Medicare Part D Application for New PACE Organizations
2012 Contract Year

I. GENERAL INFORMATION (§423.1- §423.910)

Background

The Medicare Prescription Drug Benefit program was established by section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) and is codified in section 1860D-1 through 1860 D-42 of the Social Security Act (the Act). Section 101 of the MMA amended Title XVIII of the Social Security Act by redesignating Part D as Part E and inserting a new Part D, which establishes the Voluntary Prescription Drug Benefit Program (hereinafter referred to as "Part D").

The Patient Protection and Affordable Care Act (PPACA) as amended by the Health Care and Education Reconciliation Act of 2010 (HCERA) adds section 1860D-43 which will close the Medicare Prescription Drug Benefit's coverage gap by implementing a manufacturer discount program and providing coverage to generic drugs over a span of 10 years. PPACA also added or revised existing Part D requirements, including requirements associated with low-income subsidy, calculation of true out-of-pocket spending, drug classes and categories, LTC pharmacy dispensing techniques, establishment of a single uniform exceptions and appeals model, and strengthened CMS' ability to deny bids.

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.

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.

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

Summary Instruction 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.

Summary Instruction 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.

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.

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.

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.

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 dis-enrollments 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.

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.

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.

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.

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.

II. GENERAL INSTRUCTIONS

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 2012. Applicants projecting PACE provider status by 1/1/2012 may submit the Part D application (chapter 11 of the PACE provider application) up until July 1, 2011. Applicants must use the 2012 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.

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.

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 six (5) 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 five paper copies of the Part D application each applicant must submit five (5) 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.

III. INSTRUCTIONS FOR COMPLETION OF GENERAL APPLICATION REQUIREMENTS

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

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.

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
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***	Part D bid submission deadline

Part D Regulation	**Regulatory Requirement(s)** **Description**
June deadline.	
423.401(a)(1)	Licensure
423.420	Solvency standards for non-licensed entities
423.462	Medicare secondary payer procedures
423.464(c)	Coordination of benefits and user fees
423.464(f)(2) and 423.464(f)(4)	Coordination with other prescription drug coverage
423.502(b)(1)(i-ii)	Documentation of State licensure or Federal waiver
423.504(b)(2-3), 423.504(b)(4)(i-v) and (vi)(A-E), 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

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.

IV. APPLICATION FORMS

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

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 PERSON: NAME TITLE ADDRESS E-MAIL FAX TELEPHONE NUMBER	

Management and Operations

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**	**Subcontractor(s)** (first tier, downstream and related entities)	**Off-Shore** Yes/No
	A pharmacy benefit program that performs adjudication and processing of pharmacy claims at the point of sale.		
	A pharmacy benefit program that performs negotiation with prescription drug manufacturers and others for rebates, discounts, or other price concessions on prescription drugs		
	A pharmacy benefit program that performs administration and tracking of enrollees' drug benefits in real time, including TrOOP balance processing.		
	A pharmacy benefit program that performs coordination with other drug benefit programs, including, for example, Medicaid, state pharmaceutical assistance programs, or other insurance.		
	A pharmacy benefit program that develops and maintains a pharmacy network.		

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

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 that:

1. Clearly identify the parties to the contract (or letter of agreement);

2. Describe the functions to be performed by the first tier, downstream or related entity. 42 CFR §423.505(i)(4)(i)

3. Describe the reporting requirements the first tier, downstream, or related entity has to the Applicant. 42 CFR §423.505(i)(4)(i)

4. 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).

5. Contains flow-down clauses requiring their activities be consistent and comply with the Applicant's contractual obligations as a PACE Part D sponsor. 42 CFR §423.505(i)(3)(iii)

6. Describe the payment the first tier, downstream, or related entity will receive for performance under the contract, if applicable;

7. Are signed by a representative of each party with legal authority to bind the entity;

8. Contain language obligating the first tier, downstream or related entity to abide by all applicable Federal laws and regulations and CMS instructions. 42 CFR §423.505(i)(4)(iv)

9. Contain language obligating the first tier, downstream, or related entities to abide by State and Federal privacy and security requirements, including the confidentiality and security provisions stated in the regulations for this program at 42 CFR §423.136.

10. Contain language ensuring that the first tier, downstream, or related entity will make its books and other records available in accordance with 42 CFR §423.505(e)(2) and 42 CFR §423.505(i)(2). Generally stated these regulations give HHS, the Comptroller General, or their designees the right to audit, evaluate and inspect any books, contracts, records, including medical records and documentation involving transactions related to CMS' contract with the PACE 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(i)(2)

11. Contain language that the first tier, downstream or related entity will ensure that beneficiaries are not held liable for fees that are the responsibility of the PACE Part D sponsor. 42 CFR §423.505(i)(3)(i)

12. Contain language that the first tier, downstream, or related entity indicates that any books, contracts, records, including medical records and documentation relating to the Part D program will be provided to either the sponsor to provide to CMS or its designees or will be provided directly to CMS or its designees. 42 CFR §423.505(i)(3)(iv)

13. Contain language that if the Applicant, upon becoming a PACE 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 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)

14. Contain language specifying that the Applicant, upon becoming a PACE 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);

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 the PACE Part D sponsor retains the right to approve, suspend, or terminate any arrangement with a pharmacy. 42 CFR §423.505(i)(5)

16. If the first tier, downstream, or related entity will establish the pharmacy network or select pharmacies to be included in the network contain language that 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 42 CFR §423.520

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 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(i)(3)(viii)(B)

18. If the first tier, downstream, or related entity will establish the pharmacy network or select pharmacies to be included in the network contain language that if a prescription drug pricing standard is used 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) and 42 CFR §423.505(b)(21)

19. If the first tier, downstream, or related entity will establish the pharmacy network or select pharmacies to be included in the network contain language requiring the network pharmacies to submit claims to the 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)

20. If the first tier, downstream, or related entity will adjudicate and process claims at the point of sale and/or negotiate with prescription drug manufacturers and others for rebates, discounts, or other price concessions on prescription drugs contain language that the first tier, downstream, or related entity will comply with the reporting requirements established in Section 6005 of the Patient Protection and Affordable Care Act of 2010 (PPACA).

Crosswalks of Requirements in Contracts/Administrative Services Agreements

INSTRUCTIONS: Applicants must complete the following chart for each contract/administrative services agreement submitted. Applicants must identify where specifically (i.e., section numbers, page numbers, paragraph numbers, etc.) in each contract/administrative services agreement the following elements are found. [E.g., Medicare Part D Addendum, page 14, section 3.2, paragraph 2.]	
Requirement	**Citation**
The parties to the contract	
The functions to be performed by the first tier, downstream, or related entity. 42 CFR §423.505(i)(4)(i)	
Describes the reporting requirements the first tier, downstream, or related entity has to the Applicant. 42 CFR §423.505(i)(4)(i)	
Language clearly indicating that the first tier, downstream, or related entity has agreed to participate in your Medicare Prescription Drug Benefit program (except for a network pharmacy if the existing contract would allow participation in this program).	
Contains flow-down clauses requiring the first tier, downstream, or related entity's activities to be consistent and comply with the Applicant's contractual obligations as a Part D sponsor. 42 CFR §423.505(i)(3)(iii)	
The payment the first tier, downstream, or related entity will receive for performance under the contract, if applicable.	
Are for a term of at least the one-year contract period for which application is submitted.	
Are signed by a representative of each party with legal authority to bind the entity.	
Language obligating the first tier, downstream, or related entity to abide by all applicable Federal laws and regulations and CMS instructions. 42 CFR §423.505(i)(4)(iv)	
Language obligating the first tier, downstream, or related entity to abide by State and Federal privacy and security requirements, including the confidentiality and security provisions stated in the regulations for the program at 42 CFR §423.136. 42 CFR §423.136	
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 PACE Part D sponsor and that these rights continue for a period of 10 years from the final date of the contract period or the date of audit completion, whichever is later. 42 CFR §423.505	
Language stating that the first tier, downstream, or related entity will ensure that beneficiaries are not held liable for fees that are the responsibility of the Applicant. 42 CFR §423.505(i)(3)(i)	
Contain language indicating that any books, contracts, records, including medical records and documentation relating to the Part D program will be provided to either the sponsor to provide to CMS or its designees or will be provided directly to CMS or its designees. 42 CFR §423.505(i)(3)(iv)	

Contain language that if the Applicant, upon becoming a PACE 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 sponsor determines the first tier, downstream, or related entity has not performed satisfactorily. Note: The contract/administrative services agreement may include remedies in lieu of revocation to address this requirement. 42 CFR §423.505(i)(4)(ii)	
Language specifying that the Applicant, upon becoming a Part D sponsor, will monitor the performance of the first tier, downstream, or related entity on an ongoing basis. 42 CFR §423.505(i)(4)(iii)	
Language that the Part D sponsor retains the right to approve, suspend, or terminate any arrangement with a pharmacy if the first tier, downstream, or related entity will establish the pharmacy network or select pharmacies to be included in the network. 42 CFR §423.505(i)(5)	
Language that if the first tier, downstream, or related entity will establish the pharmacy network or select pharmacies to be included in the network contain language that payment to such pharmacies (excluding long-term care and mail order) shall be issued, mailed, or otherwise transmitted with respect to all clean claims submitted by or on behalf of pharmacies within 14 days for electronic claims and within 30 days for claims submitted otherwise. 42 CFR §423.505(i)(3)(vi)	
Language that if the first tier, downstream, or related entity will establish the pharmacy network or select pharmacies to be included in the network contain language that if a standard is used for reimbursement, identify the source used by the Part D sponsor for the standard of reimbursement. 42 CFR §423.505(i)(3)(viii)(B)	
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 updates to such a standards occur not less frequently than once every 7 days beginning with an initial update on January 1 of each year, to accurately reflect the market price of acquiring the drug. 42 CFR §423.505(i)(3)(viii)(A)	
Language 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 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)	
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 that the first tier, downstream, or related entity will comply with the reporting requirements established in Section 6005 of the Patient Protection and Affordable Care Act of 2010 (~~PPACA~~the Affordable Care Act).	

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**
The functions to be performed by the first tier, downstream, or related entity. 42 CFR §423.504(i)(4)(i)	
Describes the reporting requirements the first tier, downstream, or related entity identified in the application has to the Applicant. 42 CFR §423.504(i)(4)(i)	
Language obligating the first tier, downstream, or related entity to abide by all applicable Federal laws and regulations and CMS instructions. 42 CFR §423.504(i)(4)(iv)	
Language obligating the first tier, downstream, or related entity to abide by State and Federal privacy and security requirements, including the confidentiality and security provisions stated in the regulations for the program at 42 CFR §423.136.	
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 PACE Part D sponsor and that these rights continue for a period of 10 years from the final date of the contract period or the date of audit completion, whichever is later. 42 CFR §423.505	
Language stating that the first tier, downstream, or related entity will ensure that beneficiaries are not held liable for fees that are the responsibility of the Applicant. 42 CFR §423.505(i)(3)(i)	

Contain language indicating that any books, contracts, records, including medical records and documentation relating to the Part D program will be provided to either the sponsor to provide to CMS or its designees or will be provided directly to CMS or its designees. 42 CFR §423.505(i)(3)(iv)	
Contain language that if the Applicant, upon becoming a PACE 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 sponsor determines the first tier, downstream, or related entity has not performed satisfactorily. Note: The subcontract may include remedies in lieu of revocation to address this requirement. 42 CFR §423.505(i)(3)(i)	
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)(ii)	
Provisions requiring that the long-term care pharmacy have not less than 30 days (but not more than 90 days) to submit claims to the sponsor for reimbursement under the plan. 42 CFR §423.505(i) (3)(vii)	
For those contracts that use a standard for reimbursement, a provision that indicate the source used by the Part D sponsor for the standard of reimbursement. 42 CFR §423.505(i)(3)(viii)(B)	
For those contracts that use a standard for reimbursement, a provision that updates to such a standard occur not less frequently than once every 7 days beginning with an initial update on January 1 of each year, to accurately reflect the market price of acquiring the drug. 42 CFR §423.505(i)(3)(viii)(A)	
Language requiring the network pharmacy to submit claims to the Part D sponsor or first tier, downstream or related entity whenever the membership ID card is presented or on file at the pharmacy unless the enrollee expressly requests that a particular claim not be submitted. 42 CFR §423.120(c)(3)	
Provisions governing submitting claims to a real-time claims adjudication system. 42 CFR §423.505(j) and §423.505(b)(17) Note: Applicant may indicate for I/T/U pharmacies and for certain pharmacies that are allowed to submit claims in the X 12 format that these may be batch processed.	

Provisions governing providing Part D enrollees access to negotiated prices as defined in 42 CFR 423.100. 42 CFR §423.104(g)	
Provisions regarding charging/applying the correct cost-sharing amount**.** 42 CFR §423.104(g)	

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 are required to incorporate at a minimum, 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
1. *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.	
2. *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 ~~are~~ 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.	
3. *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.	
4. *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.	
5. *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.	
6. *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.	
7. *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".	
8. *Emergency Boxes* -- NLTCPs must provide "emergency" supply of medications as required by the facility in compliance with State requirements.	
9. *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.	
10. *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.	

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 contracts. 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	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				
Contact	Name/Title	Mailing Address	Phone/Fax Numbers	Email Address

CMS Casework Communication Contact				
Part D Exceptions Contact				
Coordination of Benefits Contact				
CEO – CMS Administrator Contact				
Plan to Plan Reconciliation Contact				
CAP Report Contact for Public Website				
Financial Reporting Contact				
Plan Directory Contact for Public Website				
Best Available Evidence Contact				
Automated TrOOP Balance Transfer Contact				
Complaints Tracking Module (CTM) Contact				
Part D Reporting Requirements Contact				
Reconciliation Contact				
Fraud Investigation Contact				
DIR Contact				

B. Complete the table below:

APPLICANT MUST ATTEST 'YES' TO THE FOLLOWING			***Requesting***

QUALIFICATION TO BE APPROVED FOR A PART D CONTRACT. ATTEST 'YES' OR 'NO' TO THE FOLLOWING QUALIFICATION BY PLACING A CHECKMARK IN THE RELEVANT COLUMN:	YES	NO	*Waiver? – Yes or No*
1. Applicant agrees that CMS may release contact information to States, SPAPs, providers, Part D sponsors, and others who need the contact information for legitimate purposes.	☐	☐	☐

Business Integrity

A. Complete the table below:

APPLICANT MUST ATTEST 'YES' OR 'NO' TO THE FOLLOWING QUALIFICATION TO BE APPROVED FOR A PART D CONTRACT. ATTEST 'YES' OR 'NO' TO THE FOLLOWING QUALIFICATION BY PLACING A CHECKMARK IN THE RELEVANT COLUMN:	Yes	No	*Requesting Waiver? – Yes or No*
1. Applicant, applicant staff, and its affiliated companies, subsidiaries or first tier, downstream and related entities, and staff of 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**.** Please note that this includes any member of its board of directors, and any key management or executive staff or any major stockholder.	☐	☐	☐
2. Applicant has no past or pending investigations, legal actions, administrative actions, or matters subject to arbitration brought involving the Applicant (and Applicant's parent firm if applicable), including any key management or executive staff, by a government agency (state or federal including CMS) over the past three years on matters relating to payments from governmental entities, both federal and state, for healthcare and/or prescription drug services.	☐	☐	☐
3. Applicant's Pharmaceutical Benefit Manager (PBM) (and the PBM's parent firm if applicable) has no past or pending investigations, legal actions, administrative actions, or matters subject to arbitration brought involving the PBM (and PBM's parent firm if applicable) including any key management or executive staff, by a government agency (state or federal including CMS) over the past three years on matters relating to payments from governmental entities, both federal and state, for healthcare and/or prescription drug services.			

Compliance Plan

A. Provide as an attachment 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). In addition, the Part D compliance program must demonstrate that all 7 elements in the regulation and in Chapter 9 are being implemented and are specific to the issues and challenges presented by the Part D program. A general compliance program applicable to healthcare operations is not acceptable. Note: Please be advised that the Part D Applicant is ultimately responsible for the implementation and monitoring of the day-to-day operations of its Part D compliance program. 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. A compliance plan adopted and operated by a Part D Applicant's first tier, downstream, and related entities is not sufficient to demonstrate that the Part D Applicant meets the compliance program requirement.

B. Complete the table below. Applicant must clearly identify where each requirement can be found in the provided compliance program.

Crosswalk for the Part D Compliance Program	**Document Page Number**
Written policies, procedures, and standards of conduct that addresses Part D issues and articulates your organization's commitment to abide by all applicable Federal and State standards. For full requirement see, 42 CFR §423.504(b)(4)(vi)(A).	
Designation of an employee of the Applicant, parent organization or corporate affiliate as the compliance officer vested with day-to-day operations of the compliance program. The compliance officer and compliance committee periodically report to the governing body of the Applicant on the activities and status of the compliance program, including issues identified, investigated, and resolved by the compliance program. (Note: This requirement cannot be delegated to a first tier, downstream, or related entity). For full requirement see 42 CFR §423.504(b)(4)(vi)(B).	
Effective training and education for Applicant's employees including, the chief executive and senior administrators or managers; governing body members; and first tier, downstream, and related entities For full requirement see 42 CFR §423.504(b)(4)(vi)(C).	
Effective lines of communication between the compliance officer, members of the compliance committee, Applicant's employees, managers and governing body, and the Applicant's first tier, downstream and related entities. Such lines of communication must be accessible to all and allow compliance issues to be reported including a method for anonymous and confidential good faith reporting of potential compliance issues as they are identified. For full requirement see 42 CFR §423.504(b)(4)(vi)(D).	
Enforcement of standards through disciplinary guidelines that are	

well-publicized in the organization. For full requirement see 42 CFR §423.504(b)(4)(vi)(E).	
Effective system for routine monitoring and identification of compliance risks. The system should include internal monitoring and audits and, as appropriate, external audits to evaluate the Applicant and first tier entities' compliance with CMS requirements and the overall effectiveness of the compliance program. For full requirement see 42 CFR §423.504(b)(4)(vi)(F).	
Procedures and a system for promptly responding to compliance issues as they are raised, investigating potential compliance problems as they are 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. For full requirement see 42 CFR §423.504(b)(4)(vi)(G).	

Health Information Technology

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 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.	☐	☐	☐

Enrollment and Eligibility

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 PLACING A CHECKMARK IN THE RELEVANT COLUMN:	**YES**	**NO**	**Requesting Waiver?** ***Yes or No***
1. Applicant complies with operational guidance on Creditable Coverage and the Late Enrollment Penalty.	☐	☐	☐
2. Applicant queries the Batch Eligibility Query (BEQ) or the User Interface (UI) to receive: a) Verification of Medicare Eligibility b) The end date of the beneficiary's Part D IEP; c) Periods of enrollment in a Medicare plan that provides prescription drug coverage: and d) Periods of enrollment in a retiree prescription drug plan whose sponsor receives a retiree subsidy from Medicare.	☐	☐	☐
3. Applicant collects reviews and transmits creditable coverage information in accordance with CMS 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.	☐	☐	☐
5. Applicant does not disenroll members for failure to pay premiums (or notify them of impending disenrollment) in cases where the member has requested that premiums be withheld from his/her Social Security benefit check until the organization receives a reply from CMS indicating that the member's request has been rejected.	☐	☐	☐
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.	☐	☐	☐

Complaints Tracking

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 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 (CTM) within 2 calendar days.	☐	☐	☐
2. Applicant is expected to resolve at least 95% of complaints designated as "urgent" via the CMS CTM in accordance with CMS issued guidance.	☐	☐	☐
3. Applicant is expected to resolve at least 95% of complaints without an issue level via CMS CTM in accordance with CMS issued guidance.	☐	☐	☐
4. Applicant monitors and documents complaint resolutions for complaints attributed to their contracts in the CMS' CTM in accordance with CMS' Standard Operating Procedures for Part D sponsors.	☐	☐	☐
5. Applicant maintains Standard Operating Procedures that address how your organization will handle and quickly resolve immediate action cases.	☐	☐	☐

Coordination of Benefits

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 PLACING A CHECKMARK IN THE RELEVANT COLUMN:	**YES**	**NO**	**Requesting Waiver?** ***Yes or No***
1. Applicant complies with Coordination of Benefits guidance.	☐	☐	☐
2. Applicant has a system for notifying enrollees with other prescription drug coverage in CMS' system and for requesting enrollees to provide any 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 423.464 and Chapter 14 of the Prescription Drug Benefit Manual. For example, an SPAP may require agreements to be signed in order for the state to pay premiums on behalf of the 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.	☐	☐	☐

Tracking Out-of-Pocket Costs (TrOOP)

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 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 disenrollling Part D beneficiaries as well as receives these data 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/**

Medicare Secondary Payer

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 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 as applicable.	☐	☐	☐
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, or No-Fault, or Liability coverage and has previously established that a certain drug is being used exclusively to treat a related injury.	☐	☐	☐

Data Collection and Reporting Requirements

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 PLACING A CHECKMARK IN THE RELEVANT COLUMN:	**YES**	**NO**	***Requesting Waiver?*** *Yes or No*
REBATE DATA			
1. The Applicant or the Applicant's representative has accounting systems capable of accomplishing the provision of documentation, as specified by CMS, to support the accuracy and completeness of rebate data. Documentation will be provided to CMS in response to an audit-based request.	☐	☐	☐
2. The Applicant reports rebate dollars on a quarterly basis at the manufacturer/brand name level (unique strength and package size not required) in the manner specified by CMS.	☐	☐	☐
3. The Applicant or the Applicant's representative has accounting systems capable of accomplishing the production of financial reports to support rebate accounting. The rebate accounting must allow for step-down cost reporting in which rebates received at the aggregate level may be apportioned down to the level of plan enrollees.	☐	☐	☐

Data Exchange Between PACE Organizations and CMS

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 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 Part D application process, formulary submission process, bid submission process, ongoing operations of the Part D program, and reporting and oversight activities. PACE Organizations are required to secure access to HPMS in order to carry out these functions.	☐	☐	☐
ENROLLMENT & PAYMENT			
2. Applicant establishes connectivity to CMS 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 participate 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 has 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.	☐	☐	☐

Health Insurance Portability and Accountability Act of 1996 (HIPAA)

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 PLACING A CHECKMARK IN THE RELEVANT COLUMN:	**YES**	**NO**	***Requesting Waiver?*** *Yes or No*
1. Applicant complies with any 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.	☐	☐	☐
3. Applicant encrypts all hard drives or other storage media within the device as well as all removable media.	☐	☐	☐
4. Applicant has policies addressing the secure handling of portable media that is accessed or used by the organization.	☐	☐	☐
5. Applicant complies with any applicable standards, implementation specifications, and requirements in the Standard Unique Health Identifier for Health Care Providers under 45 CFR Part 160 and 162.	☐	☐	☐
6. Applicant agrees that when its organization receives a National Provider Identifier (NPI) in prescription drug event data, that the organization must report an NPI.	☐	☐	☐
7. Applicant agrees that when its organization receives a National Provider Identifier (NPI) it will implement a contingency plan related to compliance with the NPI provisions.	☐	☐	☐
8. Applicant complies with any applicable standards, implementation specifications, and requirements in the Standards for Electronic Transactions under 45 CFR Parts 160 and 162 subparts I *et seq*.	☐	☐	☐
9. Applicant submits the Offshore Subcontract Information and Attestation via HPMS for each offshore subcontractor (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 of the upcoming contract year.	☐	☐	☐

Prohibition on Use of SSN or Medicare ID number on Enrollee ID Cards

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 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.	☐	☐	☐

Prescription Drug Event (PDE) Records

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 clicking on the appropriate response in HPMS:	**Yes**	**No**	***Requesting Waiver?*** *Yes or No*
1. Applicant abides by CMS guidance related to PDE data. Such guidance includes the 2008 Regional Prescription Drug Event Data Participant Training Guide and Technical Assistance Resource Guide which can be found at www.csscoperations.com/new/pdic/pdd-training/pdd-training.html.			
2. Applicant submits data and information necessary for CMS to carry out payment provisions.			
3. Applicant submits PDE data at least monthly.			
4. Applicant submits the PDE data in the format described by CMS and in accordance with the National Council for Prescription Drug Programs (NCPDP) industry standard format.			
5. Applicant provides diagnosis data for risk adjustment as required by CMS.			
6. Applicant meets all data submission deadlines.			

Claims Processing

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 PLACING A CHECKMARK IN THE RELEVANT COLUMN:	**YES**	**NO**	**Requesting Waiver?** *Yes or No*
1. Applicant either: (a) Contracts with a third party that 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. System operates according to the following standards: • 98% response within 4 seconds • 99% of all claims paid with no errors • 99% system availability (b) Has internal procedures in a place to ensure accurate and timely payment of all claims submitted by network pharmacies.	☐	☐	☐
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 its claims adjudication system including: • Hardware and software; • Operating system; • Commercial organization for which Applicant receives pricing files, including file revision history; • Number of sites processing claims (including disaster recovery back-up system); • System volume in covered lives, including the number of transactions the system can support per day and per hour.	☐	☐	☐
4. Applicant has available to CMS upon request policies and procedures that include a complete description and flow chart detailing the claims adjudication process for each: • Contracted network pharmacies; • Paper claims; • Out-of-network pharmacy claims submitted by beneficiaries; • Non-electronic claims submitted by network pharmacies,	☐	☐	☐

and other payers seeking to coordinate benefits; • Batch-processed claims; and • Manual claim entry (e.g. for processing direct member reimbursement)			
5. Applicant has available to CMS upon request policies and procedures that include a complete description of claim detail management, including: • The length of time that detailed claim information is maintained online (not less than 12 months); • The data storage process after it is no longer online; • The length of time that detailed claim information is stored when it is no longer online (not less than 10 years).	☐	☐	☐
6. Applicant has available to CMS upon request policies and procedures that include a complete description of the accessibility of this information for data capture purposes and flow chart of the claims data retrieval process for each: • Entire claims history file; • File claims adjustments including records of reimbursements and recoveries due to network pharmacies and beneficiaries. • Deductible files/TrOOP/and gross covered 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 HIPPA compliant transactions where applicable, consistent with CMS requirements.	☐	☐	☐
9. Applicant documents the manner and extent to which it has tested benefit designs such as drugs excluded or quantity limitations and plan parameters such as the dual eligible plan vs. the Medicare-only plan.	☐	☐	☐
10. Applicant rapidly adopt any new messaging approved by the NCPDP Workgroup to adjudicate a Part D claim and appropriately coordinate benefits in real time.	☐	☐	☐
11. Applicant regularly updates their systems with the most current information on sanctioned providers and has processes in place to identify and prevent payment of Part D claims at point-of-sale when such claims have been prescribed by excluded providers.	☐	☐	☐
12. Applicant assigns and exclusively uses unique Part D identifiers (RxBin or RxBin/RxPCN) for each individual Part D member.	☐	☐	☐
13. Applicant agrees when it receives information that necessitates a retroactive claims adjustment, the applicant processes the adjustment and issue refunds or recovery notices within 45 days of the applicant's receipt of complete information regarding the claims adjustment.	☐	☐	☐

Record Retention

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 PLACING A CHECKMARK IN THE RELEVANT COLUMN:	**YES**	**NO**	***Requesting Waiver?*** *Yes or No*
1. The Applicant maintains, for 10 years, 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 replicated 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 D and Part D in the format(s) required by either State law or the HIPAA Privacy Rule, if applicable, or at the Applicant's discretion.	☐	☐	☐

CERTIFICATION

I, the undersigned, certify to the following:

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 Addendum with CMS, I will abide by the requirements contained in this Application and provide all required services outlined in this application and in accordance with sections 1894 and 1934 of the Act.

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 Addendum with CMS.

7) For several of the Part D program requirements described in this solicitation, CMS has issued operational policy guidance that provides more detailed instructions to Part D sponsors. Organizations submitting an application in response to this solicitation acknowledge that they are also representing to CMS that they have reviewed the associated guidance materials posted on the CMS web site and will comply with such guidance should they be approved for a Part D contract. Applicants must visit the CMS web site periodically to stay informed about new or revised guidance documents.

_____ _____

Authorized Representative Name (printed) ***Title***

_____	_____
Authorized Representative Signature	Date (MM/DD/YYYY)

Electronic Prescription Program

Only those applicants that answer yes to #1 must complete items 2 and 3 below and will be required to adhere to electronic prescription program requirements specified in 42 CFR §§ 423.159 and 423.160. All applicants must complete #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' to each of the following qualifications by clicking on the appropriate response in HPMS:	**Yes**	**No**
1. Applicant establishes an electronic prescription program.		
2. Applicant complies with electronic prescription standards relating to covered Part D drugs for Part D enrollees.		
3. Applicant establishes and maintains an electronic prescription drug program that complies with final Part D standards when 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 optional field 419 DJ and reports this code on their PDE submissions.		

Applicability of Formulary Submission Requirements

APPLICABILITY OF FORMULARY SUBMISSION REQUIREMENT

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

1. COST SHARING TIERS

Any coverage list that utilizes more than one cost sharing tier with differential co-pay or coinsurance, is considered a formulary.

2. 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.

3. 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.

4. 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.

5. 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 answer yes to 1 or more of items 1-5 listed above will be required to adhere to formulary requirements specified in 42 CFR § 423.120(b) and complete the forms that follow.

Formulary/Pharmacy and Therapeutics (P&T) Committee

A. Complete the form below:

APPLICANT MUST ATTEST 'YES' OR 'NO' TO THE FOLLOWING QUALIFICATION 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 IN HPMS.	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 meets 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 the CMS-established formulary submission deadline will be subject to an expedited Pharmacy and Therapeutic 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.		
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.		
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 if 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 form 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, TO BE APPROVED FOR A PART D CONTRACT. ATTEST 'YES' OR 'NO' BY PLACING A CHECKMARK IN THE RELEVANT COLUMN IN HPMS.	**YES**	**NO**	***Requesting Waiver?*** *Yes or No*
1. Applicant is using the P&T Committee of its PBM for purposes of the Part D benefit.			
2. If answered yes to B1, Applicant's PBM is operating under a confidentiality agreement for purposes of the P&T Committee (meaning Applicant has no knowledge of the membership of the PBM's P&T Committee). (If not applicable, check "NO.") Note: If answer is YES, then Applicant must complete P&T Committee Certification Statement and PBM must complete the P&T Committee Member List located in the Appendix entitled *Applicant Submission of P&T Committee Member List and Certification Statement*._			
3. Applicant develops and uses a P&T committee to develop and review the formulary and to ensure that the formulary is appropriately revised to adapt to both the number and types of drugs on the market.			

Note: While the P&T committee may be involved in providing recommendations regarding the placement of a particular Part D drug on a formulary cost-sharing tier, the ultimate decision maker on such formulary design issues is the Part D plan sponsor, and that decision weighs both clinical and non-clinical factors.			
4. Applicant's P&T committee first looks at medications that are clinically effective. When two or more drugs have the same therapeutic advantages in terms of safety and efficacy, the committee may review economic factors that achieve appropriate, safe, and cost-effective drug therapy.			
5. Applicant assures that the P&T committee uses appropriate scientific and economic considerations to consider utilization management activities that affect access to drugs, such as access to non-formulary drugs, prior authorization, step therapy, generic substitution, and therapeutic interchange protocols.			
6. Applicant's P&T committee reviews and approves all clinical prior authorization criteria, step therapy protocols, and quantity limit restrictions applied to each covered Part D drug.			
7. Applicant adheres to P&T guidelines that will, from time to time, be promulgated with regard to such subject areas as membership, conflict of interest, meeting schedule, meeting minutes, therapeutic classes, drug review and inclusion, formulary management, utilization management and review, formulary exceptions, and educational programs for providers.			
8. Applicant's P&T committee makes a reasonable effort to review a new FDA approved drug product within 90 days, and will make a decision on each new drug product within 180 days of its release onto the market, or a clinical justification will be provided if this timeframe is not met. These timeframes also include the review of products for which new FDA indications have been approved.			
9. Applicant's P&T committee approves inclusion or exclusion of the therapeutic classes in the formulary on an annual basis.			
10. The majority of the membership of the Applicant's P&T committee are practicing physicians and/or practicing pharmacists.			
11. The membership of the Applicant's P&T committee includes at least one practicing physician and at least one practicing pharmacist who are both free of conflict with respect to the Applicant organization and pharmaceutical manufacturers.			
12. The membership of the Applicant's P&T committee includes at least one practicing physician and at least one practicing pharmacist who are experts in the care of the elderly or disabled persons.			
13. Applicant's P&T committee recommends protocols and procedures for the timely use of and access to both formulary and non-formulary drug products.			
14. Applicant verifies that their P&T Committee members (listed in 3.2.1 C) do not appear on the HHS Office of Inspector General's Exclusion List. This list can be found at			

http://exclusions.oig.hhs.gov/search.html			

C. If Applicant is intending for its Part D benefit to include use of a formulary, then the members of the P&T committee must be provided directly by the Applicant or by the Applicant's PBM. The membership of the P&T Committee must be comprised as described below. If Applicant is providing names of P&T Committee directly, then complete the table below in HPMS on the Contract Management/Part D Data page.

Pharmacy and Therapeutics (P&T) Committee

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.) ADD ADDITIONAL ROWS AS NECESSARY.

	Practice/Expertise *Mark an 'X' in Appropriate Column*			**Free of Any Conflict of Interest** *Type Yes or No*	
Full Name of Member	Practicing Physician	Practicing Pharmacist	Elderly/Disabled Expert	With Your Organization?	With Pharmaceutical Manufacturers?
	☐	☐	☐		
	☐	☐	☐		
	☐	☐	☐		

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

This 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).

P&T Committee Member Disclosure to CMS

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

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

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, and (2) forward the attached P&T Committee Member Disclosure Form to the subcontracted PBM and direct the PBM to submit the form to CMS. The PBM should follow the mailing instructions below.

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 must assure that the PBM) notify the appropriate CMS account manager (to be assigned at a future date) within 30 days of the effective date of such change.

Mailing Instructions

1. Provide a signed cover sheet indicating that the information being sent to CMS is an addendum to the Plan's Part D Application.
2. Please mail 5 CD's or diskettes containing both the completed P&T Committee Member Disclosure form and the completed Certification for Part D Sponsors Using a Pharmacy Benefit Manager's Pharmacy and Therapeutics Committee under a Confidentiality Agreement form.
3. Please mail 5 hard copies, including one original, of both the completed P&T Committee Member Disclosure form and the completed Certification for Part D Sponsors Using a Pharmacy Benefit Manager's Pharmacy and Therapeutics Committee under a Confidentiality Agreement form.

Mail the 5 CD's or diskettes and hard copy material via courier to:
Centers for Medicare and Medicaid Services

ATTN: Jack Healey
Mail Stop: C4-21-26
7500 Security Boulevard
Baltimore, MD 21244-1850

PHARMACY AND THERAPEUTICS COMMITTEE MEMBER DISCLOSURE

Name of Part D Plan or PBM:

If Part D Plan, provide Part D Contract number(s): _____

Contact Person:

Phone Number:

Email:

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 THAT 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)**

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

A. I, the undersigned, certify, on behalf of (LEGAL NAME OF PART D SPONSOR APPLICANT) ("Applicant") _____, to the following:

1) 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.

2) 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.

3) 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.

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

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

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

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

Part D Plan Contract Number:

_____ _____

Authorized Representative Name (printed) Title

_____ _____

Authorized Representative Signature Date (MM/DD/YYYY)