exchanged with CMS in accordance with system development lifecycle standards.	☐	☐	☐
9. Applicant ensures appropriate security safeguards and protocols are in place to protect the protected health information in the system(s).	☐	☐	☐
10. Applicant maintains all pertinent system security and disaster recovery plans and procedures.	☐	☐	☐

3.13 Health Insurance Portability and Accountability Act of 1996 (HIPAA)

Complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PART D CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN:	**YES**	**NO**	***Requesting Waiver?*** *Yes or No*
1. Applicant complies with all applicable standards, implementation specifications, and requirements in the Standards for Privacy of Individually Identifiable Health Information, and Security Standards under 45 CFR Parts 160, 162, and 164.	☐	☐	☐

2. Applicant encrypts all hard drives or other storage media within the device as well as all removable media.	☐	☐	☐
3. Applicant has policies addressing the secure handling of portable media that is accessed or used by the organization.	☐	☐	☐
4. Applicant complies with all applicable standards, implementation specifications, and requirements in the Standard Unique Health Identifier for Health Care Providers final rule under 45 CFR Parts 160 and 162.	☐	☐	☐
5. Applicant agrees that when its organization receives a National Provider Identifier (NPI) in prescription drug event data, that the organization must report an NPI.	☐	☐	☐
6. Applicant agrees to implement a contingency plan related to compliance with the NPI provisions.	☐	☐	☐
7. Applicant complies with all applicable standards, implementation specifications, and requirements in the Standards for Electronic Transactions under 45 CFR Parts 160 and 162.	☐	☐	☐
8. Applicant 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.	☐	☐	☐

3.14 Prohibition on Use of SSN or Medicare ID Number on Enrollee ID Cards

Complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PART D CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN:	**YES**	**NO**	***Requesting Waiver?*** *Yes or No*
1. Applicant does not use an enrollee's Social Security Number (SSN) or Medicare ID Number on the enrollee's identification card.	☐	☐	☐

3.15 Prescription Drug Event (PDE) Records

Complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PART D CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY CLICKING ON THE APPROPRIATE RESPONSE IN HPMS:	**YES**	**NO**	***Requesting Waiver?*** *Yes or No*
2. Applicant abides by CMS guidance related to PDE data. Such guidance includes the 2008 Regional Prescription Drug Event Data Participant Training Guide and Technical Assistance Resource Guide which can be found at www.csscoperations.com/new/pdic/pdd-training/pdd-training.html.	☐	☐	☐
3. Applicant submits data and information necessary for CMS to carry out payment provisions.	☐	☐	☐
4. Applicant submits PDE data on the schedule required by applicable regulations and CMS guidance.	☐	☐	☐
5. Applicant provides diagnosis data for risk adjustment as required by CMS.	☐	☐	☐
6. Applicant submits the PDE data in the format described by CMS and in accordance with the National Council for Prescription Drug Programs (NCPDP) industry standard format.	☐	☐	☐
7. Applicant meets all data submission deadlines.	☐	☐	☐
8. Applicant pays all Plan-to-Plan payables on time.	☐	☐	☐
9. Applicant complies with Medicare Coverage Gap Discount Program requirements.	☐	☐	☐
10. Applicant complies with timely response requirements for PDE Data Quality Reviews posted on the Data Quality Validation website.	☐	☐	☐

3.16 Claims Processing

Complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A	**YE**	**NO**	**Requesting**

PART D CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN:	**S**		**Waiver?** *Yes or No*
1. Applicant has an on-line claims processing system that operates in real time to ensure accurate and timely payment of all claims submitted by network pharmacies on behalf of Part D plan enrollees. System operates according to the following standards: • 98% response within 4 seconds; • 99% of all claims paid with no errors; • 99% system availability.	☐	☐	☐
2. Applicant has a system designed to: • Pay non-electronic claims submissions from network pharmacies in accordance with 42 CFR §423.520; and • Pay requests for reimbursement from beneficiaries in accordance with 42 CFR §423.568(b).	☐	☐	☐
3. Applicant has available for CMS inspection a complete description of your claims adjudication system including: • Hardware and software; • Operating system; • Commercial organization from which Applicant receives pricing files, including file revision history; • Number of sites processing claims (including disaster recovery back-up system); • System volume in covered lives, including the number of transactions the system can support per day and per hour.	☐	☐	☐
4. Applicant has available to CMS upon request policies and procedures that include a complete description and flow chart detailing the claims adjudication process for each: • Contracted network pharmacies; • Paper claims; • Out-of-network pharmacy claims submitted by beneficiaries; • Non-electronic claims submitted by network pharmacies,	☐	☐	☐

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

10. Applicant rapidly adopts any new messaging approved by the NCPDP Workgroup to adjudicate a Part D claim and appropriately coordinate benefits in real time.	☐	☐	☐
11. Applicant regularly updates their systems with the most current information on sanctioned providers and has processes in place to identify and prevent payment of Part D claims at point-of-sale when such claims have been prescribed by excluded providers.	☐	☐	☐
12. Applicant assigns and exclusively uses unique Part D identifiers (RxBin or RxBin/RxPCN) for each individual Part D member.	☐	☐	☐
13. Applicant agrees when it receives information that necessitates a retroactive claims adjustment, the applicant processes the adjustment and issues refunds or recovery notices within 45 days of the applicant's receipt of complete information regarding the claims adjustment.	☐	☐	☐

3.17 Record Retention

Complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PART D CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN:	**YES**	**NO**	***Requesting Waiver?*** *Yes or No*
1. The Applicant maintains books, records, documents, and other evidence of accounting procedures and practices consistent with 42 CFR §423.505(d).	☐	☐	☐
2. Applicant has pharmacies, contracted for the Part D benefit, maintain prescription records in their original format for the greater of 3 years or the period required by State law and allow those records to be transferred to an electronic format that replicates the original prescription for the remaining 7 years of the 10 year record retention requirement.	☐	☐	☐
3. Applicant keeps all other records—except prescription records—that must be retained for Medicare under Part C and Part D in the format(s) required by State law or at the Applicant's discretion.	☐	☐	☐

3.18 Electronic Prescription Program

Complete the table below. Only those applicants that attest "yes" to item 1 in the table below must complete items 2 and 3 and will be required to adhere to electronic prescription program requirements specified in 42 CFR §§ 423.159 and 160. All applicants must complete item 4.

APPLICANT MUST ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PART D CONTRACT. ATTEST 'YES' OR 'NO' BY CHECKING THE APPROPRIATE BOX	YES	NO
1. Applicant establishes an electronic prescription program.	☐	☐
2. Applicant supports and complies with electronic prescription standards relating to covered Part D drugs for Part D enrollees.	☐	☐
3. Applicant has an electronic prescription drug program that complies with final Part D standards for transmitting, directly or through an intermediary, prescriptions and prescription-related information using electronic media for covered Part D drugs for Part D eligible individuals.	☐	☐
4. Applicant obtains the Prescription Origin Code on original prescriptions submitted via the NCPDP 5.1 option field 419 DJ and reports this code on their PDE submissions.	☐	☐

3.19 Formulary Submission Requirements

3.19.1 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 plan meets any of the five criteria referenced above, then their coverage list is considered a formulary and needs to be submitted to CMS for review and approval.

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

3.19.2 Formulary/Pharmacy and Therapeutics (P&T) Committee

A. Complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PART D CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY CHECKING THE APPROPRIATE BOX	YES	NO
1. Applicant will submit a formulary to CMS for the Part D benefit by the CMS specified dates.	☐	☐
2. Applicant will link all associated contracts to an initial formulary submission on or before the formulary submission deadline; otherwise, Applicant will be considered to have missed the formulary submission deadline.	☐	☐
3. Applicant complies with formulary guidance that is contained in Chapter 6 of the Prescription Drug Benefit Manual, the HPMS Formulary Submission Module and Reports Technical Manual, and all other formulary instructions.	☐	☐
4. Applicant agrees, when using a formulary, to meet all formulary submission deadlines established by CMS. Applicant further agrees that CMS may discontinue its review of the Applicant's formulary submission upon the Applicant's failure to meet any of the formulary submission deadlines. Applicant acknowledges that failure to receive CMS approval of its formulary may prevent CMS from approving the Applicant's bid(s) and contracting with the Applicant for the following benefit year.	☐	☐

5. Applicant agrees that its formulary includes substantially all drugs in the protected classes that are specified as of the CMS-established formulary submission deadline. Applicant further agrees that any new drugs or newly approved uses for drugs within the protected classes that come onto the market after a CMS-established formulary submission deadline will be subject to an expedited P&T committee review. The expedited review process requires P&T committees to make a decision within 90 days, rather than the normal 180-day requirement.	☐	☐
6. Applicant provides for an appropriate transition for new enrollees into Part D plans following the annual coordinated election period, newly eligible Medicare enrollees from other coverage, individuals who switch from one plan to another after the start of the contract year, and current enrollees remaining in the plan affected by formulary changes prescribed Part D drugs that are not on its formulary. This transition process satisfies the requirements specified in Chapter 6 of the Prescription Drug Benefit Manual.	☐	☐
7. Applicant attests that its organization's approach to transitioning beneficiaries on drug regimens that are not on the plan's Part D approved formulary meets CMS criteria. The transition policy attestation will be completed in HPMS by close of business on the CMS-established formulary submission deadline in section 1.4.	☐	☐
8. Applicant agrees to submit its organization's transition policy and a description of how the transition policy will be implemented within the applicant's claims adjudication system, including pharmacy notification via email to PartDtransition@cms.hhs.gov by close of business on the CMS-established formulary submission deadline in section 1.4.	☐	☐
9. Applicant extends, where appropriate, transition periods beyond 30 days for enrollees using non-formulary drugs that have not been transitioned to a formulary drug or gone through the plan exception process within 30 days.	☐	☐
10. Applicant ensures that staff is trained and information systems are in place to accommodate administration of the transition policy. This includes adoption of necessary information system overrides.	☐	☐
11. Applicant provides an emergency supply of non-formulary Part D drugs (31-day supplies, unless the prescription is written for fewer days) for long-term care residents to allow the plan and/or the enrollee time for the completion of an exception request to maintain coverage of an existing drug based on reasons of medical necessity.	☐	☐

12. Applicant has appropriate timeframes and "first fill" procedures for non-formulary Part D medications in long-term care and retail settings.	☐	☐
13. Applicant abides by CMS guidance related to vaccine administration reimbursement under Part D.	☐	☐

B. Complete the table below:

If Applicant is intending for its Part D benefit to include the use of a formulary, then Applicant must also provide a P&T committee member list either directly or through its pharmacy benefit manager (PBM). Applicant must attest 'yes' or 'no' that it is using its PBM's P&T committee, in order to be approved for a Part D contract. Attest 'yes' or 'no' by checking the appropriate box.	**Yes**	**No**
1. Applicant is using the P&T Committee of its PBM for purposes of the Part D benefit.	☐	☐
2. If answered yes to B1, Applicant's PBM is operating under a confidentiality agreement for purposes of the P&T Committee (meaning Applicant has no knowledge of the membership of the PBM's P&T Committee). (If not applicable, check "NO.") Note: If answer is YES, then Applicant must complete P&T Committee Certification Statement and PBM must complete the P&T Committee Member List located in the Appendix entitled Applicant Submission of P&T Committee Member List and Certification Statement.	☐	☐
3. Applicant develops and uses a P&T committee to develop and review the formulary and to ensure that the formulary is appropriately revised to adapt to both the number and types of drugs on the market. 4. 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.	☐	☐
5. Applicant's P&T committee first looks at medications that are clinically effective. When two or more drugs have the same therapeutic advantages in terms of safety and efficacy, the committee may review economic factors that achieve appropriate, safe, and cost-effective drug therapy.	☐	☐

6. Applicant assures that the P&T committee uses appropriate scientific and economic considerations to consider utilization management activities that affect access to drugs, such as access to non-formulary drugs, prior authorization, step therapy, generic substitution, and therapeutic interchange protocols.	☐	☐
7. Applicant's P&T committee reviews and approves all clinical prior authorization criteria, step therapy protocols, and quantity limit restrictions applied to each covered Part D drug.	☐	☐
8. Applicant adheres to P&T guidelines that will, from time to time, be promulgated with regard to such subject areas as membership, conflict of interest, meeting schedule, meeting minutes, therapeutic classes, drug review and inclusion, formulary management, utilization management and review, formulary exceptions, and educational programs for providers.	☐	☐
9. Applicant's P&T committee makes a reasonable effort to review a new FDA approved drug product within 90 days, and will make a decision on each new drug product within 180 days of its release onto the market, or a clinical justification will be provided if this timeframe is not met. These timeframes also include the review of products for which new FDA indications have been approved.	☐	☐
10. Applicant's P&T committee approves inclusion or exclusion of the therapeutic classes in the formulary on an annual basis.	☐	☐
11. The majority of the membership of the Applicant's P&T committee are practicing physicians and/or practicing pharmacists.	☐	☐
12. The membership of the Applicant's P&T committee includes at least one practicing physician and at least one practicing pharmacist who are both free of conflict with respect to the Applicant organization and pharmaceutical manufacturers.	☐	☐
13. The membership of the Applicant's P&T committee includes at least one practicing physician and at least one practicing pharmacist who are experts in the care of the elderly or disabled persons.	☐	☐
14. Applicant's P&T committee recommends protocols and procedures for the timely use of and access to both formulary and non-formulary drug products.	☐	☐
15. Applicant verifies that their P&T Committee members (listed in 3.2.1 C) do not appear on the HHS Office of Inspector General's Exclusion List. This list can be found at http://exclusions.oig.hhs.gov/search.html	☐	☐

C. If Applicant is intending for its Part D benefit to include use of a formulary, then the members of the P&T committee must be provided either directly by the Applicant or by the Applicant's PBM. The membership of the P&T committee must be comprised as described in items B, 10, 11 and 13 above. If Applicant is providing names of P&T committee directly, then provide the membership in HPMS' Contract Management/Part D Data page. If the PBM operates under a confidentiality agreement (where the Applicant does not know the membership of the PBM's P&T Committee) refer to the Appendix entitled Applicant Submission of P & T Committee Member List and Certification Statement for additional instructions.

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

4 CERTIFICATION

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

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

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

5 APPENDICES

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

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

I. P&T Committee Member Disclosure to CMS

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

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

II. Instructions to Plans and PBMs

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

B. In the event of any future changes to the membership of the Part D Sponsor's P&T Committee or the PBM's P&T Committee, Part D Sponsors must (or in the case of a confidential agreement the Part D Sponsor) assure that the PBM will notify the appropriate CMS account manager (to be assigned at a future date) and make the

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

III. PHARMACY AND THERAPEUTICS COMMITTEE MEMBER DISCLOSURE

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

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

A. Complete the table below.

PROVIDE THE NAMES OF THE MEMBERS OF YOUR ORGANIZATION'S P&T COMMITTEE. INDICATE WHICH MEMBERS ARE PRACTICING PHYSICIANS OR PRACTICING PHARMACISTS. FURTHER, INDICATE WHICH MEMBERS ARE EXPERTS IN THE CARE OF THE ELDERLY OR DISABLED, AND FREE OF ANY CONFLICT OF INTEREST WITH YOUR ORGANIZATION AND PHARMACEUTICAL MANUFACTURERS. (APPLICANTS SHOULD MARK THE INFORMATION AS PROPRIETARY.) SUBMIT THIS DATA BY CREATING A SPREADSHEET IN MICROSOFT EXCEL THAT MIMICS THE TABLE BELOW.					
	Practice/Expertise *Mark an 'X' in Appropriate Column*			Free of Any Conflict of Interest *Type Yes or No*	
Full Name of Member Start Date and End Date	Practicing Physician	Practicing Pharmacist	Elderly/Disabled Expert	With Your Organization?	With Pharmaceutical Manufacturers?

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

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

ADDITIONAL ROWS AS NECESSARY.		
Organization Name	Type of Application	Contract Number(s)

Applicant must upload in HPMS:

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

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

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

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

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

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

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

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

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

Part D Applicant's Contract Number: _____

_____ _____

Authorized Representative Name (printed) Title

_____ _____

Authorized Representative Signature Date (MM/DD/YYYY)

Mailing Instructions

8. Provide a signed cover sheet indicating that the information being sent to CMS is an addendum to the Plan's Part D Application.
9. Please mail 3 hard copies, including one original, of both the completed Certification for Part D Sponsors Using a Pharmacy Benefit Manager's Pharmacy and Therapeutics Committee under a Confidentiality Agreement form to:

ATTN: Jack Healey

Mail Stop: C4-21-26

7500 Security Boulevard

Baltimore, MD 21244-1850