

MEDICARE PRESCRIPTION DRUG BENEFIT

Solicitation for Applications for Medicare Prescription Drug Plan 2016 Contracts

New Medicare Prescription Drug Plan (PDP), Medicare Advantage-Prescription Drug (MA-PD) (with and without EGWP), and Expansion of an Existing Contracts with CMS for PDP and MA-PD (including 'CCP, PFFS, RPPO, Cost Plan, SNPs and EGWPs).

2016 Contract Year

PRA Disclosure Statement

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1	GENERAL INFORMATION	7
1.1	Purpose of Solicitation	7
1.2	Background.....	7
1.3	Schedule.....	8
1.4	Summary of Application Approval, Part D Bid Review, and Contracting Processes.....	9
2	INSTRUCTIONS	10
2.1	Overview.....	10
2.2	Technical Assistance	10
2.3	Health Plan Management System (HPMS) Data Entry	10
2.4	Instructions and Format of Qualifications.....	11
2.4.1	Instructions	11
2.4.1.1	Completion of Attestations.....	11
2.4.1.2	Application Review Standard.....	11
2.4.1.3	Application Review Process and Cure Periods.....	12
2.4.2	Applicant Seeking to Offer New Employer/Union-Only Group Waiver Plans (EGWPs).....	12
2.4.2.1	PDP EGWP Service Area.....	13
2.4.2.2	Applicants Seeking to Offer New Individual and “800 Series” Plans – Pharmacy Access.....	13
2.4.2.3	Applicants Seeking to Offer Only New “800 Series” Plans – Pharmacy Access	13
2.4.3	Applicant Seeking to Offer New Employer/Union Direct Contract PDPs and PFFS.....	14
2.4.4	Applicant Entity Same as Contracting Entity.....	14
2.4.5	Joint Enterprise as Applicant and Contracting Entity	14
2.4.6	Automatic Enrollment of Full-benefit Dual Eligible Individuals	15
2.4.7	Withdrawal of a Part D Application	15
2.4.8	Technical Support.....	15
2.5	Bid and Formulary Submission Software Training	16
2.6	Pharmacy Access	16
2.6.1	Retail Pharmacy Access.....	16
2.6.2	Home Infusion Pharmacy Access	17
2.6.3	Long-Term Care Pharmacy Access.....	18
2.6.4	Indian Tribe and Tribal Organization, and Urban Indian Organization (I/T/U)	18

2.6.5	Waivers Related to Pharmacy Access.....	18
2.6.5.1	Waivers for Plans in the Territories (excluding Puerto Rico).....	18
2.6.5.2	Waivers for MAPD Plans	18
2.6.5.3	Waivers for Cost Plans	19
2.7	Waivers Related to Attestations for MAPD and PDP EGWP and MAPD and PDP Direct Contract Applicants (“800 Series Plans”)	20
2.8	Waivers for MA-PD and Cost Plan Applicants	20
2.9	Standard Contract with MAPD and PDP Sponsors.....	21
2.10	Protection of Confidential Information	21
3	APPLICATION	23
3.1	Applicant Experience, Contracts, Licensure and Financial Stability.....	23
3.1.1	Management and Operations 42 CFR Part 423 Subpart K; CMS issued guidance 08/15/06 and 08/26/08; 2014 Call Letter	23
3.1.2	Licensure and Solvency 42 CFR Part 423, Subpart I; 2008 Call Letter; CMS issued guidance 03/17/09	31
3.1.3	Program Integrity 2 CFR part 376 and Compliance Program 42 CFR § 423.504(b)(4)(vi); Prescription Drug Benefit Manual, Chapter 9; CMS guidance issued 1/11/2013.....	32
3.1.4	HPMS Part D Contacts CMS Guidance issued 08/16/06, 08/22/07, 11/30/07, 08/06/07, 03/17/09, 07/09/09, 08/04/09, and 01/25/10.....	33
3.2	Benefit Design.....	37
3.2.1	Formulary/Pharmacy and Therapeutics (P&T) Committee Social Security Act §186-D-4(b)(3)(G), 42 CFR §423.120(b), 42 CFR §423.272(b)(2); Prescription Drug Benefit Manual, Chapter 6; 2014 Call Letter; CMS issued guidance 03/25/10	37
3.2.2	Utilization Management Standards 42 CFR §423.153(b); Prescription Drug Benefit Manual, Chapter 6 and Chapter 7; 2013 Call Letter; 2014 Call Letter; 2015 Call Letter.....	39
3.2.3	Quality Assurance and Patient Safety Social Security Act§ 1860D-4(c)(3); 42 CFR §423.153(c); Prescription Drug Benefit Manual, Chapter 7; 2013 Call Letter; 2014 Call Letter; 2015 Call Letter	39
3.2.4	Medication Therapy Management 42 CFR §423.153(d); Social Security Act § 1860D-4(c)(2); Prescription Drug Benefit Manual, Chapter 7; 2013 Call Letter; 2014 Call Letter; 2015 Call Letter.....	40
3.2.5	Electronic Prescription Program and Health Information Technology Standards 42 CFR §423.159; Prescription Drug Benefit Manual, Chapter 7; P.L. 111-5 (2009); 2010 Call Letter	40
3.2.6	Bids 42 CFR § 423.104, §423.265 and §423.272.....	41

3.3	Service Area/Regions 42 CFR §423.112; Prescription Drug Benefit Manual, Chapter 5.....	41
3.4	Private Fee-For-Service Pharmacy Access 42 CFR §423.120(a)(7); Prescription Drug Benefit Manual, Chapter 5	42
3.5	General Pharmacy Access 42 CFR §423.120(a); Prescription Drug Benefit Manual, Chapter 5	42
3.6	Retail Pharmacy 42 CFR §423.120(a); 42 CFR §423.859(c); Prescription Drug Benefit Manual, Chapter 5	44
3.7	Out of Network Access 42 CFR §423.124; Prescription Drug Benefit Manual, Chapter 5.....	46
3.8	Mail Order Pharmacy 42 CFR §423.120(a)(10); Prescription Drug Benefit Manual, Chapter 5; 2014 Call Letter	46
3.9	Home Infusion Pharmacy 42 CFR §423.120(a)(4); Prescription Drug Benefit Manual, Chapter 5	47
3.10	Long -Term Care (LTC) Pharmacy 42 CFR §423.120(a)(5); Prescription Drug Benefit Manual, Chapter 5; CMS issued guidance 04/28/09	47
3.11	Indian Health Service, Indian Tribe and Tribal Organization, and Urban Indian Organization (I/T/U) Pharmacy 42 CFR §423.120(a)(6); Prescription Drug Benefit Manual, Chapter 5	48
3.12	Specialty Pharmacy Prescription Drug Benefit Manual, Chapter 5	49
3.13	Enrollment and Eligibility 42 CFR §423.30; Prescription Drug Benefit Manual, Chapters 3, 4, and 13; Plan Communications User Guide; CMS issued guidance 07/21/09.....	49
3.14	Complaints Tracking Prescription Drug Benefit Manual, Chapter 7; CMS issued guidance 11/16/06, 07/28/2008, 12/09/08, and 6/8/12.....	50
3.15	Medicare Plan Finder Prescription Drug Benefit Manual, Chapter 7; CMS issued guidance 07/17/06, 11/20/07, 08/21/08, 05/20/10	50
3.16	Grievances 42 CFR Part 423 Subpart M; Prescription Drug Benefit Manual, Chapter 18.....	51
3.17	Coverage Determinations (including Exceptions) and Appeals 42 CFR Part 423 Subpart M; Prescription Drug Benefit Manual, Chapter 18; Part D QIC Reconsideration Procedures Manual.....	51
3.18	Coordination of Benefits 42 CFR Part 423 Subpart J; Prescription Drug Benefit Manual, Chapter 14; 2015 Call Letter.....	52
3.19	Tracking True Out-of-Pocket Costs (TrOOP) Social Security Act § 1860D-2(b)(4); 42 CFR Part 423 Subpart J; Prescription Drug Benefit Manual, Chapters 13 and Chapter 14.....	52
3.20	Medicare Secondary Payer 42 CFR §423.462; Prescription Drug Benefit Manual, Chapter 14; CMS issued guidance 4/23/2013.....	53

3.21	Marketing/Beneficiary Communications 42 CFR §423.128; 42 CFR §423.505; Prescription Drug Benefit Manual, Chapter 2	53
3.22	Provider Communications Prescription Drug Benefit Manual, Chapter 2	54
3.23	Reporting Requirements Social Security Act § 1150A; 42 CFR §423.514; 2012 Reporting Requirements.....	54
3.24	Data Exchange between Part D Sponsor and CMS 42 CFR §423.505(c) and (k) 55	
3.25	Health Insurance Portability and Accountability Act of 1996 (HIPAA), Health Information Technology for Economic and Clinical Health Act (HITECH Act), and Related CMS Requirements 45 CFR Parts 160, 162, and 164; CMS issued guidance 08/15/2006 and 08/26/08.....	56
3.26	Prohibition on Use of SSN or Medicare ID number on Enrollee ID Cards Prescription Drug Benefit Manual, Chapter 2	57
3.27	Record Retention 42 CFR §423.505(d)	57
3.28	Prescription Drug Event (PDE) Records; 42 CFR Part 423 Subpart G; CMS issued guidance 04/27/2006, 06/23/2006, 12/17/2010, 03/01/2011, 03/04/2011, 04/28/2011, 05/16/2011, 2/4/2013.....	58
3.29	Claims Processing; 42 CFR §423.120(c)(4); 42 CFR §423.466; CMS issued guidance 04/26/2006, 01/13/2010, and 03/29/2010	58
3.30	Premium Billing 42 CFR §423.293; CMS issued guidance 03/08/2007	59
3.31	Consumer Assessment of Healthcare Providers and Systems (CAHPS) Survey Administration 42 CFR §423.156.....	59
4	CERTIFICATION	60
5	APPENDICES	61
	APPENDIX I – Summary of Medicare Part D Regulatory Requirements Fulfilled under Part C for Medicare Advantage Prescription Drug (MA-PD) Applicants ...	62
	APPENDIX II – Summary of PDP Application Requirements Fulfilled under Part C for Cost Plan Prescription Drug Applicants	65
	APPENDIX III – Attestation for Employer/Union-Only Group Waiver Plans (800-Series)	66
	APPENDIX IV – Employer Direct Contract MA-PD Attestations	71
	APPENDIX V – Employer Direct Contract PDP Attestation	75
	APPENDIX VI – Part D Financial Solvency & Capital Adequacy Documentation	79
	APPENDIX VII – Federal Waiver of State Licensure	87
	APPENDIX VIII – Financial Solvency Documentation for Applicant Not Licensed as a Risk-bearing Entity in Any State	95
	APPENDIX IX – Organization Background and Structure	103
	APPENDIX X – Crosswalks of Section 3.1.1E Requirements in Subcontracts submitted as Attachments to Section 3.1.1	105
	APPENDIX XI – Crosswalk for Retail Pharmacy Access Contracts	108

APPENDIX XII – Crosswalk for Mail Order Pharmacy Access Contracts.....	111
APPENDIX XIII – Crosswalk for Home Infusion Pharmacy Access Contracts .	114
APPENDIX XIV – Crosswalk for Long-Term Care Pharmacy Access Contracts	117
APPENDIX XV – Crosswalk for Indian Tribe and Tribal Organization, and Urban Indian Organization (I/T/U) Pharmacy Access Contracts	122
APPENDIX XVI – Applicant Submission of P&T Committee Member List and Certification Statement	126
APPENDIX XVII – I/T/U Contract Addendum	131
APPENDIX XVIII – Compliance Program Crosswalk.....	139

1 GENERAL INFORMATION

1.1 Purpose of Solicitation

The Centers for Medicare & Medicaid Services is seeking applications from qualified entities to enter into contracts to offer prescription drug coverage and to expand the service areas of existing contracts offering prescription drug coverage as described in the Medicare Prescription Drug Benefit Final Rule published in the Federal Register on January 28, 2005 (70 Fed. Reg. 4194). This application must be used for all organizations seeking new Prescription Drug Plan (PDP) and Medicare Advantage-Prescription Drug Plan (MA-PD) contracts, seeking to expand the service area of existing contracts, and seeking to add prescription drug coverage. Please submit your applications according to the process described in Section 2.0.

1.2 Background

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

Applicants who offer either a PDP or MA-PD plan may offer national plans (with coverage in every region) or regional plans. MA-PD plan applicants may also offer local plans. CMS has identified 26 MA Regions and 34 PDP Regions; in addition, each territory is its own PDP region. Additional information about the regions can be found on the www.cms.gov website.

It is important to note that Medicare Advantage (MA) organizations offering coordinated care plans must qualify to offer at least one plan that includes both Part C and Part D drug benefits throughout the organization's approved Part C service area. Similarly, MA organizations offering a preferred provider organization (PPO) plan must offer Part D coverage throughout the PPO regions in which they are approved to offer a Part C plan. However, MA organizations offering private fee-for-service plans may, but are not required to, offer a Part D drug benefit.

Medicare Cost Plans offered under section 1876(h) of the Act may, at their election, offer prescription drug coverage as a supplemental benefit.

Part D sponsors and MA organizations have flexibility in terms of benefit design. This flexibility includes, but is not limited to, authority to establish a formulary that designates specific drugs that will be available within each therapeutic class of drugs, and the ability to have a cost-sharing structure other than the statutorily defined structure (subject to certain actuarial tests). The plans also may include supplemental benefits coverage such that the total value of the coverage exceeds the value of basic prescription drug coverage.

1.3 Schedule

2016 Milestones	
Date	Milestone
November 13, 2014	Recommended date by which applicants should submit their Notice of Intent to Apply Form to CMS to ensure access to Health Plan Management System (HPMS) by the date applications are released
December 5, 2014	CMS User ID form due to CMS
January 14, 2015	Release of the 2016 MAO/MA-PD/PDP/Service Area Expansion Applications
January 31, 2015	Deadline for NOIA form submission to CMS
February 18, 2015	2016 Applications due
February 2016	CMS releases guidance concerning updates to Parent Organization designations in HPMS
March 2015	Parent Organization Update requests from sponsors due to CMS (instructional memo to be released in February 2015)
April 2015	Plan Creation module, Plan Benefit Package (PBP), and Bid Pricing Tool (BPT) available on HPMS
April 2015	Release of the 2016 Medication Therapy Management (MTM) Program Submission Module in HPMS
May 2015	Medication Therapy Management (MTM) Program submissions due
May 2015	<ul style="list-style-type: none"> • Health Plan Management System (HPMS) formulary submission window • Transition Policy Attestations and Policy due to CMS
May 2015	CMS sends Part D contract eligibility determination to Applicants, based on review of application. Applicant's bids must still be negotiated. (see below)
June 1, 2015	All bids due
Early August 2015	CMS publishes national average Part D premium

Late August 2015	CMS completes review and approval of bid data.
September 1, 2015	CMS executes Part D contracts with those organizations who submit an acceptable bid
October 15, 2015	2016 Annual Coordinated Election Period begins

NOTE: CMS reserves the right to revise the Medicare Prescription Drug Benefit program implementation schedule, including the solicitation and bidding process timelines. This timeline does not represent an all-inclusive list of key dates related to the Medicare Prescription Drug Benefit program. CMS reserves the right to amend or cancel this solicitation at any time.

1.4 Summary of Application Approval, Part D Bid Review, and Contracting Processes

There are three distinct phases to the overall review to determine whether CMS will enter into a contract with an applicant.

The first phase is the application review process. CMS will review all applications submitted on or by February 18, 2015 to determine whether the applicant meets the qualifications we have established to enter into a Part D contract.

The second phase has two steps – the formulary upload which begins May 2015 and the bid upload which begins in May 2015. The formulary review entails determining that the proposed formulary (if one is used):

- Has at least two drugs in every therapeutic category and class (unless special circumstances exist that would allow only one drug);
- Does not substantially discourage enrollment by certain types of Part D eligible individuals;
- Includes adequate coverage of the types of drugs most commonly needed by Part D enrollees;
- Includes all drugs in certain classes and categories as established by the Secretary; and
- Includes an appropriate transition policy.

CMS will contact applicants if any issues are identified during the formulary review to provide an opportunity for applicants to make any necessary corrections prior to the Part D bid submission date. The second step involves the bid review and negotiations with applicants to ensure that valuations of the proposed benefits are reasonable and actuarially equivalent.

The third phase is contracting. Applicants judged qualified to enter into a Part D contract or addendum as a result of successfully completing phase one and two will be offered a Part D contract, or addendum to their Medicare managed care contract, by CMS.

2 INSTRUCTIONS

2.1 Overview

There are six types of entities with which CMS contracts to offer the Medicare prescription drug benefit: PDP sponsors, Medicare Advantage organizations that offer MA-PDs (including local HMO plans, local PPOs, regional PPOs, and Private Fee-for-Service plans); organizations with Cost Plans under section 1876(h) of the Act, Employer Groups (both Employer Group Waiver Plans (EGWPs), and Employer Direct), and PACE organizations. This application is for any organization seeking to offer a new PDP or MAPD, and for any organization seeking to expand or add coverage to an existing MAPD, PDP, or Cost Plan contract, including EGWP and Employer Direct contracts. There is a separate application and separate application process for PACE organizations.

2.2 Technical Assistance

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

Arianne Spaccarelli by email at Arianne.Spaccarelli@cms.hhs.gov, or by phone at 410-786-5715.

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

2.3 Health Plan Management System (HPMS) Data Entry

Organizations that submit a Notice of Intent to Apply form for an initial application are assigned a pending contract identifier (contract ID) with a prefix of either E-, H-, R-, or S-, followed by four digits. The contract ID is used throughout the application and subsequent operational processes. Applicants seeking to add or expand coverage under an existing contract use the associated contract ID.

Once CMS assigns a contract ID, and applicants apply for, and receive, their CMS User ID(s) and password(s) for HPMS access, applicants must input contact and other related information into the HPMS (see section 3.1.4). Applicants must ensure prompt entry and ongoing maintenance of data in HPMS. By keeping the information in HPMS current, applicants facilitate the tracking of their applications throughout the review process and ensure that CMS has the most current information for providing application status updates, guidance, and other correspondence.

If an applicant is awarded a contract, CMS uses this information for frequent communications during implementation and throughout the contract year. It is important that the information in HPMS remain accurate at all times.

2.4 Instructions and Format of Qualifications

Applications must be submitted by February 18, 2015. Applicants must use the 2016 solicitation. CMS will not accept or review any submissions using a prior version of the solicitation, including the use of CMS provided templates from prior years (e.g. 2015 and earlier).

2.4.1 Instructions

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

CMS will communicate with all applicants via email. The email notifications will be generated through HPMS, so organizations must ensure that the applicant's Part D contact information provided through the "Notice of Intent to Apply" process is current and correct, and that there are no firewalls in place that would prevent an email from the hpms@cms.hhs.gov web address from being delivered.

Upon completion of the HPMS online application, organizations are required to click 'Final Submit,' which time and date stamps the completion of the application. No additional work on the application may be done after the applicant clicks 'Final Submit.' Organizations will receive a confirmation number from HPMS upon clicking 'Final Submit.' Failure to obtain a confirmation number indicates that the applicant failed to properly submit its Part D application by the CMS-established deadline. Any entity that experiences technical difficulties during the submission process must contact the HPMS Help Desk **prior to the submission deadline**, and CMS will make case by case determinations where appropriate regarding the timeliness of the application submission.

2.4.1.1 Completion of Attestations

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

In many instances, applicants are directed to affirm within HPMS that they meet particular requirements by indicating "Yes" next to a statement of a particular Part D program requirement. By providing such attestation, an applicant confirms that its organization complies with the relevant requirements as of the date its application is submitted to CMS, unless a different date is stated by CMS.

2.4.1.2 Application Review Standard

CMS will check the application for completeness shortly after its receipt. Consistent with the 2010 Call Letter, CMS will make determinations concerning the validity of each organization's submission. Some examples of invalid submissions include but are not limited to the following:

- Applicants that fail to upload executed agreements or contract templates;
- Applicants that upload contract crosswalks only instead of contracts; or

- Applicants that fail to upload any pharmacy network lists.

CMS will notify any applicants that are determined to have provided invalid submissions.

In accordance with 42 CFR §423.502 and 503, applicants must demonstrate that they meet all (not “substantially all”) Part D program requirements to qualify as a Part D sponsor in their proposed service area.

2.4.1.3 Application Review Process and Cure Periods

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

As with all aspects of a Part D sponsor’s operations under its contract with CMS, we may verify a sponsor’s compliance with qualifications it attests it meets through on-site visits at the Part D sponsor’s facilities and through other program monitoring techniques. Failure to meet the requirements attested to in this solicitation and failure to operate its Part D plan(s) consistent with the requirements of the applicable statutes, regulations, call letter, guidance, and the Part D contract may delay a Part D sponsor’s marketing and enrollment activities or, if corrections cannot be made in a timely manner, the Part D sponsor will be disqualified from participation in the Part D program.

An individual with legal authority to bind the applicant must execute the certification found in Section 4. CMS reserves the right to request clarifications or corrections to a submitted application. Failure to provide requested clarifications within the time period specified by CMS for responding could result in the applicant receiving a notice of intent to deny the application.

Applicants failing to cure deficiencies following the courtesy cure period will be issued a Notice of Intent to Deny the application. Applicants receiving notices of intent to deny have 10 days to remedy their applications. The end of the 10-day period is the last opportunity an applicant has to provide CMS with clarifications or corrections. CMS will only review the last submission provided during this cure period. Application materials will not be accepted after this 10-day time period.

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

If a subsidiary, parent, or otherwise related organization is also applying to offer Part D benefits, these entities MUST submit separate applications. Entities intending to have both local MA-PD and Regional PPO contracts must submit separate MA-PD applications.

2.4.2 Applicant Seeking to Offer New Employer/Union-Only Group Waiver Plans (EGWPs)

All new Part D applicants seeking to offer new “800 series” EGWPs – with or without corresponding individual plans, including applicants that have not previously applied to

offer plans to individual beneficiaries or “800 series” EGWPs – must complete the appropriate EGWP attestation. PDP applicants should complete the attestation in Appendix III. MA-PD applications should complete the attestation found in the 2016 Application Instructions for MA Organizations to Offer New Employer/Union-Only Group Waiver Plans (for MAPD applicants). The Appendix provides the Applicant with the ability to choose between only offering “800 series” plans and participating in both the individual and group markets. The attestation provided in Appendix III specifies those individual market requirements that are not applicable in the employer market.

2.4.2.1 PDP EGWP Service Area

New PDP applicants and existing PDP Sponsors will be able to enter their EGWP service areas directly into HPMS during the application process (refer to HPMS User Guide). PDP applicants may provide coverage to employer group members wherever they reside (i.e., nationwide). However, in order to provide coverage to retirees wherever they reside, PDP applicants must set their EGWP service area to include all areas where retirees reside during the plan year (i.e., set national service areas).

SAE of Employer-only service area

Applicants with existing contracts seeking to add EGWP for the first time, or expand only the EGWP service area, will complete an abbreviated application consisting of attestations, and application certifications.

2.4.2.2 Applicants Seeking to Offer New Individual and “800 Series” Plans – Pharmacy Access

Applicants seeking to offer both individual and “800 series” plans are not required to submit separate pharmacy access lists (retail, mail order, home infusion, long-term care, I/T/U) for their “800 series” service areas in addition to those required to be submitted for their individual plan service areas. Sponsors will not initially be required to have retail and other pharmacy networks in place for those designated EGWP service areas outside of their individual plan service areas. However, in accordance with employer group waiver pharmacy access policy, pharmacy access sufficient to meet the needs of enrollees must be in place once the sponsor enrolls members of an employer or union group residing in particular geographic locations outside of its individual plan service area.

2.4.2.3 Applicants Seeking to Offer Only New “800 Series” Plans – Pharmacy Access

Applicants applying to only offer “800 series” plans (i.e., no plans will be offered to individual Medicare beneficiaries under this contract number) must submit retail and other pharmacy access lists (mail order, home infusion, long-term care, I/T/U) for the entire defined EGWP service area during the application process and demonstrate sufficient access in these areas in accordance with employer group waiver pharmacy access policy.

2.4.3 Applicant Seeking to Offer New Employer/Union Direct Contract PDPs and PFFS

New Employer/Union Direct Contract applicants must enter their service area directly into HPMS during the application process.

In general, Part D sponsors can only cover beneficiaries in the service areas in which they are licensed and approved by CMS to offer benefits. CMS has waived these requirements for Direct Contract sponsors. Direct Contract sponsors can extend coverage to all of their retirees, regardless of where in the nation they reside. In order to provide coverage to retirees wherever they reside, Direct Contract applicants must set their service areas to include all areas where retirees may reside during the plan year.

Direct Contract applicants are required to submit retail and other pharmacy access information for the entire defined service area during the application process and demonstrate sufficient access in these areas in accordance with employer group waiver pharmacy access policy.

Those employers or unions seeking to directly contract with CMS to become sponsors for their Medicare-eligible retirees must complete the following materials:

- The 2016 Medicare Advantage Application (for Direct Contract PFFS applicants ONLY)
- The 2016 Solicitation for Applications for Prescription Drug Plan Sponsors
- Appendix IV – Direct Contract MA-PD Attestations
- Appendix V—Direct Contract PDP Attestation
- Appendix VI -- Part D Financial Solvency & Capital Adequacy Documentation for Direct Contract PDP Sponsor Applicants

2.4.4 Applicant Entity Same as Contracting Entity

The legal entity that submits this application must be the same entity with which CMS enters into a Part D contract, or in the case of an MA-PD and Cost Plan sponsor, the same legal entity seeking an addendum to an MA or Cost Plan contract.

2.4.5 Joint Enterprise as Applicant and Contracting Entity

CMS will recognize as applicants those joint enterprises formed by agreement among multiple state-licensed organizations (or organizations that have applied to CMS for a licensure waiver) for the purpose of administering a stand-alone PDP or an MA Regional PPO (RPPO) in at least one entire PDP region. Each member of the joint enterprise will be contractually liable to CMS for the administration of the Part D benefit in the State(s) in which it is licensed or for which it has received a CMS licensure waiver.

The joint enterprise need submit only one application on behalf of the enterprise's member organizations and such application shall represent the joint enterprise's commitment to offering a uniform benefit in each PDP region in which it will offer Part D

benefits. However, the information requested in Section 3.1 of this solicitation must be provided for each member of the joint enterprise with separate accompanying Appendices as necessary. For example, each joint enterprise member must provide identifying information about its organization, copies of its executed contracts with entities performing critical tasks related to the delivery of the Part D benefit, and information related to its business integrity. The responses provided in the remainder of the application may be made once by the joint enterprise applicant and will be considered binding on each member of the joint enterprise. Also, a separate certification statement, shown in Section 4.0, must be provided for each joint enterprise member organization. Each certification statement must be signed by an individual specifically granted the authority to bind the member organization.

Joint enterprise applicants are required to submit to CMS for approval a copy of the executed agreement among the joint enterprise member organizations. Please see Section 3.1.1.G, for instructions concerning this requirement.

Upon CMS' determination that the members of the joint enterprise are qualified to enter into a contract and approval of the bid(s) submitted by the joint enterprise, CMS will enter into a multiple-party contract signed by authorized representatives of CMS and each member of the joint enterprise.

2.4.6 Automatic Enrollment of Full-benefit Dual Eligible Individuals

When there is more than one PDP in a region with a premium that makes it eligible for automatic enrollment of full-benefit dual eligible individuals (as provided in 42 CFR §423.34(d)), CMS enrolls beneficiaries into the eligible PDPs on a random basis. For this purpose, CMS counts the Applicant and its parent and affiliates as a single PDP, regardless of how many of those entities have bids that are at or below the low income subsidy threshold.

2.4.7 Withdrawal of a Part D Application

In those instances where an organization seeks to withdraw its application or reduce the service area of a pending application prior to the execution of a Part D contract, then the organization must send an official notice to CMS. The notice should be on organization letterhead and clearly identify the pending application number and service area (as appropriate). The notice should be delivered via email to PartD_Applications@cms.hhs.gov and, for MAPD applicants, MA_Applications@cms.hhs.gov. The subject line of the email should read "Pending application withdrawal or reduction to pending service area." The withdrawal will be considered effective as of the date of the email.

2.4.8 Technical Support

CMS conducts technical support calls, also known as user group calls, for applicants and existing Part D sponsors. CMS operational experts (e.g., from areas such as enrollment, information systems, marketing, bidding, formulary design, and coordination of benefits) are available to discuss and answer questions regarding the agenda items

for each meeting. Registration for the technical support calls and to join the list serve to get updates on CMS guidance can be found at www.mscginc.com/Registration/.

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

CMS provides two user manuals to assist applicants with the technical requirements of submitting the Part D application through the Health Plan Management System (HPMS). The *Basic Contract Management User's Manual* provides information on completing and maintaining basic information required in Contract Management. These data must be completed prior to the final submission of any application. The *Online Application User's Manual* provides detailed instructions on completing the various online applications. Both manuals can be found in HPMS by clicking on Contract Management>Basic Contract Management>Documentation.

2.5 Bid and Formulary Submission Software Training

CMS will provide technical instructions and guidance upon release of the HPMS formulary and bid functionality as well as the Plan Benefit Package (PBP) and Bid Pricing Tool (BPT) software. In addition, systems training will be available at the Bid Training in April 2015.

2.6 Pharmacy Access

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

Furthermore, Part D sponsors must provide adequate access to home infusion and convenient access to long-term care, and Indian Health Service, Indian Tribe and Tribal Organization, and Urban Indian Organization (I/T/U) pharmacies in accordance with 42 CFR § 423.120 and related CMS instructions and guidance.

2.6.1 Retail Pharmacy Access

Applicants must ensure that their retail pharmacy network meets the criteria established under 42 CFR §423.120. CMS rules require that applicants establish retail pharmacy networks in which:

- In urban areas, at least 90 percent of Medicare beneficiaries in the applicant's service area, on average, live within 2 miles of a retail pharmacy participating in the applicant's network;
- In suburban areas, at least 90 percent of Medicare beneficiaries in the applicant's service area, on average, live within 5 miles of a retail pharmacy participating in the applicant's network; and
- In rural areas, at least 70 percent of Medicare beneficiaries in the applicant's service area, on average, live within 15 miles of a retail pharmacy participating in the applicant's network.

Applicants may count I/T/U pharmacies and pharmacies operated by Federally Qualified Health Centers and Rural Health Centers towards the standards of convenient access to retail pharmacy networks.

Applicants may use their contracted pharmacy benefit manager's (PBM) existing 2015 Part D network to demonstrate compliance with retail pharmacy access standards. If an applicant is creating a new Part D network, the submission must be based on executed contracts for year 2016.

CMS conducts the review of retail pharmacy access based on the service area that the applicant has provided in HPMS by February 18, 2015. The access review is automated. Applicants must input their pending service area into HPMS per the instructions at section 3.3. As explained in section 3.6.B, applicants must upload the retail pharmacy list in HPMS. Based on the information provided by the applicant and the Medicare Beneficiary Count file available on the CMS application guidance website, CMS will generate access percentages for all applicants.

With limited exceptions, this information gathered from the pharmacy lists will be used by CMS to geo-code the specific street-level locations of the pharmacies to precisely determine retail pharmacy access. Exceptions to this process may include, but not be limited to, those instances where a street-level address cannot be precisely geo-coded. In those situations, CMS will utilize the ZIP code-level address information to geo-code the approximate pharmacy location.

The retail pharmacy lists may contain contracted pharmacies that are outside of the applicant's pending service area (to account for applicants who contract for a national pharmacy network); however, CMS will only evaluate retail pharmacy access for the pending service area.

While applicants are required to demonstrate that they meet the Part D pharmacy access requirements at the time this application is submitted to CMS, CMS expects that pharmacy network contracting will be ongoing in order to maintain compliance with our retail pharmacy access requirements.

2.6.2 Home Infusion Pharmacy Access

Applicants must demonstrate that their contracted pharmacy network provides adequate access to home infusion pharmacies. In order to demonstrate adequate access to home infusion pharmacies, Applicants must provide a list of all contracted home infusion pharmacies (see section 3.9). CMS uses this pharmacy listing to compare applicants' home infusion pharmacy network against existing Part D sponsors in the same service areas to ensure that applicants have contracted with an adequate number of home infusion pharmacies. The adequate number of home infusion pharmacies is developed based on data provided by all Part D sponsors through the annual Part D Reporting Requirements. A reference file entitled "Adequate Access to Home Infusion Pharmacies" is provided on the CMS website, http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxContracting_ApplicationGuidance.html.

2.6.3 Long-Term Care Pharmacy Access

Applicants must demonstrate that their contracted pharmacy network provides convenient access to long-term care (LTC) pharmacies. In order to demonstrate convenient access to long-term care pharmacies, applicants must provide a list of all contracted long-term care pharmacies (see section 3.10). CMS uses this pharmacy listing, as well as information reported as part of applicants' reporting requirements and complaints data, to evaluate initial and ongoing compliance with the convenient access standard. To assist applicants with preparing their LTC pharmacy network, CMS provides the LTC Facilities List on the CMS website, http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxContracting_ApplicationGuidance.html.

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

Applicants must demonstrate that they have offered standard contracts to all I/T/U pharmacies residing within the applicants' service areas. In order to demonstrate convenient access to I/T/U pharmacies, applicants must provide a list of all I/T/U pharmacies to which they have offered contracts (see section 3.11). CMS provides the current national list of all I/T/U pharmacies to assist applicants in identifying the states in which I/T/U pharmacies reside. The in the ITU Pharmacies Reference File is located on the CMS website, http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxContracting_ApplicationGuidance.html.

2.6.5 Waivers Related to Pharmacy Access

2.6.5.1 Waivers for Plans in the Territories (excluding Puerto Rico)

To ensure access to coverage in the territories, section 1860D-42(a) of the Act grants CMS the authority to waive the necessary requirements to secure access to qualified prescription drug coverage for Part D eligible individuals residing in the territories. The regulations at 42 CFR §423.859(c) allow CMS to waive or modify the requirement for access to coverage in the territories either at an applicant's request or at CMS' own determination. Under that authority, CMS will consider waiving the convenient access requirements for a plan's Part D contracted retail pharmacy network, found in 42 CFR §423.120(a)(1) for the Territories, if an applicant requests such a waiver, and demonstrates that it has made a good faith effort to meet the requirements described in Section 3.6 D of this solicitation.

2.6.5.2 Waivers for MAPD Plans

CMS guidance regarding waivers of the pharmacy access and any willing pharmacy requirements for certain MA-PD sponsors is contained at sections 50.7 and 50.8.1 of Chapter 5 of the Prescription Drug Benefit Manual. These waivers are described below.

Waiver of Retail Convenient Access Standards for MA-PDs

As described in section 50.7.1 of Chapter 5 of the Prescription Drug Benefit Manual, the requirement that MA-PD sponsors must offer their Part D plan benefit through a

contracted retail pharmacy network that meets CMS convenient access standards is waived for MA-PD sponsors that operate their own pharmacies. MA-PD sponsors must demonstrate at the plan level that a majority (50%) of the prescriptions are filled at retail pharmacies owned and operated by the organization in order to be granted the waiver. (See section 3.6F)

Waiver of Convenient Access Standards for MA-PFFS

As described in section 50.7.2 of Chapter 5 of the Prescription Drug Benefit Manual, the requirement that MA-PD sponsors must offer Part D plan benefits through a contracted pharmacy network that meets CMS convenient access standards is waived for MA-PFFS plans that meet the criteria in table 3.4. (See section 3.6.F)

Waiver of Any Willing Pharmacy Requirements for MA-PD

As described in section 50.8.2 of Chapter 5 of the Prescription Drug Benefit Manual, the requirement that MA-PD sponsors must offer a network pharmacy contract to any willing pharmacy that agrees to accept MA-PD sponsor's standard terms and conditions is waived for MA-PD sponsors that own and operate the pharmacies in their network. MA-PD sponsors must demonstrate at the plan level that at least 98% of prescriptions are filled through pharmacies that are owned and operated by plan sponsor in order to be granted the waiver. (See section 3.6G)

2.6.5.3 Waivers for Cost Plans

CMS guidance regarding waivers of the pharmacy access and any willing pharmacy requirements for certain Cost Plan sponsors is contained at sections 50.7 and 50.8.1 of Chapter 5 of the Prescription Drug Benefit Manual. These waivers are described below.

Waiver of Retail Convenient Access Standards

As described in section 50.7.1 of Chapter 5 of the Prescription Drug Benefit Manual, the requirement that Applicants must offer their Part D plan benefit through a contracted retail pharmacy network that meets CMS convenient access standards is waived for Applicants that operate their own pharmacies. Applicants must demonstrate at the plan level that a majority (50%) of the prescriptions are filled at retail pharmacies owned and operated by the organization in order to be granted the waiver.

Waiver of Any Willing Pharmacy Requirements

As described in section 50.8.2 of Chapter 5 of the Prescription Drug Benefit Manual, the requirement that Applicants must offer a network pharmacy contract to any willing pharmacy that agrees to accept Applicant's standard terms and conditions is waived for Applicants that own and operate the pharmacies in their network. Applicants must demonstrate at the plan level that at least 98% of prescriptions are filled through pharmacies that are owned and operated by plan sponsor in order to be granted the waiver. (See Sections 3.6 F & G)

2.7 Waivers Related to Attestations for MAPD and PDP EGWP and MAPD and PDP Direct Contract Applicants (“800 Series Plans”)

As a part of the application process, those organizations seeking to offer 800 series plans may submit individual waiver/modification requests to CMS. Applicants should submit an attachment via an upload in the HPMS Part D Attestations section that addresses the following:

- Specific provisions of existing statutory, regulatory, and/or CMS policy requirement(s) the applicant is requesting to be waived or modified (e.g., 42 CFR §423.32, Section 30.4 of the Part D Enrollment Manual);
- How the particular requirement(s) hinder the design of, the offering of, or the enrollment in, the employer-sponsored group plan;
- Detailed description of the waiver/modification requested including how the waiver/modification will remedy the impediment to the design of, the offering of, or the enrollment in, the employer-sponsored group prescription drug plan;
- Other details specific to the particular waiver/modification that would assist CMS in the evaluation of the request; and
- Contact information (contract number, name, position, phone, fax and email address) of the person who is available to answer inquiries about the waiver/modification request.

Note: Applicants should review the waivers currently approved by CMS in Chapter 12 of the Medicare Prescription Drug Benefit Manual to assess whether the sponsoring organization is similarly situated to qualify for an existing waiver prior to submitting a request to CMS.

2.8 Waivers for MA-PD and Cost Plan Applicants

CMS is authorized to grant waivers of Part D program requirements where requirements conflict with or duplicate a Part C or Cost Plan requirement, or where granting a waiver would improve the MA-PD or Cost Plan sponsor’s coordination of Part C and Part D benefits. Accordingly, CMS has identified the waivers it is granting to all MA-PD sponsors in the chart shown in Appendix I *Summary of Medicare Part D Regulatory Requirements Fulfilled under Part C for Medicare Advantage Prescription Drug (MA-PD) Applicants*. As a result of these CMS-granted waivers, the MA-PD sponsor application is less comprehensive than the PDP sponsor application. These waivers will be reflected in each MA-PD sponsor’s Part D addendum.

Applicant Requests for Additional Waivers: CMS may grant additional waivers upon an MA-PD or Cost Plan sponsor’s request. Any waiver granted by CMS will apply to all similarly situated MA-PD sponsors.

For each waiver request, the applicant must provide, as an upload in HPMS, a statement 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.

CMS will notify applicants whether their requests were approved via a CMS web posting of all approved waivers.

Where this application directs the applicant to attest that it will meet a particular Part D requirement for which the applicant has requested a waiver, the applicant should check both the “Yes” box and the “Waiver Requested” box within HPMS. In the event that CMS does not approve a particular waiver, the applicant will still have attested that it will meet all the applicable Part D program requirements and remain eligible to enter into a Part D addendum upon approval of its bids. This process will prevent applicants from having to submit additional application responses after the original February 18, 2015 deadline.

If, as a result of CMS’ denial of its waiver request, the applicant no longer intends to offer a Part D benefit plan, the applicant must notify CMS in writing on or before June 30, 2015. CMS will not execute a Part D addendum with applicants that submit such a notice. This notice of withdrawal should be sent following email instructions in section 2.4.7 Withdrawal of Part D Applications. No hard copies will be accepted.

2.9 Standard Contract with MAPD and PDP Sponsors

Successful applicants will be deemed qualified to enter into a Part D contract with CMS to operate one or more Medicare prescription drug plans after CMS has reviewed the Applicant’s entire submission. Only after the qualified applicant and CMS have reached agreement on the applicant’s bid submissions will the applicant be asked to execute its Part D contract.

Approved Part D applications are valid for the forthcoming contract year. Should an applicant decide to not execute a contract after receiving application approval, the applicant will be required to reapply in a subsequent year if it desires to enter a Part D contract in the future.

2.10 Protection of Confidential Information

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

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

- Disclosure of the information might impair the government's ability to obtain necessary information in the future;
- Disclosure of the information would cause substantial harm to the competitive position of the submitter;
- Disclosure would impair other government interests, such as program effectiveness and compliance; or
- Disclosure would impair other private interests, such as an interest in controlling availability of intrinsically valuable records, which are sold in the market.

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

3 APPLICATION

Nothing in this application is intended to supersede the regulations at 42 CFR Part 423, 42 CFR Part 422, the Prescription Drug Benefit Manual, the Medicare Managed Care Manual, or any other CMS guidance or instructions related to the operation of the Part D program or the MA program. Failure to reference a regulatory requirement or CMS instruction in this application does not affect the applicability of such requirement. In particular, the attestations in this application are intended to highlight examples of key requirements across a variety of functional and operational areas, but are in no way intended to reflect a complete or thorough description of all Part D requirements.

For most 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 in making the attestations stated below, they are also representing to CMS that they have reviewed and comply with the associated guidance materials posted on the CMS web site. Applicants must visit the CMS web site periodically to review new or revised guidance documents.

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

3.1 Applicant Experience, Contracts, Licensure and Financial Stability

SPECIAL INSTRUCTIONS FOR JOINT ENTERPRISE APPLICANTS: If an application is being submitted by a joint enterprise, as described above in Section 2.4, a separate set of responses to the requirements in Section 3.1 must be provided as part of this application by each member organization of the joint enterprise. The responses should be uploaded in the Part D contracting section of the application.

3.1.1 Management and Operations 42 CFR Part 423 Subpart K; CMS issued guidance 08/15/06 and 08/26/08; 2014 Call Letter

A. In HPMS, complete the table below:

Applicant must attest ‘yes’ or, if permitted, “NA”, 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	NA	Requesting a Waiver? (ONLY FOR COST AND MAPD APPLICANTS)
Applicant is a non-governmental legal entity that intends to enter into a Medicare Prescription Drug Plan contract with CMS. (For applicants applying for a new PDP contract.)				

Applicant is a legal entity that intends to enter into a Medicare Prescription Drug Plan addendum to its contract with CMS. (For applicants applying for a new MAPD contract or to add a Part D benefit to a Cost contract.)				
Applicant does not have any other related entities offering a stand-alone Prescription Drug Plan. (For applicants applying for a new PDP contract.)				
If applicant, applicant's parent organization, or any subsidiaries of applicant's parent organization has an existing contract(s) with CMS to provide Part D drug benefits at least one of those contracts has been in continuous effect since January 1, 2014 or earlier. (If the Applicant, Applicant's parent organization, or a subsidiary of Applicant's parent organization does not have any existing contracts with CMS to provide Part D drug benefits, select "NA".) (For all applicants)				
Applicant has read, understood, and complies with the regulations at 42 CFR Part 423 Subpart K and all CMS-issued guidance related to management and operations. (Not applicable for SAE applicants)				
Applicant maintains contracts or other legal arrangements between or among the entities combined to meet the functions identified in subsection 3.1.1C. (For all applicants)				

<p>Applicant does not have any covered persons who also served as covered persons for an entity that nonrenewed a contract pursuant to 42 CFR §423.507(a), or that terminated its contract with CMS by mutual consent, pursuant to 42 CFR §423.508, or unilaterally, pursuant to 42 CFR §423.510, since January 1, 2013,. “Covered persons”, as defined at 42 CFR §§ 423.507(a)(4), 423.508(f), 423.510(e)(2), include:</p> <ul style="list-style-type: none"> • All owners of nonrenewed or terminated organizations who are natural persons, other than shareholders who have an ownership interest of less than 5 percent; • An owner of a whole or part interest in a mortgage, deed of trust, note, or other obligation secured (in whole or in part) by the organization, or by any property or assets thereof, which whole or part interest is equal to or exceeds 5 percent of the total property and assets of the organization; and • A member of the board of directors or board of trustees of the entity, if the organization is organized as a corporation. <p>(Not applicable for SAE applicants)</p>				
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B. Upload organizational background and structure information. Submit this information by downloading the appropriate template found in HPMS that mimics the Appendix entitled, *Organization Background and Structure*. Also upload into HPMS proof of your organization’s incorporation, such as articles of incorporation or a certificate of good standing from your state of incorporation. (Not applicable for SAE applicants)

C. First tier, Downstream and Related Entities Function Chart (Not applicable for SAE applicants.)

A Part D sponsor may meet program requirements by delegating the performance of certain required functions to entities with which it contracts directly, referred to in the Part D regulations (§423.501) as “first tier entities.” These entities may in turn contract with other entities, defined as “downstream entities,” for the performance of the delegated function. A related entity is an entity that is a parent, subsidiary, or subsidiary of the parent of the Part D Sponsor. A related entity may be either a first tier or downstream entity.

Where an applicant has elected to use subcontractors to meet Part D requirements, it must demonstrate that it has binding contracts in place that reflect these relationships.

These contracts serve as the legal links that form the applicant’s “chain of delegation,” extending from the applicant to the entities (first tier or downstream) that will actually perform the stated function on the applicant’s behalf. Where the function is to be performed by a downstream entity, there must be contracts in place through which the applicant has delegated a function to a first tier entity, which has in turn delegated that function to the downstream entity.

Applicants must identify in the chart below the first tier and downstream entities with which it has contracted to perform the listed Part D functions.

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

In HPMS, on the Contract & Management/Part D Information/Part D Data Page, provide names of the first tier, downstream and related entities you will use to carry out each of the functions listed in this chart and whether the first tier, downstream and related entities are off-shore. Organizations applying for an SAE should ensure that the information in HPMS is up-to-date for the current contract year. (Indicate with “name of Applicant’s Organization”	Function	<u>First tier, Downstream and Related entities</u>	<u>Off-Shore yes/no</u>
	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.		

where applicant will perform those functions)	A pharmacy benefit program that performs administration and tracking of enrollees' drug benefits in real time, including TrOOP balance processing.		
	A pharmacy benefit program that performs coordination with other drug benefit programs, including, for example, Medicaid, state pharmaceutical assistance programs, or other insurance.		
	A pharmacy benefit program that develops and maintains a pharmacy network.		
	A pharmacy benefit program that operates an enrollee grievance and appeals process		
	A pharmacy benefit program that performs customer service functionality, that includes serving seniors and persons with a disability.		
	A pharmacy benefit program that performs pharmacy technical assistance service functionality.		
	A pharmacy benefit program that maintains a pharmaceutical and therapeutic committee.		

	A pharmacy benefit program that performs enrollment processing.		
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D. First Tier, Downstream, and Related Entity Relationship Chart

Prepare and upload into HPMS a chart showing the relationship between the applicant and each first tier, downstream, and related entity identified in section 3.1.1 C. This chart must include the names of all entities in the contracting chain between the applicant and the entity performing the identified function.

E. Except for SAE applicants, upload copies of executed contracts, fully executed letters of agreement, administrative services agreements, or intercompany agreements (in word-searchable .pdf format) with each first tier, downstream or related entity identified in Sections 3.1.1 C and with any first tier, downstream, or related entity that contracts with any of the identified entities on the applicant’s behalf. As noted above, this requirement applies even if an entity contracting on the applicant’s behalf is the applicant’s parent organization or a subsidiary of the applicant’s parent organization. Unless otherwise indicated, each and every contract must:

1. Clearly identify the parties to the contract (or letter of agreement). If the applicant is not a direct party to the contract (e.g., if one of the contracting entities is entering into the contract on the applicant’s behalf), **the applicant must be identified as an entity that will benefit from the services described in the contract.**
2. Describe the functions to be performed by the first tier, downstream or related entity, and the reporting requirements the first tier, downstream, or related entity has to the applicant. 42 CFR §423.505(i)(4)(i)
3. Contain language clearly indicating that the first tier, downstream, or related entity has agreed to participate in your Medicare Prescription Drug Benefit program (except for a network pharmacy if the existing contract would allow participation in this program).
4. Contain flow-down clauses requiring that any services or other activity they perform in accordance with the contract be consistent and comply with the applicant’s contractual obligations as a Part D sponsor. 42 CFR §423.505(i)(3)(iii)
5. Describe the payment or other consideration the first tier, downstream, or related entity will receive for performance under the contract.
6. Clearly indicate that the contract is for a term of at least the initial one-year contract period (i.e., January 1 through December 31) for which this application is being submitted. Where the contract is for services or products to be used in preparation for the next contract year’s Part D operations (e.g., marketing, enrollment), the initial term of such contract must include this period of performance (e.g., contracts for enrollment-related services must have a term beginning no later than October 15 extending through the full contract year ending on December 31 of the next year).
7. Be signed by a representative of each party with legal authority to bind the entity.

8. Contain language obligating the first tier, downstream, or related entity to abide by all applicable Federal laws and regulations and CMS instructions. 42 CFR §423.505(i)(4)(iv)
9. Contain language obligating the first tier, downstream, or related entity to abide by State and Federal privacy and security requirements, including the confidentiality and security provisions stated in the regulations for this program at 42 CFR §423.136.
10. Contain language ensuring that the first tier, downstream, or related entity will make its books and other records available in accordance with 42 CFR §423.505(e)(2) and 42 CFR §423.505(i)(2). Generally stated, these regulations give HHS, the Comptroller General, or their designees the right to audit, evaluate and inspect any books, contracts, records, including medical records and documentation involving transactions related to CMS' contract with the Part D sponsor and that these rights continue for a period of 10 years from the final date of the contract period or the date of audit completion, whichever is later. 42 CFR §423.505(e)(2) and (i)(2)
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 Part D sponsor. 42 CFR §423.505(i)(3)(i)
12. Contain language that delegated activities or reporting responsibilities may be revoked if CMS or the Part D sponsor determines the first tier, downstream, or related entity has not performed satisfactorily. The contract/administrative services agreement may include remedies in lieu of revocation to address this requirement. 42 CFR § 423.505(i)(4)(ii)
13. Contain language specifying that the applicant, upon becoming a Part D sponsor, will monitor the performance of the first tier, downstream, or related entity on an ongoing basis. **The contract must explicitly provide that the sponsor itself will perform ongoing monitoring. Language indicating that the sponsor has the right to monitor is not sufficient; the contract must affirmatively state that the sponsor will monitor the entity on an ongoing basis.** 42 CFR §423.505(i)(4)(iii)
14. If the first tier, downstream, or related entity will establish the pharmacy network or select pharmacies to be included in the network, contain language that the Part D sponsor retains the right to approve, suspend, or terminate any arrangement with a pharmacy. 42 CFR §423.505(i)(5)
15. If the first tier, downstream, or related entity will establish the pharmacy network or select pharmacies to be included in the network, contain language that payment to such pharmacies (excluding long-term care and mail order) shall be issued, mailed, or otherwise transmitted with respect to all clean claims submitted by or on behalf of pharmacies within 14 days for electronic claims and within 30 days for claims submitted otherwise. 42 CFR §§423.505(i)(3)(vi) and 423.520
16. If the first tier, downstream, or related entity will establish the pharmacy network or select pharmacies to be included in the network, contain language that if a prescription drug pricing standard is used for reimbursement, identify the source used by the Part D sponsor for the standard of reimbursement. 42 CFR §§423.505(b)(21) and 423.505(i)(3)(viii)(B)

17. If the first tier, downstream, or related entity will establish the pharmacy network or select pharmacies to be included in the network, and the source for any prescription drug pricing standard is not publicly available, a provision for disclosing all individual drug prices to be updated to the applicable pharmacies in advance of their use for reimbursement of claims. 42 CFR §423.505(i)(3)(vii).
18. If the first tier, downstream, or related entity will establish the pharmacy network or select pharmacies to be included in the network and a prescription drug pricing standard is used for reimbursement, contain a provision that updates to such a prescription drug pricing standard occur not less frequently than once every 7 days beginning with an initial update on January 1 of each year, to accurately reflect the market price of acquiring the drug. 42 CFR §423.505(b)(21) and (i)(3)(viii)(A)
19. If the first tier, downstream, or related entity will establish the pharmacy network or select pharmacies to be included in the network, contain language requiring the network pharmacies to submit claims to the 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 42 CFR §423.514(d) and (e).

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

F. Except for SAE applicants, upload electronic lists of the contract/administrative service agreement/intercompany agreement citations demonstrating that the requirements of Section 3.1.1 E are included in each contract and administrative service agreement. Submit these data by downloading the appropriate spreadsheet found in HPMS that mimics the crosswalk in Appendix X of this solicitation. If the applicant fails to upload crosswalks for executed agreements and contract templates, CMS cannot guarantee that the applicant will receive notice of any deficiencies in the contracting documents as part of this courtesy review.

G. In HPMS, complete the table below:

Only applicable to PDP and MA-PD initial applicants.

Attest 'yes' or 'no' to the following qualification by clicking on the appropriate response in HPMS:	Yes	No
Applicant is applying to operate as a Part D sponsor through a joint enterprise agreement.		

H. Special Requirement for Joint Enterprise Applicants: If applicant answered the attestation in section 3.1.1 G as YES, then joint enterprise applicants must upload (in .pdf format) a copy of the agreement executed by the State-licensed

entities describing their rights and responsibilities to each other and to CMS in the operation of a Medicare Part D benefit plan. Such an agreement must address at least the following issues:

- Termination of participation in the joint enterprise by one or more of the member organizations; and
- Allocation of CMS payments among the member organizations.

3.1.2 Licensure and Solvency 42 CFR Part 423, Subpart I; 2008 Call Letter; CMS issued guidance 03/17/09

Only applicable for PDP initial or SAE applicants, including those offering EGWPs. Not applicable to Employer/Union Direct applicants

A. In HPMS, on the Contract Management/General Information/NAIC Data Page, provide the National Association of Insurance Commissioners (NAIC) number if currently licensed. Note that applicants for new PDPs will not be able to complete this section in HPMS until after the courtesy review period is over.

B. In HPMS, complete the table below:

Attest 'Yes,' 'No,' or "Does Not Apply" to the following licensure requirements.	Yes	No	NA
<p>Applicant is licensed under State law as a risk-bearing entity eligible to offer health insurance or health benefits coverage in each State in which the Applicant proposes to offer Part D drug benefits.</p> <ul style="list-style-type: none"> • If the answer to this attestation is "YES," then upload in HPMS the documentation (e.g., licensing certificate or letter), from each state licensing authority of your organization's status as an entity entitled to bear risk. • If the answer to this attestation is "NO" see Attestation #2 and complete the Federal Waiver of State Licensure application found in Appendix VII for every state in your proposed service area in which you are not licensed. 			
<p>If the applicant is not State licensed as a risk-bearing entity eligible to offer health insurance or health benefits coverage in each State in which the applicant proposes to offer Part D benefits, is the applicant licensed as a risk-bearing entity in at least one State?</p> <ul style="list-style-type: none"> • If the answer to this attestation is "YES," then upload in HPMS the documentation (e.g., licensing certificate or letter), from each state licensing authority of your organization's status as an entity entitled to bear risk. • If the answer to this attestation is "NO," the applicant must submit via HPMS the Appendix entitled Financial Solvency Documentation. 			

<p>Applicant is currently under supervision, corrective action plan or special monitoring by the State licensing authority in any State.</p> <ul style="list-style-type: none"> If the answer to this attestation is “Yes”, upload in HPMS an explanation of the specific actions taken by the State license regulator. In these cases, CMS reserves the right to require the applicant to demonstrate that it meets the CMS-published financial solvency and capital adequacy requirements. 			
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3.1.3 Program Integrity 2 CFR part 376 and Compliance Program 42 CFR § 423.504(b)(4)(vi); Prescription Drug Benefit Manual, Chapter 9; CMS guidance issued 1/11/2013

Not applicable to SAE applicants.

A. In HPMS, complete the table below:

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

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

The Part D compliance program must be in accordance with 42 CFR 423.504(b)(4)(vi). The compliance program must explicitly include the name of the applicant. (The name of a parent organization is insufficient.) The Part D compliance program must include all seven elements in the regulation and in Chapter 9 and are specific to the issues and challenges presented by the Part D program. The compliance plan must explicitly state

that it encompasses Medicare Part D. A general compliance program applicable to healthcare operations is not acceptable.

Please be advised that the applicant is ultimately responsible for the implementation and monitoring of the day-to-day operations of its Part D compliance program. 42 CFR § 423.504(b)(4)(vi)(B)(1) and section 40.1 of Chapter 9 of the Prescription Drug Benefit Manual indicates that the compliance officer and compliance committee functions may not be delegated or subcontracted. This means that the Medicare Compliance Officer identified in HPMS contacts (see section entitled HPMS Part D Contacts) must be an employee of the applicant, the applicant’s parent organization, or a corporate affiliate of the applicant. A compliance program adopted and operated by an applicant’s first tier, downstream, and related entities is not sufficient to demonstrate that the applicant meets the compliance program requirement.

C. In HPMS, complete and upload the table in Appendix XVIII for the Compliance Plan.

3.1.4 HPMS Part D Contacts CMS Guidance issued 08/16/06, 08/22/07, 11/30/07, 08/06/07, 03/17/09, 07/09/09, 08/04/09, and 01/25/10

Not applicable to SAE applicants.

A. In HPMS, in the Contract Management/Contact Information/Contact Data page provide the name/title; mailing address; phone number; fax number; and email address for the following required applicant contacts:

Note 1: The same individual should not be identified for each of these contacts. If a general phone number is given then CMS requires specific extensions for the individual identified. Under no circumstances should these numbers merely lead to a company’s general automated phone response system. Further, applicants must provide specific email addresses for the individuals named.

Note 2: Contact definitions are provided in HPMS in the Contract Management/Contact Information/Contact Data/Documentation link entitled Contact Definitions. The CEO, Chief Financial Officer, Chief Operating Officer, and Medicare Compliance Officer must be employees of the applicant, the applicant’s parent organization, or a subsidiary of the applicant’s parent organization. Please note that it is CMS’ expectation that the MA and Part D Application Contact be a direct employee of the applicant.

Contact	Name/Title	Mailing Address (PO Boxes may not be used)	Phone/Fax Numbers	Email Address
Corporate Mailing				
CEO – Sr. Official for Contracting				
Chief Financial Officer				

Medicare Compliance Officer				
Enrollment Contact				
Medicare Coordinator				
System Contact				
Customer Service Operations Contact				
General Contact				
User Access Contact				
Backup User Access Contact				
Marketing Contact				
Medical Director				
Bid Primary Contact				
Payment Contact				
Part D Claims Submission Contact				
Formulary Contact				
Pharmacy Network Management Contact				
Medication Therapy Management Contact				
Part D Benefits Contact				
Part D Quality Assurance Contact				
Part D Application Contact				
Pharmacy Director				

HIPAA Security Officer				
HIPAA Privacy Officer				
Part D Price File Contact (Primary)				
Part D Price File Contact (Back-up)				
Part D Appeals				
Government Relations Contact				
Emergency Part D Contact				
Pharmacy Technical Help Desk Contact				
Processor Contact				
CMS Casework Communication Contact				
Part D Exceptions Contact				
Coordination of Benefits Contact				
CEO – CMS Administrator Contact				
Plan to Plan Reconciliation Contact				
Bid Audit Contact				
Plan Directory Contact for Public Website				
CAP Report Contact for Public Website				
Financial Reporting Contact				

Best Available Evidence Contact				
Automated TrOOP Balance Transfer Contact				
Agent/Broker Compensation Data Contact				
Complaint Tracking Module (CTM) Contact				
Part D Reporting Requirement Contact				
Fraud Investigations Contact				
Reconciliation Contact				
DIR Contact				

B. In HPMS, complete the table below:

Applicant must attest 'yes' to the following qualification to be approved for a Part D contract. Attest 'yes' or 'no' to the following qualification by clicking on the appropriate response in HPMS:	Yes	No	Requesting a Waiver? (ONLY FOR COST AND MAPD APPLICANTS)
Applicant agrees that CMS may release contact information to States, SPAPs, providers, Part D sponsors, and others who need the contact information for legitimate purposes.			

3.2 Benefit Design

Not applicable to SAE applicants.

3.2.1 Formulary/Pharmacy and Therapeutics (P&T) Committee Social Security Act §186-D-4(b)(3)(G), 42 CFR §423.120(b), 42 CFR §423.272(b)(2); Prescription Drug Benefit Manual, Chapter 6; 2014 Call Letter; CMS issued guidance 03/25/10

A. In HPMS, complete the table below:

Applicant must attest ‘yes’ to each of the following qualifications to be approved for a Part D contract. Attest ‘yes’ or ‘no’ to each of the following qualifications by clicking on the appropriate response in HPMS:	Yes	No	Requesting a Waiver? (ONLY FOR COST AND MAPD APPLICANTS)
Applicant will submit a formulary to CMS for the Part D benefit by the date listed in section 1.3. 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.			
Applicant has reviewed, understands, and complies with formulary guidance that is contained in the Code of Federal Regulations (42 CFR §423.120(b)), Chapter 6 of the Prescription Drug Benefit Manual, the HPMS Formulary Submission Module and Reports Technical Manual, and all other formulary instructions.			
Applicant agrees, when using a formulary, to meet all formulary submission deadlines established by CMS. Applicant further agrees that CMS may discontinue its review of the applicant’s formulary submission upon the applicant’s failure to meet any of the formulary submission deadlines. Applicant acknowledges that failure to receive CMS approval of its formulary may prevent CMS from approving the applicant’s bid(s) and contracting with the applicant for the following benefit year.			

B. In HPMS, complete the table below:

<p>If applicant is intending for its Part D benefit to include the use of a formulary, then Applicant must also provide a P&T committee member list either directly or through its pharmacy benefit manager (PBM). Applicant must attest ‘yes’ or ‘no’ that it is using its PBM’s P&T committee, in order to be approved for a Part D contract. Attest ‘yes’ or ‘no’ by clicking the appropriate response in HPMS:</p>	<p>Yes</p>	<p>No/OR N/A</p>
<p>Applicant is using the P&T Committee of its PBM for purposes of the Part D benefit.</p>		
<p>If answered yes to B1, Applicant’s PBM is operating under a confidentiality agreement for purposes of the P&T Committee (meaning Applicant has no knowledge of the membership of the PBM’s P&T Committee). (If not applicable, check “NO.”) Note: If answer is YES, then applicant must complete P&T Committee Certification Statement and PBM must complete the P&T Committee Member List located in Appendix XVI entitled <i>Applicant Submission of P&T Committee Member List and Certification Statement</i>.</p>		
<p>Applicant has reviewed, understands, and complies with the requirements related to the use and development of a P&T Committee contained in the Code of Federal Regulations (42 CFR §423.120(b)(1)), Chapter 6 of the Prescription Drug Benefit Manual, the HPMS Formulary Submission Module and Reports Technical Manual, and all other guidance related to P&T committees..</p> <p>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.</p>		

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

3.2.2 Utilization Management Standards 42 CFR §423.153(b); Prescription Drug Benefit Manual, Chapter 6 and Chapter 7; 2013 Call Letter; 2014 Call Letter; 2015 Call Letter

In HPMS, complete the table below:

Applicant must attest 'yes' to the following qualification to be approved for a Part D contract. Attest 'yes' or 'no' to the following qualification by clicking on the appropriate response in HPMS:	Yes	No	Requesting a Waiver? (ONLY FOR COST AND MAPD APPLICANTS)
Applicant has reviewed, understands, and complies with utilization management requirements in 42 CFR §423.153(b), Chapters 6 and 7 of the Prescription Drug Benefit Manual, and related CMS guidance.			

3.2.3 Quality Assurance and Patient Safety Social Security Act§ 1860D-4(c)(3); 42 CFR §423.153(c); Prescription Drug Benefit Manual, Chapter 7; 2013 Call Letter; 2014 Call Letter; 2015 Call Letter

In HPMS, complete the table below:

Applicant must attest 'yes' to the following qualification to be approved for a Part D contract. Attest 'yes' or 'no' to the following qualification by clicking on the appropriate response in HPMS:	Yes	No	Requesting a Waiver? (ONLY FOR COST AND MAPD APPLICANTS)
Applicant has reviewed, understands, and complies with requirements related to quality assurance and patient safety in section 1860D-4(c)(3) of the Act, 42 CFR §423.153(c), Chapter 7 of the Prescription Drug Benefit Manual, and related CMS guidance. This includes requirements related to drug utilization review, medication error identification, and prevention of wasteful dispensing of prescription drugs.			

3.2.4 Medication Therapy Management 42 CFR §423.153(d); Social Security Act § 1860D-4(c)(2); Prescription Drug Benefit Manual, Chapter 7; 2013 Call Letter; 2014 Call Letter; 2015 Call Letter

In HPMS, complete the table below:

Applicant must attest 'yes' to each of the following qualifications to be approved for a Part D contract. Attest 'yes' or 'no' to each of the following qualifications by clicking on the appropriate response in HPMS:	Yes	No	Requesting a Waiver? (ONLY FOR COST AND MAPD APPLICANTS)
Applicant has reviewed, understands, and complies with requirements related to developing and implementing a Medication Therapy Management (MTM) program described in section 1860D-4(c)(2) of the Act, 42 CFR §423.153(d), Chapter 7 of the Prescription Drug Benefit Manual, and related guidance.			
The Applicant agrees to submit a description of its MTM program including, but not limited to, policies, procedures, services, payments and criteria used for identifying beneficiaries eligible for the MTM program. Note: Instructions to submit a description of your MTM program will be forthcoming in future guidance from CMS and this description is not due at the time of this application.			

3.2.5 Electronic Prescription Program and Health Information Technology Standards 42 CFR §423.159; Prescription Drug Benefit Manual, Chapter 7; P.L. 111-5 (2009); 2010 Call Letter

In HPMS, complete the table below:

Applicant must attest 'yes' to the following qualification to be approved for a Part D contract. Attest 'yes' or 'no' to the following qualification by clicking on the appropriate response in HPMS:	Yes	No	Requesting a Waiver? (ONLY FOR COST AND MAPD APPLICANTS)
Applicant has reviewed, understands, and complies with electronic prescription and Health Information Technology requirements contained in P.L. 111-5 (2009), 42 CFR §423.159, Chapter 7 of the Prescription Drug Benefit Manual, and all related guidance.			

3.2.6 Bids 42 CFR § 423.104, §423.265 and §423.272

Not applicable to Cost Plan applicants or employer only applicants.

In HPMS, complete the table below:

Applicant must attest 'yes' to the following qualification to be approved for a Part D contract. Attest 'yes' or 'no' to the following qualification by clicking on the appropriate response in HPMS:	Yes	No	Requesting a Waiver? (ONLY FOR MAPD APPLICANTS)
Applicant limits the number of submitted bids in a service area to those that would demonstrate meaningful differences in benefit packages or plan costs to a beneficiary.			

3.3 Service Area/Regions 42 CFR §423.112; Prescription Drug Benefit Manual, Chapter 5

Not applicable to Cost Plan applicants.

A. Complete in HPMS, in the Contract Management/Contract Service Area/Service Area Data page, the service area information indicating the regions (including territories) you plan to serve. PDP and MA-PD region and Territory information may be found on the www.cms.gov/ website. Be sure to list both the region/territory name and associated number. Note: CMS bases its pharmacy network analyses on the service area your organization inputs into HPMS. Please make sure that the service area information you input into HPMS corresponds to the pharmacy lists that are provided under the Pharmacy Access section of the application.

B. In HPMS, complete the table below. Only applicants for new PDPs or new RPPOs should complete this table.

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 a Waiver? (Only for RPPO applicants)
For all regions in which the applicant offers a prescription drug plan, the applicant provides coverage in the entire region. (Only PDP applicants will complete this attestation.)			
Applicant offers Part D coverage for the entire MA region(s) to be operated under the Regional PPO plan. (Only RPPO applicants will complete this attestation.)			

3.4 Private Fee-For-Service Pharmacy Access 42 CFR §423.120(a)(7); Prescription Drug Benefit Manual, Chapter 5

In HPMS, complete the table below **ONLY** if you are a Private Fee For Service applicant, including both initial applications and SAEs. Otherwise, proceed directly to General Pharmacy Access.

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
Applicant uses a contracted network of pharmacies and therefore meets the retail pharmacy convenient access standards; LTC and I/T/U pharmacy convenient access standards; and home infusion pharmacy adequate access standards.			
If applicant attests 'NO' to 3.4.1, applicant has reviewed, understands, and complies with requirements related to coverage of prescription drugs for PFFS plans that do not utilize contracted pharmacy networks. These requirements are found in 42 CFR §423.120(a)(7), Chapter 5 of the Prescription Drug Benefit Manual, and related guidance.			

If applicant attests No to 3.4 1, and Yes to 3.4 2, applicant may move directly to Section 3.6 and will be granted a waiver of convenient access.

3.5 General Pharmacy Access 42 CFR §423.120(a); Prescription Drug Benefit Manual, Chapter 5

Not applicable for SAE applicants.

A. In HPMS, complete the table below:

Applicant must attest 'yes' to each of the following qualifications to be approved for a Part D contract. Attest 'Yes' or 'No' to each of the following qualifications by clicking on the appropriate response in HPMS:	Yes	No	Requesting a Waiver? (ONLY FOR COST AND MAPD APPLICANTS)
Applicant has reviewed, understands, and complies with requirements related to pharmacy access and contracting contained in 42 CFR §423.120(a), Chapter 5 of the Prescription Drug Benefit Manual, and related guidance.			

Applicant agrees to notify CMS when the applicant changes its pharmacy benefit manager.			
Applicant agrees to notify CMS about any substantive change in its pharmacy network that may impact its ability to maintain a Part D pharmacy network that meets CMS' requirements.			

B. Upload in HPMS a contract template in .pdf format for each for the following types of pharmacies: Retail, Mail Order, Home Infusion, Long-Term Care and I/T/U. The mail order contract template is only necessary if the plan is offering mail order. The I/T/U template is only necessary if the Applicant's service area includes states in which I/T/U pharmacies reside. If Applicant has contracted with a Pharmacy Benefit Manager to provide a pharmacy network, those downstream contract templates must also be uploaded. If there are several different types of standard terms and conditions for the same type of pharmacy, please provide a contract template for all versions and label according to type of pharmacy. For example, if different terms for retail pharmacies apply depending upon geographic location, a separate template representing each variation must be provided. Each contract template type must contain the unsigned standard terms and conditions, including the provisions listed in the Appendices entitled:

- Crosswalk for Retail Pharmacy Contracts
- Crosswalk for Mail Order Pharmacy Contracts
- Crosswalk for Home Infusion Pharmacy Access Contracts
- Crosswalk for Long-Term Care Pharmacy Access Contracts
- Crosswalk for I/T/U Pharmacy Access Contracts.

C. Upload in HPMS crosswalks of the Pharmacy Access Contract Citations [for Retail, Mail Order (if offered), Home Infusion, Long-Term Care and I/T/U Pharmacy networks] demonstrating that all applicable requirements are included in such contracts. Submit this data by downloading the Microsoft Excel worksheets from HPMS that are located on the Pharmacy Upload page, complete the worksheets and upload the finished document back into HPMS for each of the Appendices entitled:

- Crosswalk for Retail Pharmacy Contracts
- Crosswalk for Mail Order Pharmacy Contracts
- Crosswalk for Home-Infusion Pharmacy Access Contracts
- Crosswalk for Long-Term Care Pharmacy Access Contracts
- Crosswalk for I/T/U Pharmacy Access Contracts.

3.6 Retail Pharmacy 42 CFR §423.120(a); 42 CFR §423.859(c); Prescription Drug Benefit Manual, Chapter 5

A. In HPMS, complete the table below:

Applicant must attest ‘yes’ to each of the following qualifications to be approved for a Part D contract. Attest ‘yes’ or ‘no’ to each of the following qualifications by clicking on the appropriate response in HPMS:	Yes	No
Applicant has reviewed, understands, and complies with all requirements related to retail pharmacy access contained in 42 CFR §§423.120(a) & 423.859(c), Chapter 5 of the Prescription Drug Benefit Manual, and related guidance.		
Applicant is requesting a waiver of convenient access requirements (only applicable for MAPD and Cost Plan applicants). If “yes”, complete parts E and F, below.		
Applicant is requesting a waiver of any willing pharmacy requirements (only applicable for MAPD and Cost Plan applicants). If “yes”, complete part G, below.		

B. Upload in HPMS the Retail Pharmacy List (not applicable to Employer/Union Only Group Waiver Plan SAE applicants):

To submit retail pharmacy listings to CMS, applicants must download the Microsoft Excel worksheet from HPMS that is located specifically on the Pharmacy Upload page, complete the worksheet and upload the finished document back into HPMS.

C. Submission of Supporting Discussion in Areas Failing to Meet Access Standards (not applicable to Employer/Union Only Group Waiver Plan SAE applicants)

CMS will consider supporting discussion provided by an applicant in evaluating the applicant’s application to determine if applicant is qualified to be a Part D Sponsor. While you have the opportunity to provide this discussion, CMS’ expectation is that your organization will meet the required access standards in all cases. Providing the discussion below does not mean CMS will allow you to fail the access standards, but in extreme or unusual circumstances, we may consider this information.

Provide as an upload in HPMS, in .pdf format, the following information to demonstrate that meeting the access standard within the service area is not practical or is impossible.

1. Indicate the geographic areas in which the applicant cannot demonstrate that it meets the retail pharmacy convenient access standards
2. Explain why these standards cannot be met. Include in the discussion relevant information such as geographic barriers, pharmacy infrastructure barriers, and/or market barriers.

- Describe how the pharmacies in the applicant’s retail contracted network will provide access to all eligible Part D individuals enrolled in the applicant’s plan(s) in each of the geographic areas defined in item 1 above.

D. In HPMS, indicate whether you are seeking a waiver of the convenient access standards for the territories in which your organization intends to offer the Part D benefit. If your organization is not intending to offer the Part D benefit in the territories check N/A within HPMS. (Not applicable to Employer/Union Only Group Waiver Plan SAE applicants.)

Request for a Waiver of Convenient Access Standards for the Territories	Yes	No	N/A
Region 35 – American Samoa			
Region 36 – Guam			
Region 37 – Northern Mariana Islands			
Region 39 – US Virgin Islands			

E. Complete the following if you marked YES to requesting a waiver of convenient access standards for any of the territories in 3.4.1D. In HPMS, in .pdf format, provide the following information (not applicable to Employer/Union Only Group Waiver Plan SAE applicants):

- Explain why your organization cannot demonstrate compliance with the access standards or why these standards cannot be met.
- Describe the applicant’s efforts to identify and contract with all of the retail pharmacies in each of the applicable territories.
- Describe how the pharmacies in the applicant’s contracted network demonstrate convenient access to all eligible Part D individuals enrolled in the applicant’s plan(s) in each of the territories listed above as not meeting the standards in §423.120(a)(1).

F. If you marked YES to requesting a waiver of convenient access standards for any of the territories in 3.4.1D, in HPMS complete the table below (not applicable to PDP and Employer/Union Only Group Waiver Plan SAE applicants):

Waiver of Retail Convenient Access Standards for MA-PDs	
Provide the number of prescriptions provided in 2013 by retail pharmacies owned and operated by applicant.	
Provide the number of prescriptions provided in 2013 at all retail pharmacies contracted by applicant.	

NOTE: CMS will determine the percentage of prescriptions provided at retail pharmacies owned and operated by applicant over total prescriptions provided at all retail pharmacies contracted by applicant.

G. If you marked “YES” to requesting a waiver of any willing pharmacy requirements, in HPMS complete the table below (not applicable to PDP applicants and Employer/Union Only Group Waiver Plan SAE applicants):

Waiver of Any Willing Pharmacy Requirements for MA-PDs	
Provide the number of prescriptions provided in 2013 by all pharmacies owned and operated by applicant.	
Provide the number of prescriptions provided in 2013 at all pharmacies contracted by applicant.	

NOTE: CMS will determine the percentage of prescriptions provided at all pharmacies owned and operated by applicant over total prescriptions provided at all pharmacies contracted by applicant.

3.7 Out of Network Access 42 CFR §423.124; Prescription Drug Benefit Manual, Chapter 5

Not applicable to SAE applicants.

In HPMS, complete the table below:

Applicant must attest ‘yes’ to the following qualification to be approved for a Part D contract. Attest ‘yes’ or ‘no’ to the following qualification by clicking on the appropriate response in HPMS:	Yes	No	Requesting a Waiver? (ONLY FOR COST AND MAPD APPLICANTS)
Applicant has reviewed, understands, and complies with requirements related to access to drugs at out-of-network pharmacies contained in 42 CFR §423.124, Chapter 5 of the Prescription Drug Benefit Manual, and related guidance.			

3.8 Mail Order Pharmacy 42 CFR §423.120(a)(10); Prescription Drug Benefit Manual, Chapter 5; 2014 Call Letter

A. In HPMS, complete the table below:

Applicants may offer a mail order option in addition to their contracted Part D pharmacy network but mail order pharmacies do not count in meeting network adequacy standards. Indicate in HPMS ‘yes’ or ‘no’ whether such mail order pharmacy is offered.	Yes	No
Applicant offers mail order pharmacy as part of its Part D plans.		

B. Mail Order Pharmacy List (not applicable to EGWP-only service area/coverage expansion applicants):

To submit mail order pharmacy lists to CMS, applicants must download the Microsoft Excel worksheet from HPMS that is located on the Pharmacy Upload page, complete the worksheet, and upload the finished document back into HPMS.

3.9 Home Infusion Pharmacy 42 CFR §423.120(a)(4); Prescription Drug Benefit Manual, Chapter 5

Home Infusion Pharmacy List (not applicable to EGWP-only service area/coverage expansion applicants):

To submit home infusion pharmacy listings to CMS, applicants must download the Microsoft Excel worksheet template from HPMS that is located on the Pharmacy Upload page, complete the worksheet, and upload the finished document back into HPMS.

3.10 Long -Term Care (LTC) Pharmacy 42 CFR §423.120(a)(5); Prescription Drug Benefit Manual, Chapter 5; CMS issued guidance 04/28/09

A. In HPMS, complete the table below:

Applicant must attest 'yes' to each of the following qualifications to be approved for a Part D contract. Attest 'yes' or 'no' to each of the following qualifications by clicking on the appropriate response in HPMS:	Yes	No	Requesting a Waiver? (ONLY FOR COST AND MAPD APPLICANTS)
Applicant offers standard contracting terms and conditions to all long-term care pharmacies in its service area. These terms and conditions must include all the performance and service criteria for long-term care pharmacies that are cited in section 50.5.2 of Chapter 5 of the Prescription Drug Benefit Manual.			
Applicant has reviewed, understands, and complies with requirements related to long term care pharmacy access and contracting contained in 42 CFR §423.120(a)5), Chapter 5 of the Prescription Drug Benefit Manual, and all related guidance.			

<p>Applicant readily negotiates with States with regard to contracting with State-run and operated LTC pharmacies in facilities such as ICFs/MR, IMDs, and LTC hospitals. States may not be able to agree to certain clauses in some LTC standard contracts because of constitutional and legal restraints. Applicants should be prepared to negotiate with States to address these issues.</p>			
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B. LTC Pharmacy List (not applicable to EGWP-only service area/coverage expansion applicants)

To submit LTC pharmacy listings to CMS, applicants must download the Microsoft Excel worksheet template from HPMS that is located on the Pharmacy Upload page, complete the worksheet and upload the finished document back into HPMS.

3.11 Indian Health Service, Indian Tribe and Tribal Organization, and Urban Indian Organization (I/T/U) Pharmacy 42 CFR §423.120(a)(6); Prescription Drug Benefit Manual, Chapter 5

A. In HPMS, complete the table below:

<p>Not all Part D regions have I/T/U pharmacies. If the Applicant’s service area covers <u>any</u> region that includes I/T/U pharmacies, then the Applicant must attest ‘yes’ to the following qualifications to be approved for a Part D contract. To determine if I/T/U pharmacies reside in your service area, review the I/T/U reference file located on the CMS webpage: www.cms.gov/prescriptiondrugcovcontra/ ITU LTC HI Reference Files”. Attest ‘yes,’ ‘no’ or ‘n/a’ to the following qualification by clicking on the appropriate response in HPMS:</p>	Ye s	No	N/A
<p>Applicant has reviewed, understands, and complies with requirements related to I/T/U access and contracting contained in 42 CFR §423.120(a)(6), Chapter 5 of the Prescription Drug Benefit Manual, and all related guidance.</p>			

B. I/T/U Pharmacy List (not applicable to EGWP-only service area/coverage expansion applicants):

In order to demonstrate that a Part D applicant meets these requirements, applicants must submit a complete list of all I/T/U pharmacies to which it has offered contracts. CMS provides the current list of I/T/U pharmacies, including the official name, address, and provider number (when applicable). The applicant’s list must be submitted using the Microsoft Excel template provided by CMS on the HPMS Pharmacy Upload page, and must include all I/T/U pharmacies residing in any and all states within its service area.

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

3.12 Specialty Pharmacy Prescription Drug Benefit Manual, Chapter 5

Not applicable to SAE applicants.

In HPMS, complete the table below.

Applicant must attest 'yes' to the following qualification to be approved for a Part D contract. Attest 'yes' or 'no' to the following qualification by clicking on the appropriate response in HPMS:	Yes	No	Requesting a Waiver? (ONLY FOR COST AND MAPD APPLICANTS)
Applicant has reviewed, understands, and complies with all requirements related to specialty pharmacies contained in Chapter 5 of the Prescription Drug Benefit Manual and all related guidance.			

3.13 Enrollment and Eligibility 42 CFR §423.30; Prescription Drug Benefit Manual, Chapters 3, 4, and 13; Plan Communications User Guide; CMS issued guidance 07/21/09

Not applicable to SAE applicants.

In HPMS, complete the table below:

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

3.14 Complaints Tracking Prescription Drug Benefit Manual, Chapter 7; CMS issued guidance 11/16/06, 07/28/2008, 12/09/08, and 6/8/12

Not applicable to SAE applicants.

In HPMS, complete the table below:

Applicant must attest ‘yes’ to each of the following qualifications to be approved for a Part D contract. Attest ‘yes’ or ‘no’ to each of the following qualifications by clicking on the appropriate response in HPMS:	Yes	No	Requesting a Waiver? (ONLY FOR COST AND MAPD APPLICANTS)
Applicant has reviewed, understands, and complies with all requirements related to complaints tracking and resolution contained in Chapter 7 of the Prescription Drug Benefit Manual and all related guidance.			

3.15 Medicare Plan Finder Prescription Drug Benefit Manual, Chapter 7; CMS issued guidance 07/17/06, 11/20/07, 08/21/08, 05/20/10

Not applicable to SAE applicants.

In HPMS, complete the table below:

Applicant must attest ‘yes’ to the following qualification to be approved for a Part D contract. Attest ‘yes’ or ‘no’ to the following qualification by clicking on the appropriate response in HPMS:	Yes	No	Requesting a Waiver? (ONLY FOR COST AND MAPD APPLICANTS)
Applicant has reviewed, understands, and complies with all requirements related to data submission and quality assurance for Medicare Plan Finder data contained in Chapter 7 of the Prescription Drug Benefit Manual and all related guidance.			

3.16 Grievances 42 CFR Part 423 Subpart M; Prescription Drug Benefit Manual, Chapter 18

Not applicable to SAE applicants.

In HPMS, complete the table below:

Applicant must attest ‘yes’ to the following qualification to be approved for a Part D contract. Attest ‘yes’ or ‘no’ to the following qualification by clicking on the appropriate response in HPMS:	Yes	No	Requesting a Waiver? (ONLY FOR COST AND MAPD APPLICANTS)
Applicant has reviewed, understands, and complies with all requirements related to beneficiary grievances contained in 42 CFR Part 423 Subpart M, Chapter 18 of the Prescription Drug Benefit Manual, and all related guidance.			

3.17 Coverage Determinations (including Exceptions) and Appeals 42 CFR Part 423 Subpart M; Prescription Drug Benefit Manual, Chapter 18; Part D QIC Reconsideration Procedures Manual

Not applicable to SAE applicants.

In HPMS, complete the table below:

Applicant must attest ‘yes’ to the following qualification to be approved for a Part D contract. Attest ‘yes’ or ‘no’ to the following qualification by clicking on the appropriate response in HPMS:	Yes	No	Requesting a Waiver? (ONLY FOR COST AND MAPD APPLICANTS)
Applicant has reviewed, understands, and complies with requirements related to beneficiary coverage determinations (including exceptions) and appeals contained in 42 CFR Part 423 subparts M & U, Chapter 18 of the Prescription Drug Benefit Manual, the Part D QIC Reconsiderations Procedures Manual, and all related guidance.			

3.18 Coordination of Benefits 42 CFR Part 423 Subpart J; Prescription Drug Benefit Manual, Chapter 14; 2015 Call Letter

Not applicable to SAE applicants.

In HPMS, complete the table below:

Applicant must attest ‘yes’ to the following qualification to be approved for a Part D contract. Attest ‘yes’ or ‘no’ to the following qualification by clicking on the appropriate response in HPMS:	Yes	No	Requesting a Waiver? (ONLY FOR COST AND MAPD APPLICANTS)
Applicant has reviewed, understands, and complies with requirements related to coordination of benefits contained in 42 CFR Part 423 Subpart J, Chapter 14 of the Prescription Drug Benefit Manual, and related guidance.			

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

Not applicable to SAE applicants.

In HPMS, complete the table below:

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

NOTE: For information regarding the TrOOP facilitator, Applicant may link to <https://medifacd.ndchealth.com/>

3.20 Medicare Secondary Payer 42 CFR §423.462; Prescription Drug Benefit Manual, Chapter 14; CMS issued guidance 4/23/2013

Not applicable to SAE applicants.

In HPMS, complete the table below:

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

3.21 Marketing/Beneficiary Communications 42 CFR §423.128; 42 CFR §423.505; Prescription Drug Benefit Manual, Chapter 2

Not applicable to SAE applicants.

In HPMS, complete the table below:

Applicant must attest ‘yes’ to the following qualification to be approved for a Part D contract. Attest ‘yes’ or ‘no’ to the following qualification by clicking on the appropriate response in HPMS:	Yes	No	Requesting a Waiver? (ONLY FOR COST AND MAPD APPLICANTS)
Applicant has reviewed, understands, and complies with all requirements related to marketing and beneficiary communications, including those contained in 42 CFR §§423.128 & 423.505, Chapter 2 of the Prescription Drug Benefit Manual, and all related guidance.			

3.22 Provider Communications Prescription Drug Benefit Manual, Chapter 2

Not applicable to SAE applicants.

In HPMS, complete the table below:

Applicant must attest 'yes' to the following qualification to be approved for a Part D contract. Attest 'yes' or 'no' to the following qualification by clicking on the appropriate response in HPMS:	Yes	No	Requesting a Waiver? (ONLY FOR COST AND MAPD APPLICANTS)
Applicant has reviewed, understands, and complies with all requirements related to provider communications, including those contained in Chapter 2 of the Prescription Drug Benefit Manual and all related guidance.			

3.23 Reporting Requirements Social Security Act § 1150A; 42 CFR §423.514; 2012 Reporting Requirements

Not applicable to SAE applicants.

In HPMS, complete the table below:

Applicant must attest 'yes' to each of the following qualifications to be approved for a Part D contract. Attest 'yes' or 'no' to each of the following qualifications by clicking on the appropriate response in HPMS:	Yes	No	Requesting a Waiver? (ONLY FOR COST AND MAPD APPLICANTS)
Reporting Requirements Guidance			
Applicant has reviewed, understands, and complies with the Reporting Requirements Guidance that is posted on the http://www.cms.gov/ website.			
Business Transactions and Financial Requirements			
Applicant has reviewed, understands, and complies with requirements for reporting financial and business transaction information to CMS, including those contained in 42 CFR §§423.514(b) & 423.501.			
PBM Transparency			
The applicant's PBM provides information related to PBM transparency as specified in section 1150A of the Act.			

3.24 Data Exchange between Part D Sponsor and CMS 42 CFR §423.505(c) and (k)

Not applicable to SAE applicants.

In HPMS, complete the table below:

Applicant must attest 'yes' to each of the following qualifications to be approved for a Part D contract. Attest 'yes' or 'no' to each of the following qualifications by clicking on the appropriate response in HPMS:	Yes	No	Requesting a Waiver? (ONLY FOR COST AND MAPD APPLICANTS)
HPMS			
Applicant uses HPMS to communicate with CMS in support of the application process, formulary submission process, bid submission process, ongoing operations of the Part D program, and reporting and oversight activities. Part D sponsors are required to secure access to HPMS in order to carry out these functions.			
Enrollment & Payment			
Applicant establishes connectivity to CMS as noted in the instructions provided by the MAPD Help Desk at 1-800-927-8069 or via the MAPD HelpDesk webpage, www.cms.gov/mapdhelpdesk , in the Plan Reference Guide for CMS Part C/D Systems link.			
Applicant has reviewed, understands, and complies with all requirements related to data exchange between sponsors and CMS, including those contained in 42 CFR §423.505(c) & (k).			
In accordance with 42 CFR §423.322, the Applicant provides CMS with any data required to ensure accurate prospective, interim, and/or final reconciled payments including, but not limited to, the following: test data, Prescription Drug Event (PDE) records, enrollment transactions, Direct and Indirect Remuneration (DIR) data, discrepancy records, and premium payment data.			

3.25 Health Insurance Portability and Accountability Act of 1996 (HIPAA), Health Information Technology for Economic and Clinical Health Act (HITECH Act), and Related CMS Requirements 45 CFR Parts 160, 162, and 164; CMS issued guidance 08/15/2006 and 08/26/08

Not applicable to SAE applicants.

In HPMS, complete the table below:

Applicant must attest ‘yes’ to each of the following qualifications to be approved for a Part D contract. Attest ‘yes’ or ‘no’ to each of the following qualifications by clicking on the appropriate response in HPMS:	Yes	No	Requesting a Waiver? (ONLY FOR COST AND MAPD APPLICANTS)
Applicant has reviewed, understands, and complies with all applicable standards, implementation specifications, and requirements in the Standards for Privacy of Individually Identifiable Health Information and Security Standards, Standards for Electronic Transactions, and the Standard Unique Health Identifier for Health Care Providers under 45 CFR Parts 160, 162, and 164.			
Applicant transmits payment and remittance advice consistent with the HIPAA-adopted ACS X12N 835, Version 5010: Health Care Claim Payment and Remittance Advice Implementation Guide (“835”).			
Applicant has reviewed, understands, and complies with the Offshore Subcontractor requirements, and as applicable, submits the Offshore Subcontract Information and Attestation via HPMS for each offshore subcontractor (first tier, downstream and related entities) (including downstream offshore subcontractors’ first tier, downstream and related entities) that receive, process, transfer, handle, store, or access Medicare beneficiary protected health information (PHI) by the last Friday in September for the upcoming contract year.			

3.26 Prohibition on Use of SSN or Medicare ID number on Enrollee ID Cards Prescription Drug Benefit Manual, Chapter 2

Not applicable to SAE applicants.

In HPMS, complete the table below:

Applicant must attest ‘yes’ to the following qualification to be approved for a Part D contract. Attest ‘yes’ or ‘no’ to the following qualification by clicking on the appropriate response in HPMS:	Yes	No	Requesting a Waiver? (ONLY FOR COST AND MAPD APPLICANTS)
Applicant does not use an enrollee’s Social Security Number (SSN) or Medicare ID Number on the enrollee’s identification card.			

3.27 Record Retention 42 CFR §423.505(d)

Not applicable to SAE applicants.

In HPMS, complete the table below:

Applicant must attest ‘yes’ to the following qualification to be approved for a Part D contract. Attest ‘yes’ or ‘no’ to the following qualification by clicking on the appropriate response in HPMS:	Yes	No	Requesting a Waiver? (ONLY FOR COST AND MAPD APPLICANTS)
The applicant maintains, and requires its first tier, downstream, and related entities to maintain, books, records, documents, and other evidence of accounting procedures and practices consistent with 42 CFR §423.505(d).			

3.28 Prescription Drug Event (PDE) Records; 42 CFR Part 423 Subpart G; CMS issued guidance 04/27/2006, 06/23/2006, 12/17/2010, 03/01/2011, 03/04/2011, 04/28/2011, 05/16/2011, 2/4/2013

Not applicable to SAE applicants.

In HPMS, complete the table below:

Applicant must attest ‘yes’ to each of the following qualifications to be approved for a Part D contract. Attest ‘yes’ or ‘no’ to each of the following qualifications by clicking on the appropriate response in HPMS:	Yes	No	Requesting a Waiver? (ONLY FOR COST AND MAPD APPLICANTS)
Applicant has reviewed, understands, and complies with CMS requirements and guidance related to submission of PDE data, including 42 CFR Part 423 Subpart G, the Regional Prescription Drug Event Data Participant Training Guide and Technical Assistance Resource Guides under the link, USERGROUP/technical Assistance (www.csscooperations.com/) and related guidance.			
Applicant meets all data submission deadlines.			
Applicant pays all Plan-to-Plan payables on time.			
Applicant complies with Medicare Coverage Gap Discount Program requirements.			

3.29 Claims Processing; 42 CFR §423.120(c)(4); 42 CFR §423.466; CMS issued guidance 04/26/2006, 01/13/2010, and 03/29/2010

Not applicable to SAE applicants.

In HPMS, complete the table below:

Applicant must attest ‘yes’ to the following qualification to be approved for a Part D contract. Attest ‘yes’ or ‘no’ to the following qualification by clicking on the appropriate response in HPMS:	Yes	No	Requesting a Waiver? (ONLY FOR COST AND MAPD APPLICANTS)
Applicant has reviewed, understands, and complies with all requirements related to processing of electronic and paper claims contained in 42 CFR §§423.120(c)(4), 423.466, & 423.520 and all related CMS guidance.			

**3.30 Premium Billing 42 CFR §423.293; CMS issued guidance
03/08/2007**

Not applicable to SAE applicants.

In HPMS, complete the table below:

Applicant must attest ‘yes’ to the following qualification to be approved for a Part D contract. Attest ‘yes’ or ‘no’ to the following qualification by clicking on the appropriate response in HPMS:	Yes	No	Requesting a Waiver? (ONLY FOR COST AND MAPD APPLICANTS)
Applicant has reviewed, understands, and complies with all requirements related to accurate premium billing, including 42 CFR §423.293 and all related guidance.			

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

Not applicable to SAE applicants.

In HPMS, complete the table below:

Applicant must attest ‘yes’ to each of the following qualifications to be approved for a Part D contract. Attest ‘yes’ or ‘no’ to each of the following qualifications by clicking on the appropriate response in HPMS:	Yes	No	Requesting a Waiver? (ONLY FOR COST AND MAPD APPLICANTS)
Applicant agrees once its enrollment is more than 600 enrollees (as of July in the preceding contract year), it will contract with an approved CAHPS survey vendor and pay for the CAHPS data collection costs.			
Applicant agrees to abide by CMS guidance on contracting with approved CAHPS survey vendors.			

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

4 CERTIFICATION

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

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

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

5 APPENDICES

APPENDIX I – Summary of Medicare Part D Regulatory Requirements Fulfilled under Part C for Medicare Advantage Prescription Drug (MA-PD) Applicants

Part D Regulation	Regulatory Requirement(s) Description	Basis for Waiver
42 CFR 423 Subpart I, excepting 42 CFR §423.440 (which concerns Federal preemption of State law and prohibition of State premium taxes)	Licensure and Solvency – Applicant must be licensed to bear risk in the State in which it intends to operate or apply for a licensure waiver and meet CMS solvency standards.	Duplicative of MA Organization requirements for licensure and solvency under 42 CFR §422.400; and 42 CFR §422.501.
42 CFR §423.153(b) Waiver applies to MA-PFFS only	Utilization Management - Applicant must have a cost effective utilization management system.	Waiver stated in regulations at 42 CFR §423.153(e) excuses MA PFFS organizations from meeting the utilization management requirements specified in 42 CFR §423.153(b).
42 CFR §423.153(d) Waiver applies to MA-PFFS only	Medication Therapy Management Program – Applicant must have a program to manage medication therapy to optimize outcomes, reduce adverse drug interactions.	Waiver stated in regulations at 42 CFR §423.153(e) excuses MA PFFS organizations from meeting Medication Therapy Management Program requirements specified in 42 CFR §423.153(d).
42 CFR §423.112(a)	Service Area – Applicant must offer a Part D plan that serves at least an entire PDP region.	Conflicts with MA regulations (42 CFR § 422.2) that allow MA organizations to offer local MA plans (i.e., plans that serve less than an entire state).
42 CFR §423.120(a)(7)(i) Waiver applies only to MA-PDs that operate their own pharmacies	Pharmacy Network – Applicant must offer its Part D plan benefit through a contracted retail pharmacy network that meets CMS convenient access standards.	Waiver stated in regulations at 42 CFR § 423.120(a)(7)(i) excuses from the Part D convenient access standards those MA organizations that administer their Part D benefit through pharmacies owned and operated by the MA organization if that organization’s pharmacy network access meets the MA convenient access standards.

Part D Regulation	Regulatory Requirement(s) Description	Basis for Waiver
<p>42 CFR §423.120(a)(7)(ii)</p> <p>Waiver applies to MA-PFFS plan that provides access through all pharmacies.</p>	<p>Pharmacy Network – Applicant must offer its Part D plan benefit through a contracted retail pharmacy network that meets CMS convenient access standards</p>	<p>Waiver stated in regulations at 42 CFR §423.120(a)(7)(ii). excuses from the Part D convenient access standards those MA-PFFS organizations that offer a qualified prescription drug coverage, and provide plan enrollees with access to covered Part D drugs dispensed at all pharmacies, without regard to whether they are contracted network pharmacies and without charging cost-sharing in excess of the requirements for qualified prescription drug coverage.</p>
<p>42 CFR §423.120(a)(8)(i)</p> <p>Waiver applies only to MA-PDs that operate their own pharmacies</p>	<p>Pharmacy Network – Applicant must offer its Part D benefit through any willing pharmacy that agrees to meet reasonable and relevant standard network terms and conditions.</p>	<p>Waiver promotes the coordination of Parts C and D benefits. Excuses from Part D any-willing-pharmacy requirement those MA organizations that administer their Part D benefit through pharmacies owned and operated by the MA organization and dispense at least 98% of all prescriptions through pharmacies owned and operated by Applicant.</p>
<p>42 CFR §423.34 42 CFR §423.36 42 CFR §423.38 42 CFR §423.40 42 CFR §423.44</p>	<p>Enrollment and Eligibility – Applicant agrees to accept Part D plan enrollments and determine Part D plan eligibility consistent with Part D program requirements.</p>	<p>Duplicative of MA requirements under 42 CFR §422 Subpart B - Eligibility, Election, and Enrollment. MA organizations will conduct enrollment and determine eligibility consistent with MA program requirements. These requirements mirror those stated in the Part D regulation.</p>
<p>42 CFR §423.514(b) and (c)</p>	<p>Reporting Requirements – Applicant must report information concerning significant business transactions.</p>	<p>Duplicative of MA requirements for reporting significant transactions under 42 CFR §422.500 and 42 CFR §422.516(b) and (c) and requirements for providing annual financial statements.</p>
<p>42 CFR §423.514(e)</p>	<p>Reporting Requirements – Applicant must notify CMS of any loans or any other special arrangements it makes with contractors, subcontractors, and related entities.</p>	<p>Duplicative of MA requirement for reporting loans or special arrangements under 42 CFR §422.516(e).</p>

Part D Regulation	Regulatory Requirement(s) Description	Basis for Waiver
42 CFR §423.512	Experience and Capabilities – Applicant must reach the minimum enrollment standard within the first year it offers a Part D benefit.	Conflicts with MA regulation at 42 CFR §422.514 that permits three years to achieve the minimum enrollment level.

APPENDIX II – Summary of PDP Application Requirements Fulfilled under Part C for Cost Plan Prescription Drug Applicants

Part D Regulation	Regulatory Requirement(s) Description	Basis for Waiver
<p>42 CFR 423 Subpart I, excepting 42 CFR §423.440 (which concerns Federal preemption of State law and prohibition of State premium taxes)</p>	<p>Licensure and Solvency – Applicant must be licensed to bear risk in the State in which it intends to operate or apply for a licensure waiver and meet CMS solvency standards.</p>	<p>Duplicative of Cost Plan requirements for licensure and solvency under 42 CFR §417.404 (General requirements) and 42 CFR §417.407 (Requirements for a Competitive Medical Plan (CMP)). All Cost Plans are State licensed in some manner or have authority to offer a Cost Plan in all states in which they operate.</p>
<p>42 CFR §423.112(a)</p>	<p>Service Area – Applicant must offer a Part D plan that serves at least an entire PDP region.</p>	<p>Conflicts with Cost Plan regulations (42 CFR §417.1) defining the service area for HMOs and CMPs offering Medicare reasonable Cost Plans.</p>
<p>42 CFR §423.120(a)(3) <i>Waiver applies only to Cost contractors that operate their own pharmacies</i></p>	<p>Pharmacy Network – Applicant must offer its Part D plan benefit through a contracted retail pharmacy network that meets CMS standards for convenient access.</p>	<p>Waiver stated in regulations at 42 CFR §423.120(a)(7)(i) excuses from the Part D standards for convenient access those Cost contractors that administer their Part D benefit through pharmacies owned and operated by the Cost contractor if that organization’s pharmacy network access meets the Cost Plan convenient access standards . <i>{Note: Applicants will be expected to provide comparable information in the application for organizational pharmacies}</i></p>
<p>42 CFR §423.120(a)(8)(i) <i>Waiver applies only to Cost contractors that operate their own pharmacies</i></p>	<p>Pharmacy Network – Applicant must offer its Part D benefit through any willing pharmacy that agrees to meet reasonable and relevant standard network terms and conditions.</p>	<p>Waiver promotes the coordination of Parts C and D benefits. Excuses from Part D any-willing-pharmacy requirement those Cost contractors that administer their Part D benefit through pharmacies owned and operated by the Cost contractor and dispense at least 98% of all prescriptions through pharmacies owned and operated by Applicant.</p>

APPENDIX III – Attestation for Employer/Union-Only Group Waiver Plans (800-Series)

DESIGNATION OF APPLICATION AS “800 SERIES” EGWP ONLY (NO INDIVIDUAL PLANS WILL BE OFFERED)

Checking the box below is optional. Only check the box below if you are applying to only offer “800 series” plans under this contract (no plans to individual beneficiaries will be offered). Do not check the box below if you intend to offer plans to individual beneficiaries and “800 series” plans under this contract number.

I am hereby designating this application as one which will only offer “800 series” plans. No plans will be offered to individual Medicare beneficiaries under this contract number.

{Entity MUST complete if it is applying to only offer “800 series” EGWPs (no plans will be offered to individual Medicare beneficiaries under this contract number).}

EGWP Attestation for Contract _____

1. EGWP SERVICE AREA & PHARMACY ACCESS REQUIREMENTS

PDP Sponsor Applicants may provide coverage to employer group members wherever they reside (i.e., nationwide). However, in order to provide coverage to retirees wherever they reside, PDP Sponsor Applicants must set their service areas to include all areas where retirees may reside during the plan year (i.e., set national service areas).

New PDP Sponsors Offering Individual and “800 Series” Plans – Pharmacy Access:

PDP Sponsors will not initially be required to have retail and other pharmacy networks in place for those designated EGWP service areas outside of their individual plan service areas. However, in accordance with employer group waiver pharmacy access policy, pharmacy access sufficient to meet the needs of enrollees must be in place once the PDP Sponsor enrolls members of an employer or union group residing in particular geographic locations outside of its individual plan service area.

New PDP Sponsors Only Offering “800 Series” Plans – Pharmacy Access:

PDP Sponsors only offering “800 series” plans (i.e., no plans will be offered to individual Medicare beneficiaries under this contract number) will be required to submit retail and other pharmacy access information (mail order, home infusion, long-term care, I/T/U) for the entire defined EGWP service area during the application process and demonstrate sufficient access in these areas in accordance with employer group waiver pharmacy access policy.

I certify that I am an authorized representative, officer, chief executive officer, or general partner of the business organization that is applying for qualification to offer employer/union-only group waiver plans in association with my organization’s Prescription Drug Plan Contract with CMS. I have read, understand, and agree to comply with the above statement about service areas and pharmacy access. If I need further information, I will contact one of the individuals listed in the instructions for this application.

{Entity MUST complete for a complete application.}

2. CERTIFICATION

This appendix, along with the underlying solicitation to which it is appended, comprises the entire “800 series” EGWP application for PDP Sponsor. All provisions of the solicitation apply to all employer/union-only group waiver plan benefit packages offered by PDP Sponsor except where the provisions are specifically modified and/or superseded by particular employer/union-only group waiver guidance, including those waivers/modifications set forth below (specific sections of the solicitation that have been waived or modified for new PDP Sponsor Applicants are noted in parentheses).

For existing PDP Sponsors, this appendix comprises the entire “800 series” EGWP application for PDP Sponsor. All provisions of the PDP Sponsor’s existing contract with CMS apply to all employer/union-group waiver plan benefit packages offered by PDP Sponsor except where the provisions are specifically modified and/or superseded by particular employer/union-only group waiver guidance, including those waivers/modifications set forth below.

I, the undersigned, certify to the following:

- 1) Applicant is applying to offer new employer/union-only group waiver (“800 series”) prescription drug plans (PDPs) and agrees to be subject to and comply with all CMS employer/union-only group waiver guidance.
- 2) In order for new PDP Sponsors to be eligible for the CMS employer group waiver that allows PDP Sponsors to offer employer/union-only group waiver plan benefit packages without offering plans to individual beneficiaries, Applicant must complete the underlying solicitation in addition to this appendix.
- 3) In order for new PDP Sponsors to be eligible for the CMS employer group waiver that allows PDP Sponsors to offer employer/union-only group waiver plan benefit packages without offering plans to individual beneficiaries, Applicant must be licensed in at least one state.
- 4) Applicant understands and agrees that it is not required to submit a 2016 Part D bid (i.e., bid pricing tool) to offer its employer/union-only group waiver plans, but it must create plans in the HPMS by the bid deadline.
- 5) In order for new PDP Sponsors to be eligible for the CMS employer group waiver that allows PDP Sponsors to offer employer/union-only group waiver plan benefit packages without offering plans to individual beneficiaries, Applicant understands and agrees that as part of its completion of the solicitation, it submits retail pharmacy lists and other pharmacy access submissions (mail order, home infusion, long-term care, I/T/U) required at the time of application for its entire designated service area.
- 6) PDP Sponsor applicants applying to offer employer/union-only group waiver plans and plans to individual beneficiaries understand and agree that they are not initially required to have networks in place for those designated EGWP service areas outside of their individual plan service areas or submit retail pharmacy and other pharmacy access submissions required in the solicitation for its designated EGWP service area. However, access sufficient to meet

the needs of enrollees must be in place once an applicant enrolls members of an employer or union group residing in particular geographic locations outside of its individual plan service area.

- 7) In order to be eligible for the CMS retail pharmacy access waiver of 42 CFR §423.120(a)(1), Applicant attests that its retail pharmacy network is sufficient to meet the needs of its enrollees throughout the employer/union-only group waiver PDP's service area, including situations involving emergency access, as determined by CMS. Applicant acknowledges and understands that CMS may review the adequacy of the Applicant's pharmacy networks and potentially require expanded access in the event of beneficiary complaints or for other reasons it determines in order to ensure that the Applicant's network is sufficient to meet the needs of its employer group population.
- 8) Applicant agrees to restrict enrollment in its employer/union-only group waiver PDPs to those Part D eligible individuals eligible for the employer's/union's employment-based retiree prescription drug coverage.
- 9) Applicant understands that its employer/union-only group waiver PDPs are not included in the processes for auto-enrollment (for full-dual eligible beneficiaries) or facilitated enrollment (for other low income subsidy eligible beneficiaries).
- 10) Applicant understands that its employer/union-only group waiver plans are not subject to the requirements contained in 42 CFR §423.48 to submit information to CMS, including the requirements to submit information (e.g., pricing and pharmacy network information) to be publicly reported on www.medicare.gov and the Medicare Plan Finder.
- 11) Applicant understands that dissemination of materials for its employer/union-only group waiver PDPs are not subject to the requirements contained in 42 CFR §423.128 to be submitted for review and approval by CMS prior to use. However, Applicant agrees to submit these materials to CMS at the time of use in accordance with the procedures outlined in Chapter 12 of the Prescription Drug Benefit Manual. Applicant also understands CMS reserves the right to review these materials in the event of beneficiary complaints or for any other reason it determines to ensure the information accurately and adequately informs Medicare beneficiaries about their rights and obligations under the plan.
- 12) Applicant understands that its employer/union-only group waiver PDPs is not subject to the requirements regarding the timing for issuance of certain dissemination materials, such as the Annual Notice of Change/ Evidence of Coverage (ANOC/EOC), Summary of Benefits (SB), Formulary, and LIS rider when an employer's or union's open enrollment period does not correspond to Medicare's Annual Coordinated Election Period. For these employers and unions, the timing for issuance of the above dissemination materials should be appropriately based on the employer/union sponsor's open enrollment period. For example, the Annual Notice of Change/Evidence of Coverage (ANOC/EOC), Summary of Benefits (SB), LIS rider, and Formulary are required to be received by beneficiaries no later than 15 days before the beginning of the employer/union group health plan's open enrollment period. The timing for other dissemination materials that are based on the start of the Medicare plan (i.e., calendar) year should be appropriately based on the employer/union sponsor's plan year.
- 13) Applicant understands that the dissemination requirements set forth in 42 CFR §423.128 do not apply to its employer/union-only group waiver PDPs when the employer/union sponsor is

subject to alternative disclosure requirements (e.g., the Employee Retirement Income Security Act of 1974 (“ERISA”)) and complies with such alternative requirements. Applicant complies with the requirements for this waiver contained in employer/union-only group waiver guidance, including those requirements contained in Chapter 12 of the Prescription Drug Benefit Manual.

- 14)** Applicant understands that its employer/union-only group waiver plans is not subject to the Part D beneficiary customer service call center hours and call center performance requirements. Applicant ensures that a sufficient mechanism is available to respond to beneficiary inquiries and provides customer service call center services to these members during normal business hours. However, CMS may review the adequacy of these call center hours and potentially require expanded beneficiary customer service call center hours in the event of beneficiary complaints or for other reasons in order to ensure that the entity’s customer service call center hours are sufficient to meet the needs of its enrollee population.
- 15)** Applicant understands that CMS has waived the requirement that the employer/union-only group waiver plans must provide beneficiaries the option to pay their premium through Social Security withholding. Thus, the premium withhold option is not available for enrollees in Applicant’s employer/union-only group waiver plans.
- 16)** This Certification is deemed to incorporate any changes that are required by statute to be implemented during the term of the contract, and any regulations and policies implementing or interpreting such statutory provisions.
- 17)** 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 CMS immediately and in writing.
- 18)** 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.
- 19)** 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.
- 20)** I acknowledge that I am aware that there is operational policy guidance, including the forthcoming Call Letter, relevant to this application that is posted on the CMS website and that it is continually updated. My organization will comply with such guidance should it be approved for a Part D contract.
 I certify that I am an authorized representative, officer, chief executive officer, or general partner of the business organization that is applying for qualification to offer employer/union-only group waiver plans (“800 series” EGWPs) in association with my organization’s PDP Contract with CMS. I have read and agree to comply with the above certifications.

{Entity MUST check box for a complete application.}

{Entity MUST create 800-series PBPs during plan creation and designate EGWP service areas.}

APPENDIX IV – Employer Direct Contract MA-PD Attestations

1. EGWP SERVICE AREA & PHARMACY ACCESS REQUIREMENTS

In general, Part D plans can only cover beneficiaries in the service areas in which they are licensed and approved by CMS to offer benefits. CMS has waived this requirement for Direct Contract MA-PD Sponsors. Direct Contract MA-PD Sponsors can extend coverage to all of their retirees, regardless of whether they reside in one or more MA regions in the nation. In order to provide coverage to retirees wherever they reside, Direct Contract MA-PD Sponsors must set their service areas to include all areas where retirees may reside during the plan year. Applicants are required to submit retail and other pharmacy access information (mail order, home infusion, long-term care, I/T/U) for the entire defined service area during the application process and demonstrate sufficient access in these areas in accordance with employer group waiver pharmacy access policy.

I certify that I am an authorized representative, officer, chief executive officer, or general partner of the business organization that is applying for qualification to offer employer/union Direct Contract MA-PD. I have read, understand, and agree to comply with the above statement about service areas and pharmacy access. If I need further information, I will contact one of the individuals listed in the instructions for this application.

{Entity MUST complete for a complete application.}

2. CERTIFICATION

All provisions of the underlying solicitation apply to all plan benefit packages offered by the Direct Contract MA-PD except where the provisions are specifically modified and/or superseded by particular employer/union-only group waiver guidance, including those waivers/modifications set forth below (specific sections of the underlying application that have been waived or modified for new Direct Contract MA-PD Applicants are noted in parentheses).

I, the undersigned, certify to the following:

- 1)** Applicant is applying to offer new employer/union-only Direct Contract Medicare Advantage Prescription Drug Plans and agrees to be subject to and comply with all CMS employer/union-only group waiver guidance.
- 2)** Applicant must complete and submit the application in addition to the Appendix entitled “Part D Financial Solvency & Capital Adequacy Documentation for Direct Contract MA-PD Applicants.” All these documents comprise new Direct Contract MA-PD Applicant’s entire Direct Contract MA-PD application.
- 3)** Applicant agrees to restrict enrollment in its Direct Contract MA-PD plans to those Medicare eligible individuals eligible for the employer’s/union’s employment-based group coverage.
- 4)** Applicant is not required to submit a 2016 Part D bid (i.e., bid pricing tool) to offer its Direct Contract MA-PD, but it must create plans in HPMS by the bid deadline.
- 5)** In order to be eligible for the CMS retail pharmacy access waiver of 42 CFR §423.120(a)(1), Applicant attests that its retail pharmacy network is sufficient to meet the needs of its

enrollees throughout the Direct Contract MA-PD's service area, including situations involving emergency access, as determined by CMS. Applicant acknowledges and understands that CMS reviews the adequacy of the Applicant's pharmacy networks and may potentially require expanded access in the event of beneficiary complaints or for other reasons it determines in order to ensure that the Applicant's network is sufficient to meet the needs of its employer group population.

- 6) Applicant understands and agrees that as part of its completion of the underlying application, it submits retail pharmacy access and other pharmacy access submissions (mail order, home infusion, long-term care, I/T/U) required at the time of application for its entire designated service area.
- 7) Applicant understands that its Direct Contract MA-PD plans are not included in the processes for auto-enrollment (for full-dual eligible beneficiaries) or facilitated enrollment (for other low income subsidy eligible beneficiaries).
- 8) Applicant understands that CMS has waived the requirement that the Direct Contract MA-PD provide beneficiaries the option to pay their premium through Social Security withholding. Thus, the premium withhold option is not available for enrollees in Applicant's Direct Contract MA-PD.
- 9) Applicant understands that dissemination materials for its Direct Contract MA-PD plans are not subject to the requirements contained in 42 CFR §423.128 to be submitted for review and approval by CMS prior to use. However, Applicant agrees to submit these materials to CMS at the time of use in accordance with the procedures outlined in Chapter 9 of the Medicare Managed Care Manual (MMCM). Applicant also understands that CMS reserves the right to review these materials in the event of beneficiary complaints or for any other reason it determines to ensure the information accurately and adequately informs Medicare beneficiaries about their rights and obligations under the plan.
- 10) Applicant understands that its Direct Contract MA-PD is not subject to the requirements regarding the timing for issuance of certain dissemination materials, such as the Annual Notice of Change/Evidence of Coverage (ANOC/EOC), Summary of Benefits (SB), Formulary, and LIS rider when an employer's or union's open enrollment period does not correspond to Medicare's Annual Coordinated Election Period. For these employers and unions, the timing for issuance of the above dissemination materials should be appropriately based on the employer/union sponsor's open enrollment period. For example, the Annual Notice of Change/Evidence of Coverage (ANOC/EOC), Summary of Benefits (SB), LIS rider, and Formulary are required to be received by beneficiaries no later than 15 days before the beginning of the employer/union group health plan's open enrollment period. The timing for other dissemination materials that are based on the start of the Medicare plan (i.e., calendar) year should be appropriately based on the employer/union sponsor's plan year.
- 11) Applicant understands that the dissemination requirements set forth in 42 CFR §423.128 do not apply to its Direct Contract MA-PD plans when the employer/union sponsor is subject to alternative disclosure requirements (e.g., the Employee Retirement Income Security Act of 1974 ("ERISA")) and complies with such alternative requirements. Applicant complies with the requirements for this waiver contained in employer/union-only group waiver guidance, including those requirements contained in Chapter 9 of the MMCM.

- 12)** Applicant understands that its Direct Contract MA-PD plans are not subject to the requirements contained in 42 CFR §423.48 to submit information to CMS, including the requirements to submit information (e.g., pricing and pharmacy network information) to be publicly reported on www.medicare.gov (Medicare Plan Finder).
- 13)** Applicant understands that its Direct Contract MA-PD plans are not subject to the Part D beneficiary customer service call center hours and call center performance requirements. Applicant has a sufficient mechanism available to respond to beneficiary inquiries and provides customer service call center services to these members during normal business hours. However, CMS may review the adequacy of these call center hours and potentially require expanded beneficiary customer service call center hours in the event of beneficiary complaints or for other reasons in order to ensure that the entity's customer service call center hours are sufficient to meet the needs of its enrollee population.
- 14)** In general, Part D plan Sponsors must report certain information to CMS, to their enrollees, and to the general public (such as the cost of their operations and financial statements) under 42 CFR §423.514(a). Applicant understands that in order to avoid imposing additional and possibly conflicting public disclosure obligations that would hinder the offering of employer sponsored group plans, CMS modifies these reporting requirements for Direct Contract MA-PDs to allow information to be reported to enrollees and to the general public to the extent required by other law (including ERISA or securities laws), or by contract.
- 15)** This Certification is deemed to incorporate any changes that are required by statute to be implemented during the term of the contract, and any regulations and policies implementing or interpreting such statutory provisions.
- 16)** 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 CMS immediately and in writing.
- 17)** 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.
- 18)** 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.
- 19)** I acknowledge that I am aware that there is operational policy guidance, including the forthcoming Call Letter, relevant to this application that is posted on the CMS website and that it is continually updated. My organization will comply with such guidance should it be approved for a Part D contract.

I certify that I am an authorized representative, officer, chief executive officer, or general partner of the business organization that is applying for qualification to offer employer/union Direct Contract plans in association with my organization's MA-PD Contract with CMS. I have read and agree to comply with the above certifications.

{Entity MUST check box for a complete application.}

APPENDIX V – Employer Direct Contract PDP Attestation

Direct Contract PDP Attestations for Contract _____

1. SERVICE AREA & PHARMACY ACCESS REQUIREMENTS

In general, Part D plans can only cover beneficiaries in the service areas in which they are licensed and approved by CMS to offer benefits. CMS has waived this requirement for Direct Contract PDP Sponsors. Direct Contract PDP Sponsors can extend coverage to all of their retirees, regardless of whether they reside in one or more other PDP regions in the nation. In order to provide coverage to retirees wherever they reside, Direct Contract PDP Sponsors must set their service areas to include all areas where retirees may reside during the plan year (**no mid-year service area expansions will be permitted**). Applicants are required to submit retail and other pharmacy access information (mail order, home infusion, long-term care, I/T/U) for the entire defined service area during the application process and demonstrate sufficient access in these areas in accordance with employer group waiver pharmacy access policy.

I certify that I am an authorized representative, officer, chief executive officer, or general partner of the business organization that is applying for qualification to offer employer/union-only Direct Contract PDP. I have read, understand, and agree to comply with the above statement about service areas and pharmacy access. If I need further information, I will contact one of the individuals listed in the instructions for this application.
{Entity MUST complete for a complete application.}

2. CERTIFICATION

All provisions of the underlying solicitation apply to all plan benefit packages offered by PDP Sponsor except where the provisions are specifically modified and/or superseded by particular employer/union-only group waiver guidance, including those waivers/modifications set forth below (specific sections of the underlying application that have been waived or modified for new PDP Sponsor Applicants are noted in parentheses).

I, the undersigned, certify to the following:

- 1) Applicant is applying to offer new employer/union Direct Contract prescription drug plans (PDPs) and agrees to be subject to and comply with all CMS employer/union-only group waiver guidance.
- 2) Applicant must complete and submit the underlying application in addition to this Appendix in its entirety. The 2016 solicitation along with the Appendix entitled “Part D Financial Solvency & Capital Adequacy Documentation” and this attestation comprise a new Direct Contract PDP Sponsor Applicant’s entire application.
- 3) A Part D Sponsor must be organized and licensed under State law as a risk-bearing entity eligible to offer health insurance or health benefits coverage in each State in which it offers its coverage (42 CFR §423.504(b)(2)). However, CMS has waived the state licensing requirement for all Direct Contract PDP Sponsors along with the requirement to be a nongovernmental legal entity (42 CFR §423.4). As a condition of this waiver, Applicant meets the financial solvency and capital adequacy standards contained in the Appendix

entitled “Part D Financial Solvency and Capital Adequacy Documentation” of this application.

- 4) Applicant is not required to submit a 2016 Part D bid (i.e., bid pricing tool) to offer its Direct Contract PDP, however it must create plans in HPMS by the bid deadline.
- 5) Applicant restricts enrollment in its Direct Contract PDP to those Part D eligible individuals eligible for the Direct Contract PDP’s employment-based retiree prescription drug coverage. Applicant does not enroll active employees into its Direct Contract PDP.
- 6) In order to be eligible for the CMS retail pharmacy access waiver of 42 CFR §423.120(a)(1), Applicant attests that its retail pharmacy network is sufficient to meet the needs of its enrollees throughout the Direct Contract PDP’s service area, including situations involving emergency access, as determined by CMS. Applicant acknowledges and understands that CMS reviews the adequacy of the Applicant’s pharmacy networks and may potentially require expanded access in the event of beneficiary complaints or for other reasons it determines in order to ensure that the Applicant’s network is sufficient to meet the needs of its employer group population.
- 7) Applicant understands and agrees that as part of its completion of the underlying solicitation, submits retail pharmacy access and other pharmacy access submissions (mail order, home infusion, long-term care, I/T/U) required at the time of application in Section 3.4 for its entire designated service area.
- 8) Applicant understands that its Direct Contract PDP is not included in the processes for auto-enrollment (for full-dual eligible beneficiaries) or facilitated enrollment (for other low income subsidy eligible beneficiaries).
- 9) Applicant understands that CMS has waived the requirement that the Direct Contract PDP provide beneficiaries the option to pay their premium through Social Security withholding. Thus, the premium withhold option is not available for enrollees in Applicant’s Direct Contract PDP.
- 10) Applicant understands that dissemination materials for its Direct Contract PDP are not subject to the requirements contained in 42 CFR §423.128 to be submitted for review and approval by CMS prior to use. However, Applicant agrees to submit these materials to CMS at the time of use in accordance with the procedures outlined in Chapter 12 of the Prescription Drug Benefit Manual. Applicant also understands that CMS reserves the right to review these materials in the event of beneficiary complaints or for any other reason it determines to ensure the information accurately and adequately informs Medicare beneficiaries about their rights and obligations under the plan.
- 11) Applicant understands that its Direct Contract PDP is not subject to the requirements regarding the timing for issuance of certain dissemination materials, such as the Annual Notice of Change/ Evidence of Coverage (ANOC/EOC), Summary of Benefits (SB), Formulary, and LIS rider when an employer’s or union’s open enrollment period does not correspond to Medicare’s Annual Coordinated Election Period. For these employers and unions, the timing for issuance of the above dissemination materials should be appropriately based on the employer/union sponsor’s open enrollment period. For example, the Annual Notice of Change/Evidence of Coverage (ANOC/EOC), Summary of Benefits (SB), LIS rider, and Formulary are required to be received by beneficiaries no later than 15 days before the

beginning of the employer/union group health plan's open enrollment period. The timing for other dissemination materials that are based on the start of the Medicare plan (i.e., calendar) year should be appropriately based on the employer/union sponsor's plan year.

- 12)** Applicant understands that the dissemination requirements set forth in 42 CFR §423.128 do not apply to its Direct Contract PDP when the employer/union sponsor is subject to alternative disclosure requirements (e.g., the Employee Retirement Income Security Act of 1974 ("ERISA")) and complies with such alternative requirements. Applicant complies with the requirements for this waiver contained in employer/union-only group waiver guidance, including those requirements contained in Chapter 12 of the Prescription Drug Benefit Manual.
- 13)** Applicant understands that its Direct Contract PDP is not subject to the requirements contained in 42 CFR §423.48 to submit information to CMS, including the requirements to submit information (e.g., pricing and pharmacy network information) to be publicly reported on www.medicare.gov and the Medicare Plan Finder.
- 14)** Applicant understands that its Direct Contract PDP is not subject to the Part D beneficiary customer service call center hours and call center performance requirements. Applicant has a sufficient mechanism available to respond to beneficiary inquiries and provides customer service call center services to these members during normal business hours. However, CMS may review the adequacy of these call center hours and potentially require expanded beneficiary customer service call center hours in the event of beneficiary complaints or for other reasons in order to ensure that the entity's customer service call center hours are sufficient to meet the needs of its enrollee population.
- 15)** Applicant understands that the management and operations requirements of 42 CFR §423.504(b)(4)(i)-(iii) are waived if the employer or union (or to the extent applicable, the business associate with which it contracts for prescription drug benefit services) is subject to ERISA fiduciary requirements or similar state or federal law standards. However, Applicant understands that it (or its business associates) are not relieved from the record retention standards applicable to other Part D Sponsors set forth in 42 CFR §423.505(d).
- 16)** In general, Part D plan Sponsors must report certain information to CMS, to their enrollees, and to the general public (such as the cost of their operations and financial statements) under 42 CFR §423.514(a). Applicant understands that in order to avoid imposing additional and possibly conflicting public disclosure obligations that would hinder the offering of employer sponsored group plans, CMS modifies these reporting requirements for Direct Contract PDPs to allow information to be reported to enrollees and to the general public to the extent required by other law (including ERISA or securities laws), or by contract.
- 17)** This Certification is deemed to incorporate any changes that are required by statute to be implemented during the term of the contract, and any regulations and policies implementing or interpreting such statutory provisions.
- 18)** 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 CMS immediately and in writing.
- 19)** 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.

20) 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.

21) I acknowledge that I am aware that there is operational policy guidance, including the forthcoming Call Letter, relevant to this application that is posted on the CMS website and that it is continually updated. My organization will comply with such guidance should it be approved for a Part D contract.

I certify that I am an authorized representative, officer, chief executive officer, or general partner of the business organization that is applying for qualification to offer employer/union-only Direct Contract plans in association with my organization's PDP Contract with CMS. I have read and agree to comply with the above certifications.

{Entity MUST check box for a complete application.}

APPENDIX VI – Part D Financial Solvency & Capital Adequacy Documentation

(For Direct PDP Contract applicants only)

Background and Instructions:

A PDP Sponsor generally must be licensed by at least one state as a risk-bearing entity (42 CFR §423.401(a)(1)). CMS has waived the requirement for Direct Contract PDP Sponsors. Direct Contract PDP Sponsors are not required to be licensed, but must meet CMS Part D financial solvency and capital adequacy requirements. Each Direct Contract PDP Sponsor Applicant must demonstrate that it meets the requirements set forth in this Appendix and provide all required information set forth below. CMS may in its discretion approve, on a case-by-case basis, waivers of such requirements upon a demonstration from the Direct Contract PDP Sponsor Applicant that its fiscal soundness is commensurate with its financial risk and that through other means the entity can assure that claims for benefits paid for by CMS and beneficiaries will be covered. In all cases, CMS requires that the employer's/union's contracts and sub-contracts provide beneficiary hold harmless provisions.

The information required in this Appendix must be submitted electronically through HPMS as a supporting documentation upload to the Licensure and Solvency section of the Part D supporting file section in accordance with the instructions contained in this application.

I. EMPLOYER/UNION ORGANIZATIONAL INFORMATION

A. Complete the information in the table below.

IDENTIFY YOUR ORGANIZATION BY PROVIDING THE FOLLOWING INFORMATION:
Organization's Full Legal Name:
Full Address of Your Organization's Headquarters (<i>Street, City, State, Zip</i>):
Type of Entity (place a checkmark in <u>all</u> applicable boxes): <input type="checkbox"/> Employer <input type="checkbox"/> Fund established by one or more employers or labor organizations <input type="checkbox"/> Union <input type="checkbox"/> Government

<input type="checkbox"/> Church Group <input type="checkbox"/> Publicly-Traded Corporation <input type="checkbox"/> Privately- Held Corporation <input type="checkbox"/> Other (list type) _____	
Name of Your Organization's Parent Organization, if any:	
Is Applicant subject to ERISA? <input type="checkbox"/> Yes <input type="checkbox"/> No	Tax Status: <input type="checkbox"/> For Profit <input type="checkbox"/> Not-for-Profit
State in Which your Organization is Incorporated or Otherwise Organized to do Business:	

B. Summary Description

Briefly describe the organization in terms of its history and its present operations. Cite significant aspects of its current financial, general management, and health services delivery activities. Please include the following:

1. The extent of the current Medicare population served by the Applicant, if any, and the maximum number of Medicare beneficiaries that could be served as a Direct Contract PDP.
2. The manner in which benefits are currently provided to the current Medicare population served by the Applicant, if any, the number of beneficiaries in each employer sponsored group option currently made available by the Applicant and how these options are currently funded (self-funded or fully insured).
3. The current benefit design for each of the options described in B above, including premium contributions made by the employer and/or the retiree, deductible, co-payments, or co-insurance, etc. (Applicant may attach a summary plan description of its benefits or other relevant materials describing these benefits.)
4. Information about other Medicare contracts held by the Applicant, (e.g., 1876, fee for service, PPO, etc.). Provide the names and contact information for all CMS personnel with whom Applicant works on their other Medicare contract(s).
5. The factors that are most important to Applicant in considering to apply to become a Direct Contract PDP for its retirees and how becoming a Direct Contract PDP will benefit the Applicant and its retirees.

C. If the Applicant is a state agency, labor organization, or a trust established by one or more employers or labor organizations, Applicant must provide the required information listed below:

1. State Agencies:

If Applicant is a state agency, instrumentality or subdivision, please provide the relationship between the entity that is named as the Direct Contract PDP Applicant and the state or commonwealth with respect to which the Direct Contract PDP Applicant is an agency, instrumentality or subdivision. Also, Applicant must provide the source of Applicant's revenues, including whether applicant receives appropriations and/or has the authority to issue debt.

2. Labor Organizations:

If Applicant is a labor organization including a fund or trust, please provide the relationship (if any) between Applicant and any other related labor organizations such as regional, local or international unions, or welfare funds sponsored by such related labor organizations. If Applicant is a jointly trustee Taft-Hartley fund, please include the names and titles of labor-appointed and management-appointed trustees.

3. Trusts:

If Applicant is a trust, such as a voluntary employee beneficiary association under section 501(c)(9) of the Internal Revenue Code, please provide the names of the individual trustees and the bank, trust company or other financial institution that has custody of Applicant's assets.

D. Policymaking Body (42 CFR §423.504(b)(4)(i)-(iii))

In general, an entity seeking to contract with CMS as a Direct Contract PDP Sponsor must have policymaking bodies exercising oversight and control to ensure actions are in the best interest of the organization and its enrollees, appropriate personnel and systems relating to medical services, administration and management, and an executive manager whose appointment and removal are under the control of the policymaking body.

An employer or union directly contracting with CMS as a Direct Contract PDP Sponsor may be subject to other, potentially different standards governing its management and operations, such as ERISA fiduciary requirements, state law standards, and certain oversight standards created under the Sarbanes-Oxley Act. In most cases, they will also contract with outside vendors (i.e., business associates) to provide health benefit plan services. To reflect these issues and avoid imposing additional (and potentially conflicting) government oversight that may hinder employers and unions from considering applying to offer Direct Contract PDPs, the management and operations requirements under 42 CFR §423.504(b)(4)(i)-(iii) are waived if the employer or union (or to the extent applicable, the business associate with which it contracts for health benefit plan services) is subject to ERISA fiduciary requirements or similar state or federal laws and standards. However, such entities (or their business associates) are not relieved from the record retention standards applicable to other PDP Sponsors. In accordance with the terms of this waiver, please provide the following information:

1. List the members of the organization's policymaking body (name, position, address, telephone number, occupation, term of office and term expiration date). Indicate whether any of the members are employees of the Applicant.

2. If the Applicant is a line of business versus a legal entity, does the Board of Directors of the corporation serve as the policymaking body of the organization? If not, describe the policymaking body and its relationship to the corporate Board.
3. Does the Federal Government or a State regulate the composition of the policymaking body? If yes, please identify all Federal and State regulations that govern your policymaking body (e.g., ERISA).

II. FINANCIAL DOCUMENTATION

A. Minimum Net Worth: \$1.5 Million - Documentation of Minimum Net Worth

The Direct Contract PDP Applicant must demonstrate financial solvency through furnishing two years of independently audited financial statements to CMS. If the Direct Contract PDP Applicant has not been in operation at least twelve months, it may choose to: 1) obtain independently audited financial statements for a shorter time period; or 2) demonstrate that it has the minimum net worth through presentation of un-audited financial statements that contain sufficient detail to allow CMS to verify the validity of the financial presentation. The un-audited financial statement must be accompanied by an actuarial opinion from a qualified actuary regarding the assumptions and methods used in determining loss reserves, actuarial liabilities and related items.

A “qualified actuary” for purposes of this application means a member in good standing of the American Academy of Actuaries, a person recognized by the Academy as qualified for membership, or a person who has otherwise demonstrated competency in the field of actuarial science and is satisfactory to CMS.

If the Direct Contract PDP Applicant’s auditor is not one of the 10 largest national accounting firms in accordance with the list of the 100 largest public accounting firms published by the CCH Public Accounting Report, the Applicant should enclose proof of the auditor’s good standing from the relevant state board of accountancy.

B. Liquidity

The Direct Contract PDP Applicant must have sufficient cash flow to meet its financial obligations as they become due. The amount of the minimum net worth requirement to be met by cash or cash equivalents is \$750,000. Cash equivalents are short-term highly liquid investments that can be readily converted to cash. To be classified as cash equivalents, investments must have a maturity date not longer than 3 months from the date of purchase.

1. In determining the ability of a Direct Contract PDP Applicant to meet this requirement, CMS will consider the following:
 - a) The timeliness of payment,
 - b) The extent to which the current ratio is maintained at 1:1 or greater, or whether there is a change in the current ratio over a period of time; and
 - c) The availability of outside financial resources.
2. CMS may apply the following corresponding corrective remedies:

- a) If a PDP Sponsor fails to pay obligations as they become due, CMS will require the PDP Sponsor to initiate corrective action to pay all overdue obligations.
- b) CMS may require the PDP Sponsor to initiate corrective action if any of the following are evident:
 - (i) The current ratio declines significantly; or
 - (ii) A continued downward trend in the current ratio. The corrective action may include a change in the distribution of assets, a reduction of liabilities, or alternative arrangements to secure additional funding to restore the current ratio to at least 1:1.
- c) If there is a change in the availability of outside resources, CMS will require the PDP Sponsor to obtain funding from alternative financial resources.

C. Methods of Accounting

A Direct Contract PDP Applicant generally must use the standards of Generally Accepted Accounting Principles (GAAP). Generally Accepted Accounting Principles (GAAP) are those accounting principles or practices prescribed or permitted by the Financial Accounting Standards Board. However, a Direct Contract PDP Sponsor whose audited financial statements are prepared using accounting principles or practices other than GAAP, such as a governmental entity that reports in accordance with the principles promulgated by the Governmental Accounting Standards Board (GASB), may utilize such alternative standard.

D. Bonding and Insurance

A Direct Contract PDP Applicant may request a waiver in writing of the bonding and/or insurance requirements set forth at 42 CFR §423.504(b)(4)(iv) and (v). Relevant considerations will include demonstration that either or both of the foregoing requirements are unnecessary based on the entity's individualized circumstances, including maintenance of similar coverage pursuant to other law, such as the bonding requirement at ERISA Section 412.

E. Additional Information

A Direct Contract PDP Applicant must furnish the following financial information to CMS to the extent applicable:

1. **Self-Insurance/Self Funding:** If the Direct Contract PDP Applicant's health plan(s) are self-insured or self-funded, it must forward proof of stop-loss coverage (if any) through copies of policy declarations.
2. **Trust:** If the Direct Contract PDP Applicant maintains one or more trusts with respect to its health plan(s), a copy of the trust documents, and if the trust is intended to meet the requirements of Section 501(c)(9) of the Internal Revenue Code, the most recent IRS approval letter.
3. **Forms 5500 and M-1:** The two most recent annual reports on Forms 5500 and M-1 (to the extent applicable) for the Direct Contract PDP Applicant's health plans that cover prescription drugs for retirees that are Part D eligible individuals.

4. **ERISA Section 411(a) Attestation:** Each applicant (including an applicant that is exempt from ERISA) must provide a signed attestation that no person serves as a fiduciary, administrator, trustee, custodian, counsel, agent, employee, consultant, adviser or in any capacity that involves decision-making authority, custody, or control of the assets or property of any employee benefit plan sponsored by the Direct Contract PDP Applicant if he or she has been convicted of, or has been imprisoned as a result of his or her conviction of, one of the felonies set forth in ERISA Section 411(a), for 13 years after such conviction or imprisonment (whichever is later).
5. **Defined Benefit Pension Plan:** If the Direct Contract PDP Applicant sponsors one or more defined benefit pension plans (within the meaning of ERISA Section 3(35)) that is subject to the requirements of Title IV of ERISA, the latest actuarial report for each such plan.
6. **Multi-Employer Pension Plan:** If the Direct Contract PDP Applicant is a contributing employer with respect to one or more multi-employer pension plans within the meaning of ERISA section 3(37), the latest estimate of contingent withdrawal liability.
7. **Tax-Exempt Applicants Only:** A copy of the most recent IRS tax-exemption.

III. INSOLVENCY REQUIREMENTS

A. Hold Harmless and Continuation of Coverage/Benefits

A Direct Contract PDP Applicant shall be subject to the same hold harmless and continuation of coverage/benefit requirements as Medicare Advantage contractors.

B. Insolvency Deposit

A Direct Contract PDP Applicant generally must forward confirmation of its establishment and maintenance of an insolvency deposit of at least \$100,000, to be held in accordance with CMS requirements by a qualified U.S. Financial Institution. A "qualified U.S. financial institution" means an institution that:

1. Is organized or (in the case of a U.S. office of a foreign banking organization) licensed under the laws of the United States or any state thereof; and
2. Is regulated, supervised, and examined by the U.S. Federal or State authorities having regulatory authority over banks and trust companies.

A Direct Contract PDP Applicant may request a waiver in writing of this requirement.

IV. GUARANTEES (only applies to an Applicant that utilizes a Guarantor)

A. General Policy

A Direct Contract PDP Applicant, or the legal entity of which the Direct Contract PDP Applicant is a component, may apply to CMS to use the financial resources of a Guarantor for the purpose

of meeting the requirements of a Direct Contract PDP Applicant set forth above. CMS has the sole discretion to approve or deny the use of a Guarantor.

B. Request to Use a Guarantor

To apply to use the financial resources of a Guarantor, a Direct Contract PDP Applicant must submit to CMS:

1. Documentation that the Guarantor meets the requirements for a Guarantor under paragraph (C) of this section; and
2. The Guarantor's independently audited financial statements for the current year-to-date and for the two most recent fiscal years. The financial statements must include the Guarantor's balance sheets, profit and loss statements, and cash flow statements.

C. Requirements for Guarantor

To serve as a Guarantor, an organization must meet the following requirements:

1. Is a legal entity authorized to conduct business within a State of the United States.
2. Not be under Federal or State bankruptcy or rehabilitation proceedings.
3. Have a net worth (not including other guarantees, intangibles and restricted reserves) equal to three times the amount of the PDP Sponsor guarantee.
4. If a State insurance commissioner or other State official with authority for risk-bearing entities regulates the Guarantor, it must meet the net worth requirement in Section II.A above with all guarantees and all investments in and loans to organizations covered by guarantees excluded from its assets.
5. If the Guarantor is not regulated by a State insurance commissioner or other similar State official, it must meet the net worth requirement in Section II.A above with all guarantees and all investments in and loans to organizations covered by a guarantee and to related parties (subsidiaries and affiliates) excluded from its assets.

D. Guarantee Document

If the guarantee request is approved, a Direct Contract PDP Applicant must submit to CMS a written guarantee document signed by an appropriate Guarantor. The guarantee document must:

1. State the financial obligation covered by the guarantee;
2. Agree to:
 - a) Unconditionally fulfill the financial obligation covered by the guarantee; and
 - b) Not subordinate the guarantee to any other claim on the resources of the Guarantor;

3. Declare that the Guarantor must act on a timely basis, in any case not more than 5 business days, to satisfy the financial obligation covered by the guarantee; and
4. Meet any other conditions as CMS may establish from time to time.

E. Ongoing Guarantee Reporting Requirements

A Direct Contract PDP Sponsor must submit to CMS the current internal financial statements and annual audited financial statements of the Guarantor according to the schedule, manner, and form that CMS requires.

F. Modification, Substitution, and Termination of a Guarantee

A Direct Contract PDP Sponsor cannot modify, substitute or terminate a guarantee unless the Direct Contract PDP Sponsor:

1. Requests CMS's approval at least 90 days before the proposed effective date of the modification, substitution, or termination;
2. Demonstrates to CMS's satisfaction that the modification, substitution, or termination will not result in insolvency of the Direct Contract PDP Applicant; and
3. Demonstrates how the Direct Contract PDP Applicant will meet the requirements of this section.

G. Nullification

If at any time the Guarantor or the guarantee ceases to meet the requirements of this section, CMS will notify the Direct Contract PDP Sponsor that it ceases to recognize the guarantee document. In the event of this nullification, a Direct Contract PDP Sponsor must:

1. Meet the applicable requirements of this section within 15 business days; and
2. If required by CMS, meet a portion of the applicable requirements in less than the 15 business days in paragraph (G.1.) of this section.

V. ONGOING REPORTING REQUIREMENTS

An approved Direct Contract PDP Applicant is required to update financial information set forth in Sections II and III above to CMS on an ongoing basis. The schedule, manner, and form of reporting will be in accordance with CMS requirements.

APPENDIX VII – Federal Waiver of State Licensure

Only if applying to request a federal waiver of state licensure requirement for Prescription Drug Plan then download, complete and upload into HPMS the following form:

Application to Request Federal Waiver of State Licensure Requirement for Prescription Drug Plan (PDP)

I. Complete the table below.

Contract# _____

Identify the corporation seeking waiver of state licensure requirement for PDP plan	
Full Legal Corporate Name:	D.B.A:
Full Address of Corporation: <i>(Street, City, State, Zip – No Post Office Boxes):</i>	
Corporation Telephone Number:	Corporation Fax Number:
Provide the corporation’s contact information for the person who will act as the main contact	
Name of Individual:	Title:
Address of Individual: <i>(Street, City, State, Zip – No Post Office Boxes):</i>	
Direct Telephone Number:	Fax Number:
Email Address:	

II. Request

I, on behalf of the legal entity identified in Section A, above, hereby request that the Secretary of Health and Human Services, pursuant to the authority granted under

section 1855(a)(2) and section 1860D-12(c) of the Social Security Act, grant a waiver of the requirement that our organization be licensed under (Name of State or for Regional Plan Waiver, States) _____ State laws as a risk-bearing entity eligible to sponsor prescription drug benefits coverage.

III. Certification

The undersigned officer has read this completed request for federal waiver form and does hereby declare that the facts, representations, and statements made in this form together with any attached information are true and complete to the best of my knowledge, information, and belief. The information herein declared by me represents matters about which I am competent, qualified, and authorized to represent the corporation. If any events, including the passage of time, should occur that materially change any of the answers to this request for federal waiver, the corporation agrees to notify the Centers for Medicare & Medicaid Services immediately.

Corporate Name: _____

Date: _____

By: _____

Print Name: _____

Title: _____

Witness/Attest: _____

IV. Instructions for completing the cover sheet of licensure waiver application

Section A

Contract # _____

- Enter the corporate name
- Enter the name under which your PDP will do business (D.B.A)
- Enter the street address, telephone number and facsimile number of the Corporation at its corporate headquarters
- Enter the name, title, telephone number, fax number, and email address of the main contact person

Section B

- Indicate the State for which you are requesting a waiver or the States for which you are requesting a Regional Plan Waiver

Section C

- Have a duly appointed corporate officer sign and date this form in the presence of a witness

If you have any questions regarding this form please contact:

Joseph Millstone

410-786-2976

Instructions Follow

Supporting Documentation for Request of Federal Waiver of State Licensure Requirement for Prescription Drug Plan (PDP) Sponsors

Complete Sections II and IV

I. Background and Purpose

This waiver request form is for use by Applicants who wish to enter into a contract with the Centers for Medicare & Medicaid Services (CMS) to become Prescription Drug Plan (PDP) sponsors and provide prescription drug plan benefits to eligible Medicare beneficiaries without a State risk-bearing entity license.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) generally requires Applicants who wish to become PDP sponsors to be licensed under State law as a risk-bearing entity eligible to offer health insurance or health benefits coverage in each State in which the Applicant wishes to offer a PDP. However, the MMA created several exceptions to this State licensure requirement.

In general, there are two types of waivers – both of which are more fully explained in Section II below. The waivers are: (1) Single State waivers. For these waivers, the Applicant should submit a separate waiver request for each State, and the waiver is effective only with respect to the single State. (2) Regional plan waivers. These waivers may be obtained if an Applicant is licensed in one State in a region and wishes to receive a waiver for all the other States in the region in which it is not licensed. In this case, the entity need only submit one waiver request – not one for each and every State in which it is not licensed.

Waiver requests should be submitted to CMS using the criteria described below. Approval of a waiver request, in no way suggests that the Applicant is approved for a Medicare contract with CMS. In addition to approval of a waiver request, the Applicant is required to submit a Medicare contract application that demonstrates that the Applicant meets the Federal definition of a PDP sponsor and that the prescription drug plan being offered meets all plan requirements for PDPs.

Waiver Applicants must also comply with CMS standards for financial solvency and capital adequacy.

II. Waiver Eligibility

The following constitute the waivers available to Applicants. These are the sole grounds for receiving waivers.

A. Single State Waiver

The Applicant is requesting a single state waiver for the following state: _____.

Please indicate in your response to section IV. (Information to be included in this request/ the grounds upon which you are requesting a waiver (cover all applicable areas).)

1. The State has failed to complete action on a licensing application within 90 days of the date of the State's receipt of a substantially complete application. 42 CFR §423.410(b)(1).
 - a) In order to apply for a CMS waiver based on the ground that a State did not act within 90 days of receiving a substantially complete application, the State must have had a substantially complete application for at least 90 days at the time the waiver applicant applies to CMS for a waiver. Therefore, in order to use this ground as a basis for a waiver, any new State license application must have been received by a State(s) no later than November 1st of the year prior to submission of the licensure waiver application to CMS. This will insure that the State had time to confirm "the receipt and completeness of the application" which is necessary to establish that the 90-day period has been met. A state's denial of an application that was not complete does not create grounds for waiver approval.
2. The State does not have a licensing process in effect with respect to PDP sponsors. 42 CFR §423.410(c).
3. The State has denied the license application on the basis of one of the following:
 - a) material requirements, procedures, or standards (other than solvency requirements) not generally applied by the State to other entities engaged in a substantially similar business; or
 - b) the State requires, as a condition of licensure, the Applicant to offer any product or plan other than a PDP. 42 CFR §423.410(b)(2).
4. The State has denied the licensure application, in whole or in part, for one of the following reasons:
 - a) on the basis of the Applicant's failure to meet solvency requirements that are different from the solvency standards developed by CMS; or

- b) the State has imposed, as a condition of licensing, any documentation or information requirements relating to solvency that are different from the information or documentation requirements in the solvency standards developed by CMS. 42 CFR §423.410(b)(3).
5. The State has denied the licensure application on the basis of grounds other than those required under Federal law. 42 CFR §423.410(b)(4).

NOTE: To meet the conditions for CMS to grant a state licensure waiver pursuant to 42 CFR §423.410(b), the waiver applicant must demonstrate that by the time the waiver application is submitted to CMS, either:

- a) The State failed to complete action on the licensing application within 90 days of the date that the state received a substantially complete application. States must confirm the receipt and completeness of the application, which is necessary to establish that the 90-day period has been met; or
- b) The State denied the substantially complete license application for one of the reasons specified in 42 CFR §423.410 (b)(2) through (b)(4), relating to Single State Waivers.

B. Regional Plan Waivers

The Applicant is State-licensed in the State(s) of _____ and is applying for a regional plan waiver in the following region(s): _____ as provided under 42 CFR §423.415(a). The Applicant must demonstrate that it submitted a substantially complete licensure application in each State in the region for which it does not already have State licensure, except that no such application is necessary if CMS determines that the State does not have a licensing process for potential PDP sponsors.

III. Waiver Duration

A. Single State Waiver

The Single State waiver listed in II.A is effective for up to 36 months only and cannot be renewed unless CMS determines that the State in question does not have a licensing process in effect with respect to PDP sponsors. Thus, prior to the CMS renewal notice deadline for the fourth year the PDP sponsor must be State-licensed if it wishes to continue as a PDP sponsor and receive a contract for the subsequent year, unless CMS determines that the State in question has chosen not to create a licensing process for PDP sponsors – in which case the waiver can continue until CMS determines that a licensure process has been created. Single State waivers automatically terminate if the PDP sponsor obtains State licensure.

B. Regional Plan Waivers

The Regional Plan waivers expire at the end of the time period the Secretary determines is appropriate for timely processing of the licensure application, but in no case will a waiver extend beyond the end of the calendar year.

C. All Waivers

For both Single State and Regional Plan waivers, the waiver will terminate if the contract with Medicare terminates.

IV. Information to be Included in this Request

While the applicant should provide information concerning each of the following areas, the specific information and documentation requested below are not necessarily all inclusive for CMS to approve or deny the request. Applicants should provide any information and all documentation necessary to substantiate their request.

A. Single-State Waiver:

1. Specify the grounds from section II.A above, upon which you are requesting a waiver. Provide a narrative of the circumstances leading to the PDP's eligibility for a waiver based on one of the grounds listed above. Include information about the state risk-bearing entity license for which the PDP applied, the application process that the PDP followed, and any relevant interaction with the state.
2. Provide documentation to substantiate the narrative required in (1). Depending on the grounds for waiver eligibility, this documentation should include but is not necessarily limited to the list below:
 - a) Evidence of state's failure to act on a licensure application on a timely basis, including a copy of the dated cover sheet to the application submitted to the state, state confirmation of the receipt and completeness of the application, state requests for additional information, and all pertinent correspondence with the state relating to the status of the application, etc.
 - b) Evidence of denial of the application based on discriminatory treatment, including:
 - (i) Documentation in 2.a above, and,
 - (ii) Copy of denial letter from the state, copy of "discriminatory" material requirements (including, state laws and regulation), procedures or standards to which the PDP was required to comply that are not generally applicable to other entities engaged in a substantially similar business, a copy of state licensure requirements that the PDP offer a particular product or plan in addition to a Medicare plan, and any supplemental material received from the state explaining its rationale for the denial, etc.

3. PDPs seeking a waiver on the grounds that they are subject to requirements, procedures and standards not applicable to entities engaged in a “substantially similar business” must demonstrate through submission of these and other appropriate materials:
 - a) The types of entities subject to the different requirements, procedures and standards are engaged in a “substantially similar business”.
 - b) The state requirements, procedures and standards imposed on the PDP entity are not applicable to other “substantially similar business” entities.
4. Evidence of denial of the application based on solvency requirements
 - a) Documentation in 2.a above, and,
 - b) Copy of denial letter from the state, copy of state solvency requirements, demonstration of the difference between state solvency requirements, procedures and standards and Federal PDP solvency requirements, procedures and standards, any other state information regarding documentation, information, and other material requirements, procedures or standards relating to solvency, or any correspondence detailing the reason the application was denied, etc.
5. Evidence of State denial of the application based on licensure standards other than those required by Federal law
 - a) Documentation in 2.a above, and,
 - b) Copy of denial letter from the state, memo identifying the state licensure standards by reference to relevant state law, regulation, or policy guidance and describing how those standards differ from those required by Federal law.
6. Provide the name, address and telephone number of all state regulatory officials involved in the state application and/or denial proceedings.
7. Provide any other information that you believe supports your request for a waiver.

B. Regional Plan Waivers

1. Evidence of licensure in one state within the region and
2. Copy of the dated cover sheet to the application(s) submitted to the unlicensed state(s), state confirmation of the receipt and completeness of each application, state requests for additional information, and all pertinent correspondence with

the state(s) relating to the status of the application, etc. – unless CMS determines that there is no PDP licensing process in effect in a state.

3. Provide the name, address and telephone number of all state regulatory officials involved in the state application and/or denial proceedings.
4. Provide any other information that you believe supports your request for a waiver.

V. Overview of Waiver Request Process

For single-state waivers, section 1860D-12(c) and section 1855(a)(2) of the Act require the Secretary to grant or deny this waiver request within 60 days after the date the Secretary determines that a substantially complete application has been filed. Upon receipt of a waiver request, CMS will review it to determine whether it contains sufficient information to approve or deny the request. The 60-day review period begins at the time CMS determines that the application is substantially complete.

APPENDIX VIII – Financial Solvency Documentation for Applicant Not Licensed as a Risk-bearing Entity in Any State

(For individual market applicants only)

Upload all appropriate documentation in pdf format into HPMS on the Part D Financial Solvency Upload Page.

I. DOCUMENTATION

A. Documentation of Net Worth - Minimum Net Worth: \$1.5 million

At the time of application, the potential PDP Sponsor not licensed in any state must show evidence of the required minimum net worth. The PDP Sponsor must demonstrate this through an independently audited financial statement if it has been in operation at least twelve months.

If the organization has not been in operation at least twelve months it may choose to 1) obtain an independently audited financial statement for a shorter time period; or 2) demonstrate that it has the minimum net worth through presentation of an unaudited financial statement that contains sufficient detail that CMS may verify the validity of the financial presentation. The unaudited financial statement must be accompanied by an actuarial opinion by a qualified actuary regarding the assumptions and methods used in determining loss reserves, actuarial liabilities and related items.

A qualified actuary for the purposes of this application means a member in good standing of the American Academy of Actuaries or a person recognized by the Academy as qualified for membership, or a person who has otherwise demonstrated competency in the field of actuarial determination and is satisfactory to CMS.

B. Financial Plan

1. Plan Content and Coverage

At the time of application, the PDP Sponsor must upload in HPMS on the Part D Financial Solvency Upload page a business plan (with supporting financial projections and assumptions, satisfactory to CMS), covering the first twelve months of operation under the Medicare contract and meeting the requirements stated below. If the plan projects losses, the business plan must cover the period for twelve months past the date of projected break-even.

The business plan must include a financial plan with:

- a) A detailed marketing plan;
- b) Statements of revenue and expense on an accrual basis;
- c) A cash flow statement;
- d) Balance sheets;
- e) The assumptions in support of the financial plan;
- f) If applicable, availability of financial resources to meet projected losses; (if no projected losses this does not preclude applicant from calculating projected losses as prescribed by CMS in 2. b. below)and
- g) Independent actuarial certification of business plan assumptions and plan feasibility by a qualified actuary.

2. Funding for Projected Losses

- a) Allowable sources of funding:

In the financial plan, the PDP Sponsor must demonstrate that it has the resources available to meet the projected losses for the time-period to breakeven. Except for the use of guarantees as provided in section (i) below, letters of credit as provided in section (ii) below, and other means as provided in section (iii) below, the resources must be assets on the balance sheet of the PDP Sponsor in a form that is either cash or is convertible to cash in a timely manner (i.e. cash or cash equivalents), pursuant to the financial plan.

- (i) Guarantees will be acceptable as a resource to meet projected losses under the conditions detailed in Section III, Guarantees.
- (ii) An irrevocable, clean, unconditional, evergreen letter of credit may be used in place of cash or cash equivalents if prior approval is obtained from CMS. It must be issued or confirmed by a qualified United States financial institution as defined in Section II.B, Insolvency, below. The letter of credit shall contain an issue date and expiration date and shall stipulate that the beneficiary need only draw a sight draft under the letter of credit and present it to obtain funds and that no other document need be presented.
 - (a) "Beneficiary" means the PDP sponsor for whose benefit the credit has been established and any successor of the PDP sponsor by operation of law. If a court of law appoints a successor in interest to the named beneficiary, then the named beneficiary includes the court appointed bankruptcy trustee or receiver.
 - (b) The letter of credit also shall indicate that it is not subject to any condition or qualifications any other agreement, documents or entities.

- (c) CMS must be notified in writing thirty days prior to the expiration without renewal or the reduction of a proposed or existing letter of credit or replacement of a letter of credit by one for a reduced amount.
 - (d) Prior written approval of CMS should be secured by the PDP sponsor of any form of proposed letter of credit arrangements before it is concluded for purposes of funding for projected losses.
- (iii) If approved by CMS, based on appropriate standards promulgated by CMS, a PDP sponsor may use the following to fund projected fund losses for periods after the first year: lines of credit from regulated financial institutions, legally binding agreements for capital contributions, or other legally binding contracts of a similar level of reliability.

NOTE: A plan needs to maintain its \$1.5 million in net worth to meet the net worth standard (Section A, above) and may not use any portion of the \$1.5 million in net worth to fund the projected losses. Net worth in excess of \$1.5 million, which is funded through the forms allowable for meeting projected losses (i.e., cash, or cash equivalents,) may be counted in the projected losses funding however the minimum \$750,000 liquidity requirement (Section C, below) must still be met and may not be used to meet the projected losses.

b) Calculation of projected losses:

- (i) An applicant that has had state licensure waived must demonstrate that in order to cover projected losses, the applicant possesses allowable sources of funding sufficient to cover the greater of:
 - (a) 7.5 percent of the aggregated projected target amount for a given year (aggregated projected target amount is calculated by estimating the average monthly per capita cost of benefits (excluding administrative costs) and multiplying that amount by member months for a 12 month period), or
 - (b) Resources to cover 100% of any projected losses, if the business plan projects losses greater than 7.5% of the aggregated projected target amount.
- (ii) The applicant must upload in HPMS with the application, a worksheet calculating the aggregated projected target amount as defined above.
- (iii) Enrollment projections, once submitted to CMS as part of the Applicant's originally submitted financial solvency documentation, may be revised only when accompanied by supporting documentation providing an explanation for the revision along with a revised financial plan. CMS will not accept revisions made solely to ensure that the calculation of required funding for projected losses results in an amount less than or equal to the Applicant's available financial resources. Additionally, the Applicant must upload in HPMS an attestation signed by the CEO, CFO, or an individual designated to sign on his or her behalf and who reports directly to the officer, describing the basis for the changes in enrollment projections (e.g., updated Medicare Part D market analysis information).

C. Liquidity

The PDP Sponsor must have sufficient cash flow to meet its financial obligations as they become due. The amount of minimum net worth requirement to be met by cash or cash equivalents is \$750,000. Cash equivalents are short term highly liquid investments that can be readily converted to cash. To be classified as cash equivalents these investments must have a maturity date not longer than 3 months from the date of purchase

1. In determining the ability of a PDP Sponsor to meet this requirement, CMS will consider the following:
 - a) The timeliness of payment,
 - b) The extent to which the current ratio is maintained at 1:1 or greater, or whether there is a change in the current ratio over a period of time, and
 - c) The availability of outside financial resources.
2. CMS may apply the following corresponding corrective action remedies:
 - a) If the PDP Sponsor fails to pay obligations as they become due, CMS will require the PDP Sponsor to initiate corrective action to pay all overdue obligations.
 - b) CMS may require the PDP Sponsor to initiate corrective action if any of the following are evident:
 - (i) The current ratio declines significantly; or
 - (ii) A continued downward trend in the current ratio. The corrective action may include a change in the distribution of assets, a reduction of liabilities or alternative arrangements to secure additional funding to restore the current ratio to at least 1:1.
3. If there is a change in the availability of the outside resources, CMS will require the PDP Sponsor to obtain funding from alternative financial resources.

D. Methods of Accounting

1. The PDP Sponsor may use the standards of Generally Accepted Accounting Principles (GAAP) or it may use the standards of Statutory Accounting Principles (SAP) applicable to the type of organization it would have been licensed as at the state level if a waiver were not granted by CMS. Whether GAAP or SAP is utilized however, there are certain additional differences cited below for waived PDP Sponsors.
 - a) Generally Accepted Accounting Principles (GAAP) are those accounting principles or practices prescribed or permitted by the Financial Accounting Standards Board.
 - b) Statutory Accounting Principles are those accounting principles or practices prescribed or permitted by the domiciliary State insurance department in the State in which the PDP Sponsor operates.

2. Waivered organizations should note that the maximum period of waiver is limited by Federal regulation. At such time as the waiver expires, the PDP Sponsor would have to obtain a risk bearing license.
3. Waivered PDP Sponsors should adjust their balance sheets as follows:
 - a) Calculation-Assets: The following asset classes will not be admitted as assets:
 - (i) Good will;
 - (ii) Acquisition costs;
 - (iii) Other similar intangible assets.
 - b) Calculation- Liabilities: Net worth means the excess of total admitted assets over total liabilities, but the liabilities shall not include fully subordinated debt.
 - (i) Subordinated debt means an obligation that is owed by an organization, that the creditor of the obligation, by law, agreement, or otherwise, has a lower repayment rank in the hierarchy of creditors than another creditor. The creditor would be entitled to repayment only after all higher ranking creditor's claims have been satisfied. A debt is fully subordinated if it has a lower repayment rank than all other classes of creditors and is payable out of net worth in excess of that required under Section IA, Net Worth and under Section IC, Liquidity above.
 - (ii) In order to be considered fully subordinated debt for the purpose of calculating net worth, the subordinated debt obligation must be a written instrument and include:
 - (a) The effective date, amount, interest and parties involved.
 - (b) The principal sum and/or any interest accrued thereon that are subject to and subordinate to all other liabilities of the PDP sponsor, and upon dissolution or liquidation, no payment of any kind shall be made until all other liabilities of the PDP sponsor have been paid.
 - (c) The instrument states that the parties agree that the PDP sponsor must obtain written approval from CMS prior to the payment of interest or repayment of principal.

E. Financial Indicators and Reporting

1. The PDP Sponsor must upload a Health Blank Form (in the same format as utilized by the National Association of Insurance Commissioners) to CMS. The portion of the Health Blank Form submitted to CMS will be limited to the following pages:
 - a) Jurat Page;
 - b) Assets;
 - c) Liabilities, Capital and Surplus;

- d) Statement of Revenue and Expenses;
 - e) Capital and Surplus Account;
 - f) Cash Flow;
 - g) Actuarial Opinion (the actuarial opinion is required only of annual report filings).
2. In addition, the PDP Sponsor shall submit an annual independently audited financial statement with management letter.
 3. Reporting shall be on the following schedule:
 - a) Quarterly reporting PDP sponsors shall report within 45 days of the close of a calendar quarter ending on the last day of March, June and September. No separate quarterly report shall be required for the final quarter of the year.
 - b) Annually reporting and quarterly reporting PDP sponsors shall report annually within 120 days of the close of the calendar year i.e. by April 30th or within 10 days of the receipt of the annual audited financial statement, whichever is earlier.
 - c) Note: Future frequency of reporting will be both quarterly (first, second, and third quarters only) and annually to CMS. CMS may choose to initiate monthly reporting from certain PDP Sponsors who because of their financial status CMS deems may require additional monitoring.
 4. Financial reporting may be the General Accepted Accounting Principles (GAAP) or under Statutory Accounting Principles (SAP) applicable to similar organizations of similar type within the state where the organization is based. However, if an organization chooses to report under GAAP, it may not report under GAAP for a period longer than 36 months unless a state has chosen to not license such organizations.

II. INSOLVENCY

A. Hold Harmless and Continuation of Coverage/Benefits

PDP Sponsors shall be subject to the same hold harmless and continuation of coverage/benefit requirements as Medicare Advantage contractors.

B. Insolvency Deposit

\$100,000 held in accordance with CMS requirements by a qualified U.S. financial Institution. A qualified U.S. financial institution means an institution that:

1. Is organized or (in the case of a U. S. office of a foreign banking organization) licensed, under the laws of the United States or any state thereof; and
2. Is regulated, supervised and examined by U. S. Federal or State authorities having regulatory authority over banks and trust companies.

III. GUARANTEES

A. General policy.

A PDP Sponsor, or the legal entity of which the PDP Sponsor is a Component, may apply to CMS to use the financial resources of a Guarantor for the purpose of meeting the requirements of a PDP Sponsor. CMS has the discretion to approve or deny approval of the use of a Guarantor.

B. Request to use a Guarantor.

To apply to use the financial resources of a Guarantor, a PDP Sponsor must upload in HPMS:

1. Documentation that the Guarantor meets the requirements for a Guarantor under paragraph (C) of this section; and
2. The Guarantor's independently audited financial statements for the current year-to-date and for the two most recent fiscal years. The financial statements must include the Guarantor's balance sheets, profit and loss statements, and cash flow statements.

C. Requirements for Guarantor.

To serve as a Guarantor, an organization must meet the following requirements:

1. Be a legal entity authorized to conduct business within a State of the United States.
2. Not be under Federal or State bankruptcy or rehabilitation proceedings.
3. Have an adjusted net worth (not including other guarantees, intangibles and restricted reserves) equal to three times the amount of the PDP Sponsor guarantee.
4. If a State insurance commissioner regulates the Guarantor, or other State official with authority for risk-bearing entities, it must meet the adjusted net worth requirement in this document with all guarantees and all investments in and loans to organizations covered by guarantees excluded from its assets.
5. If the Guarantor is not regulated by a State insurance commissioner, or other similar State official it must meet the adjusted net worth requirement in this document with all guarantees and all investments in and loans to organizations covered by a guarantee and to related parties (subsidiaries and affiliates) excluded from its assets and determination of adjusted net worth.

D. Guarantee document.

If the guarantee request is approved, a PDP Sponsor must upload in HPMS a written guarantee document signed by an appropriate Guarantor. The guarantee document must:

1. State the financial obligation covered by the guarantee;
2. Agree to:

- a) Unconditionally fulfill the financial obligation covered by the guarantee; and
 - b) Not subordinate the guarantee to any other claim on the resources of the Guarantor;
3. Declare that the Guarantor must act on a timely basis, in any case not more than 5 business days, to satisfy the financial obligation covered by the guarantee; and
 4. Meet other conditions as CMS may establish from time to time.

E. Reporting requirement.

A PDP Sponsor must submit to CMS the current internal financial statements and annual audited financial statements of the Guarantor according to the schedule, manner, and form that CMS requests.

F. Modification, substitution, and termination of a guarantee.

A PDP Sponsor cannot modify, substitute or terminate a guarantee unless the PDP Sponsor:

1. Requests CMS' approval at least 90 days before the proposed effective date of the modification, substitution, or termination;
2. Demonstrates to CMS' satisfaction that the modification, substitution, or termination will not result in insolvency of the PDP Sponsor; and
3. Demonstrates how the PDP Sponsor will meet the requirements of this section.

G. Nullification.

If at any time the Guarantor or the guarantee ceases to meet the requirements of this section, CMS will notify the PDP Sponsor that it ceases to recognize the guarantee document. In the event of this nullification, a PDP Sponsor must:

1. Meet the applicable requirements of this section within 15 business days; and
2. If required by CMS, meet a portion of the applicable requirements in less than the time period granted in paragraph (G.1.) of this section.

APPENDIX IX – Organization Background and Structure

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

A. Legal Entity Background

Date Legal Entity Established: _____

State of Incorporation

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

B. Experience of Legal Entity

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

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

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

Date

C. Management of Legal Entity

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

Identify all covered persons of the legal entity. "Covered persons", as defined at 42 CFR §§423.507(a)(4), 423.508(f), and 423.510(e)(2), include:

- All owners of nonrenewed or terminated organizations who are natural persons, other than shareholders who have an ownership interest of less than 5 percent;
- An owner of a whole or part interest in a mortgage, deed of trust, note, or other obligation secured (in whole or in part) by the organization, or by any property or assets thereof, which whole or part interest is equal to or exceeds 5 percent of the total property and assets of the organization; and
- A member of the board of directors or board of trustees of the entity, if the organization is organized as a corporation.

D. Parent Organization Information

Name of Parent Organization

Date Parent Organization established

E. Organizational Charts

Provide an organizational chart of the legal entity's parent organization, affiliates, subsidiaries and related entities.

Provide an organizational chart solely of the internal structure of the legal entity by department (e.g., marketing, compliance, pharmacy network/contracting, and claims adjudication). Do not provide the internal structure of the parent organization.

APPENDIX X – Crosswalks of Section 3.1.1E Requirements in Subcontracts submitted as Attachments to Section 3.1.1

Requirement	Citation
The parties to the contract. If the applicant is not a party to the contract, it must be identified as an entity that will benefit from the services described in the contract.	
The functions to be performed by the first tier, downstream, or related entity. Describe the reporting requirements the first tier, downstream, or related entity identified in Section 3.1.1C of the application has to the applicant. 42 CFR §423.505(i)(4)(i)	
Language clearly indicating that the first tier, downstream, or related entity has agreed to participate in your Medicare Prescription Drug Benefit program (except for a network pharmacy if the existing contract would allow participation in this program).	
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. Note: Where the contract is for services or products to be used in preparation for the next contract year's Part D operations (marketing, enrollment), the initial term of such contract must include this period of performance (e.g., contracts for enrollment-related services must have a term beginning no later than October 15 extending through the full contract year ending on December 31 of the next year).	
Are signed by a representative of each party with legal authority to bind the entity.	
Language obligating the first tier, downstream, or related entity to abide by all applicable Federal laws and regulations and CMS instructions. 42 CFR §423.505(i)(4)(iv)	
Language obligating the first tier, downstream, or related entity to abide by State and Federal privacy and security requirements, including the confidentiality and security provisions stated in the regulations for the program at 42 CFR §423.136.	

<p>Language ensuring that the first tier, downstream, or related entity will make its books and other records available in accordance with 42 CFR 423.505(e)(2) and 42 CFR 423.505(i)(2). Generally stated these regulations give HHS, the Comptroller General, or their designees the right to audit, evaluate and inspect any books, contracts, records, including medical records and documentation involving transactions related to CMS' contract with the Part D sponsor and that these rights continue for a period of 10 years from the final date of the contract period or the date of audit completion, whichever is later. 42 CFR §423.505</p>	
<p>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)</p>	
<p>Language ensuring that if the Applicant, upon becoming a Part D sponsor, delegates an activity or responsibility to the first tier, downstream, or related entity, that such activity or responsibility may be revoked if CMS or the Part D sponsor determines the first tier, downstream, or related entity has not performed satisfactorily. Note: The contract/administrative services agreement may include remedies in lieu of revocation to address this requirement. 42 CFR §423.505(i)(4)(ii)</p>	
<p>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)</p>	
<p>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)</p>	
<p>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)</p>	
<p>Language that if the first tier, downstream, or related entity will establish the pharmacy network or select pharmacies to be included in the network and a prescription drug pricing standard is used for reimbursement, identifies the source used by the Part D sponsor for the prescription drug pricing standard of reimbursement. 42 CFR §423.505(i)(3)(viii)(B)</p>	

<p>If the first tier, downstream, or related entity will establish the pharmacy network or select pharmacies to be included in the network, and the source for any prescription drug pricing standard is not publicly available, a provision for disclosing all individual drug prices to be updated to the applicable pharmacies in advance of their use for reimbursement of claims. 42 CFR §423.505(i)(3)(vii).</p>	
<p>If the first tier, downstream, or related entity will establish the pharmacy network or select pharmacies to be included in the network and a prescription drug pricing standard is used for reimbursement, a provision requiring that updates to such a standard occur not less frequently than once every 7 days beginning with an initial update on January 1 of each year, to accurately reflect the market price of acquiring the drug. 42 CFR §423.505(i)(3)(viii)(A)</p>	
<p>If the first tier, downstream, or related entity will establish the pharmacy network or select pharmacies to be included in the network, language requiring the network pharmacies to submit claims to the Part D sponsor or first tier, downstream or related entity whenever the membership ID card is presented or on file at the pharmacy unless the enrollee expressly requests that a particular claim not be submitted. 42 CFR §423.120(c)(3)</p>	
<p>Language that if the first tier, downstream, or related entity will adjudicate and process claims at the point of sale and/or negotiate with prescription drug manufacturers and others for rebates, discounts, or other price concessions on prescription drugs contain language requiring that the first tier, downstream, or related entity will comply with the reporting requirements established in 42 CFR §423.514(d) and (e).</p>	

APPENDIX XI – Crosswalk for Retail Pharmacy Access Contracts

<p>INSTRUCTIONS: Applicants must complete and upload in HPMS the following chart (which contains applicable Section 3.11D requirements AND additional requirements specific to Pharmacy Access) for each Retail pharmacy contract template submitted under Section 3.6. Applicants must identify where <u>specifically</u> (i.e., the .pdf page number) in each contract template the following elements are found.</p>	
<p>The provisions listed below must be in all pharmacy contracts. If contracts reference policies and procedures to which the pharmacy must comply, provide the relevant documentation as evidence and cite this documentation accordingly.</p>	
Requirement	Citation
The functions to be performed by the first tier, downstream, or related entity. Describes the reporting requirements the first tier, downstream, or related entity identified in Section 3.1.1C of the application has to the Applicant. 42 CFR §423.505(i)(4)(i)	
Language obligating the first tier, downstream, or related entity to abide by all applicable Federal laws and regulations and CMS instructions. 42 CFR §423.505(i)(4)(iv)	
Language obligating the first tier, downstream, or related entity to abide by State and Federal privacy and security requirements, including the confidentiality and security provisions stated in the regulations for the program at 42 CFR §423.136.	
Language ensuring that the first tier, downstream, or related entity will make its books and other records available in accordance with 42 CFR 423.505(e)(2) and 42 CFR 423.505(i)(2). Generally stated these regulations give HHS, the Comptroller General, or their designees the right to audit, evaluate and inspect any books, contracts, records, including medical records and documentation involving transactions related to CMS' contract with the Part D sponsor and that these rights continue for a period of 10 years from the final date of the contract period or the date of audit completion, whichever is later. 42 CFR §423.505	
Language stating that the first tier, downstream, or related entity will ensure that beneficiaries are not held liable for fees that are the responsibility of the Applicant. 42 CFR §423.505(i)(3)(i)	

Language ensuring that if the Applicant, upon becoming a Part D sponsor, delegates an activity or responsibility to the first tier, downstream, or related entity, that such activity or responsibility may be revoked if CMS or the Part D sponsor determines the first tier, downstream, or related entity has not performed satisfactorily. Note: The contract 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)	
Provisions requiring that payment shall be issued, mailed or otherwise transmitted with respect to all clean claims submitted by or on behalf of pharmacies within 14 days for electronic claims and within 30 days for claims submitted otherwise. 42 CFR §423.505(i)(3)(vi)	
For those contracts that use a prescription drug pricing standard for reimbursement, a provision indicating the source used by the Part D sponsor for the prescription drug pricing standard of reimbursement. 42 CFR §423.505(i)(3)(viii)(B)	
If the source for any prescription drug pricing standard is not publicly available, a provision for disclosing all individual drug prices to be updated to the applicable pharmacies in advance of their use for reimbursement of claims. 42 CFR §423.505(i)(3)(vii).	
For those contracts that use a prescription drug pricing standard for reimbursement, a provision that updates to such a standard occur not less frequently than once every 7 days beginning with an initial update on January 1 of each year, to accurately reflect the market price of acquiring the drug.42 CFR §423.505(i)(3)(viii)(A)	
Language requiring the network pharmacy to submit claims to the 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	
Provisions governing informing the Part D enrollee at the point of sale (or at the point of delivery for mail order drugs) of the lowest-priced, generically equivalent drug, if one exists for the beneficiary's prescription, as well as any associated differential in price. 42 CFR §423.132	

APPENDIX XII – Crosswalk for Mail Order Pharmacy Access Contracts

<p>INSTRUCTIONS: Applicants must complete and upload in HPMS the following chart (which contains applicable Section 3.1.1D requirements AND additional requirements specific to Pharmacy Access) for each Mail Order pharmacy contract template submitted under Section 3.8. Applicants must identify where <u>specifically</u> (i.e., the .pdf page number) in each contract template the following elements are found.</p>	
<p>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.</p>	
Requirement	Citation
The functions to be performed by the first tier, downstream, or related entity, and describes the reporting requirements the first tier, downstream, or related entity identified in Section 3.1.1C of the application has to the Applicant. 42 CFR §423.505(i)(4)(i)	
Language obligating the first tier, downstream, or related entity to abide by all applicable Federal laws and regulations and CMS instructions. 42 CFR §423.505(i)(4)(iv)	
Language obligating the first tier, downstream, or related entity to abide by State and Federal privacy and security requirements, including the confidentiality and security provisions stated in the regulations for the program at 42 CFR §423.136.	
Language ensuring that the first tier, downstream, or related entity will make its books and other records available in accordance with 42 CFR 423.505(e)(2) and 42 CFR 423.505(i)(2). Generally stated these regulations give HHS, the Comptroller General, or their designees the right to audit, evaluate and inspect any books, contracts, records, including medical records and documentation involving transactions related to CMS' contract with the Part D sponsor and that these rights continue for a period of 10 years from the final date of the contract period or the date of audit completion, whichever is later. 42 CFR §423.505	
Language stating that the first tier, downstream, or related entity will ensure that beneficiaries are not held liable for fees that are the responsibility of the Applicant. 42 CFR §423.505(i)(3)(i)	

Language ensuring that if the Applicant, upon becoming a Part D sponsor, delegates an activity or responsibility to the first tier, downstream, or related entity, that such activity or responsibility may be revoked if CMS or the Part D sponsor determines the first tier, downstream, or related entity has not performed satisfactorily. Note: The contract may include remedies in lieu of revocation to address this requirement. 42 CFR §423.505(i)(4)(ii)	
Language specifying that the Applicant, upon becoming a Part D sponsor, will monitor the performance of the first tier, downstream, or related entity on an ongoing basis. 42 CFR §423.505(i)(4)(iii)	
For those contracts that use a prescription drug pricing standard for reimbursement, a provision indicating the source used by the Part D sponsor for the prescription drug pricing standard of reimbursement. 42 CFR §423.505(i)(3)(viii)(B)	
If the source for any prescription drug pricing standard is not publicly available, a provision for disclosing all individual drug prices to be updated to the applicable pharmacies in advance of their use for reimbursement of claims. 42 CFR §423.505(i)(3)(vii).	
For those contracts that use a prescription drug pricing standard for reimbursement, a provision that updates to such a standard occur not less frequently than once every 7 days beginning with an initial update on January 1 of each year, to accurately reflect the market price of acquiring the drug.42 CFR §423.505(i)(3)(viii)(A)	
Language requiring the network pharmacy to submit claims to the 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	

Provisions governing informing the Part D enrollee at the point of sale (or at the point of delivery for mail order drugs) of the lowest-priced, generically equivalent drug, if one exists for the beneficiary's prescription, as well as any associated differential in price. 42 CFR §423.132	
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APPENDIX XIII – Crosswalk for Home Infusion Pharmacy Access Contracts

<p>INSTRUCTIONS: Applicants must complete and upload in HPMS the following chart (which contains applicable Section 3.1.1D requirements AND additional requirements specific to Pharmacy Access) for each Home Infusion pharmacy contract template submitted under Section 3.9. Applicants must identify where <u>specifically</u> (i.e., the .pdf page number) in each contract template the following elements are found.</p>	
<p>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.</p>	
Requirement	Citation
The functions to be performed by the first tier, downstream, or related entity, and describes the reporting requirements the first tier, downstream, or related entity identified in Section 3.1.1C of the application has to the Applicant. 42 CFR §423.505(i)(4)(i)	
Language obligating the first tier, downstream, or related entity to abide by all applicable Federal laws and regulations and CMS instructions. 42 CFR §423.505(i)(4)(iv)	
Language obligating the first tier, downstream, or related entity to abide by State and Federal privacy and security requirements, including the confidentiality and security provisions stated in the regulations for the program at 42 CFR §423.136.	
Language ensuring that the first tier, downstream, or related entity will make its books and other records available in accordance with 42 CFR 423.505(e)(2) and 42 CFR 423.505(i)(2). Generally stated these regulations give HHS, the Comptroller General, or their designees the right to audit, evaluate and inspect any books, contracts, records, including medical records and documentation involving transactions related to CMS' contract with the Part D sponsor and that these rights continue for a period of 10 years from the final date of the contract period or the date of audit completion, whichever is later. 42 CFR §423.505	
Language stating that the first tier, downstream, or related entity will ensure that beneficiaries are not held liable for fees that are the responsibility of the Applicant. 42 CFR §423.505(i)(3)(i)	

Language ensuring that if the Applicant, upon becoming a Part D sponsor, delegates an activity or responsibility to the first tier, downstream, or related entity, that such activity or responsibility may be revoked if CMS or the Part D sponsor determines the first tier, downstream, or related entity has not performed satisfactorily. Note: The contract 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)	
Provisions requiring that payment shall be issued, mailed or otherwise transmitted with respect to all clean claims submitted by or on behalf of pharmacies within 14 days for electronic claims and within 30 days for claims submitted otherwise. 42 CFR §423.505(i)(3)(vi)	
For those contracts that use a standard for reimbursement, a provision indicating the source used by the Part D sponsor for the standard of reimbursement. 42 CFR §423.505(i)(3)(viii)(B)	
If the source for any prescription drug pricing standard is not publicly available, a provision for disclosing all individual drug prices to be updated to the applicable pharmacies in advance of their use for reimbursement of claims. 42 CFR §423.505(i)(3)(vii).	
For those contracts that use a standard for reimbursement, a provision that updates to such a standard occur not less frequently than once every 7 days beginning with an initial update on January 1 of each year, to accurately reflect the market price of acquiring the drug.42 CFR §423.505(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	
Provisions governing informing the Part D enrollee at the point of sale (or at the point of delivery for mail order drugs) of the lowest-priced, generically equivalent drug, if one exists for the beneficiary's prescription, as well as any associated differential in price. 42 CFR §423.132	
Provisions ensuring that before dispensing home infusion drugs, pharmacy ensures that the professional services and ancillary supplies are in place.423.120(a)(4)(iii)	
Provisions ensuring that a pharmacy that delivers home infusion drugs provides delivery of home infusion drugs within 24 hours of discharge from an acute care setting, or later if so prescribed. 423.120(a)(4)(iv)	

APPENDIX XIV – Crosswalk for Long-Term Care Pharmacy Access Contracts

<p>INSTRUCTIONS: Applicants must complete and upload in HPMS the following chart (which contains applicable Section 3.1.1D requirements AND additional requirements specific to Pharmacy Access) for each Long-Term Care pharmacy contract template submitted under Section 3.10. Applicants must identify where <u>specifically</u> (i.e., the .pdf page number) in each contract template the following elements are found.</p>	
<p>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.</p>	
Requirement	Citation
The functions to be performed by the first tier, downstream, or related entity, and describes the reporting requirements the first tier, downstream, or related entity identified in 3.1.1C of the application has to the Applicant. 42 CFR §423.505(i)(4)(i)	
Language obligating the first tier, downstream, or related entity to abide by all applicable Federal laws and regulations and CMS instructions. 42 CFR §423.505(i)(4)(iv)	
Language obligating the first tier, downstream, or related entity to abide by State and Federal privacy and security requirements, including the confidentiality and security provisions stated in the regulations for the program at 42 CFR §423.136. 42 CFR §423.136	
Language ensuring that the first tier, downstream, or related entity will make its books and other records available in accordance with 42 CFR 423.505(e)(2) and 42 CFR 423.505(i)(2). Generally stated these regulations give HHS, the Comptroller General, or their designees the right to audit, evaluate and inspect any books, contracts, records, including medical records and documentation involving transactions related to CMS' contract with the Part D sponsor and that these rights continue for a period of 10 years from the final date of the contract period or the date of audit completion, whichever is later. 42 CFR §423.505	
Language stating that the first tier, downstream, or related entity will ensure that beneficiaries are not held liable for fees that are the responsibility of the Applicant. 42 CFR §423.505(i)(3)(i)	

Language ensuring that if the Applicant, upon becoming a Part D sponsor, delegates an activity or responsibility to the first tier, downstream, or related entity, that such activity or responsibility may be revoked if CMS or the Part D sponsor determines the first tier, downstream, or related entity has not performed satisfactorily. Note: The contract may include remedies in lieu of revocation to address this requirement. 42 CFR §423.505(i)(4)(ii)	
Language specifying that the Applicant, upon becoming a Part D sponsor, will monitor the performance of the first tier, downstream, or related entity on an ongoing basis. 42 CFR §423.505(i)(4)(iii)	
For those contracts that use a standard for reimbursement, a provision indicating the source used by the Part D sponsor for the standard of reimbursement. 42 CFR §423.505(i)(3)(viii)(B)	
If the source for any prescription drug pricing standard is not publicly available, a provision for disclosing all individual drug prices to be updated to the applicable pharmacies in advance of their use for reimbursement of claims. 42 CFR §423.505(i)(3)(vii).	
For those contracts that use a standard for reimbursement, a provision that updates to such a standard occur not less frequently than once every 7 days beginning with an initial update on January 1 of each year, to accurately reflect the market price of acquiring the drug.42 CFR §423.505(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	
Provisions governing informing the Part D enrollee at the point of sale (or at the point of delivery for mail order drugs) of the lowest-priced, generically equivalent drug, if one exists for the beneficiary's prescription, as well as any associated differential in price. 42 CFR §423.132	

Provide that long-term care pharmacies must have not less than 30 days, nor more than 90 days, to submit to the Part D Sponsor claims for reimbursement under the plan. 42 CFR § 423.504(b)(20)	
Provisions requiring that long-term care pharmacies dispense drugs and report information as required by 42 CFR §423.154.	
<p>Elements Specific to Long-Term Care Contracts</p> <p>Note: CMS Long-Term Care Guidance included in Chapter 5 of the Prescription Drug Benefit Manual contains an updated list of performance and service criteria for contracting with long-term care pharmacies. Applicants must, at a minimum, incorporate these criteria in ALL LTC pharmacy network contracts.</p>	
Performance and Service Criteria	Citation
<p><i>Comprehensive Inventory and Inventory Capacity</i> – 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.</p>	
<p><i>Pharmacy Operations and Prescription Orders</i> -- NLTCPs must provide services of a dispensing pharmacist to meet the requirements of pharmacy practice for dispensing prescription drugs to LTC residents, including but not limited to the performance of drug utilization review (DUR). In addition, the NLTCP pharmacist must conduct DUR to routinely screen for allergies and drug interactions, to identify potential adverse drug reactions, to identify inappropriate drug usage in the LTC population, and to promote cost effective therapy in the LTC setting. The NLTCP must also be equipped with pharmacy software and systems sufficient to meet the needs of prescription drug ordering and distribution to an LTC facility. Further, the NLTCP must provide written copies of the NLTCP's pharmacy procedures manual and said manual must be available at each LTC facility nurses' unit. NLTCPs are also required to provide ongoing in-service training to assure that LTC facility staff is proficient in the NLTCP's processes for ordering and receiving of medications. NLTCP must be responsible for return and/or disposal of unused medications following discontinuance, transfer, discharge, or death as permitted by State Boards of Pharmacy. Controlled substances and out of date substances must be disposed of within State and Federal guidelines.</p>	

<p><i>Special Packaging</i> -- 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.</p>	
<p><i>IV Medications</i> -- 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.</p>	
<p><i>Compounding /Alternative Forms of Drug Composition</i> -- 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.</p>	
<p><i>Pharmacist On-call Service</i> -- 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.</p>	
<p><i>Delivery Service</i> -- 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”.</p>	
<p><i>Emergency Boxes</i> -- NLTCPs must provide “emergency” supply of medications as required by the facility in compliance with State requirements.</p>	
<p><i>Emergency Log Books</i> -- 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.</p>	

<p><i>Miscellaneous Reports, Forms and Prescription Ordering Supplies</i> -- 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.</p>	
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APPENDIX XV – Crosswalk for Indian Tribe and Tribal Organization, and Urban Indian Organization (I/T/U) Pharmacy Access Contracts

<p>INSTRUCTIONS: Applicants must complete and upload in HPMS the following chart (which contains applicable Section 3.1.1D requirements AND additional requirements specific to Pharmacy Access) for each I/T/U pharmacy contract template submitted under Section 3.11. Applicants must identify where <u>specifically</u> (i.e., the .pdf page number) in each contract template the following elements are found.</p>	
<p>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.</p>	
Requirement	Citation
The functions to be performed by the first tier, downstream, or related entity, and describes the reporting requirements the first tier, downstream, or related entity identified in Section 3.1.1C of the application has to the Applicant. 42 CFR §423.505(i)(4)(i)	
Language obligating the first tier, downstream, or related entity to abide by all applicable Federal laws and regulations and CMS instructions. 42 CFR §423.505(i)(4)(iv)	
Language obligating the first tier, downstream, or related entity to abide by State and Federal privacy and security requirements, including the confidentiality and security provisions stated in the regulations for the program at 42 CFR §423.136.	
Language ensuring that the first tier, downstream, or related entity will make its books and other records available in accordance with 42 CFR 423.505(e)(2) and 42 CFR 423.505(i)(2). Generally stated these regulations give HHS, the Comptroller General, or their designees the right to audit, evaluate and inspect any books, contracts, records, including medical records and documentation involving transactions related to CMS' contract with the Part D sponsor and that these rights continue for a period of 10 years from the final date of the contract period or the date of audit completion, whichever is later. 42 CFR §423.505	
Language stating that the first tier, downstream, or related entity will ensure that beneficiaries are not held liable for fees that are the responsibility of the Applicant. 42 CFR §423.505(i)(3)(i)	

Language ensuring that if the Applicant, upon becoming a Part D sponsor, delegates an activity or responsibility to the first tier, downstream, or related entity, that such activity or responsibility may be revoked if CMS or the Part D sponsor determines the first tier, downstream, or related entity has not performed satisfactorily. Note: The contract 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)	
Provisions requiring that payment shall be issued, mailed or otherwise transmitted with respect to all clean claims submitted by or on behalf of pharmacies within 14 days for electronic claims and within 30 days for claims submitted otherwise. 42 CFR §423.505(i)(3)(vi)	
For those contracts that use a standard for reimbursement, a provision indicating the source used by the Part D sponsor for the standard of reimbursement. 42 CFR §423.505(i)(3)(viii)(B)	
If the source for any prescription drug pricing standard is not publicly available, a provision for disclosing all individual drug prices to be updated to the applicable pharmacies in advance of their use for reimbursement of claims. 42 CFR §423.505(i)(3)(vii).	
For those contracts that use a standard for reimbursement, a provision that updates to such a standard occur not less frequently than once every 7 days beginning with an initial update on January 1 of each year, to accurately reflect the market price of acquiring the drug.42 CFR §423.505(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	

Elements Specific to Indian Tribe and Tribal Organization, and Urban Indian Organization (I/T/U) Pharmacy Contracts

Note: Provisions listed below are in the model I/T/U Addendum, located at Appendix XVII and at <http://www.cms.gov/PrescriptionDrugCovContra/> and all I/T/U Contracts must contain language consistent with the model addendum that addresses the following.

Item 1	Supersession of the addendum from underlying agreement.	
Item 3	The description of the provider.	
Item 4	Counting of costs paid for by provider toward any deductibles.	
Item 5	Persons eligible for services of the provider.	
Item 6	The applicability of certain Federal law.	
Item 7	The non-taxable status of the provider.	
Item 8	Insurance and indemnification.	
Item 9	Applicability of state licensing law to provider's employees.	
Item 10	Provider eligibility for payments	
Item 11	Dispute resolution.	
Item 12	Federal law as the governing law.	
Item 13	The contract will apply to all pharmacies and dispensaries operated by the provider.	
Item 14	The contract will not affect the provider's acquisition of pharmaceuticals.	
Item 15	The provider's point of sale processing capabilities.	
Item 16	Claims processing.	
Item 17	Reasonable and appropriate payment rates.	
Item 18	Any information, outreach or enrollment materials prepared by the Applicant will be supplied at no cost to the provider.	

Item 19	The provider determines the hours of service for the pharmacies or dispensaries of the provider.	
Item 20	Endorsement	
Item 21	Sovereign Immunity	

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

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

I. P&T Committee Member Disclosure to CMS

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

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

II. Instructions to Plans and PBMs

- A.** If the Part D Applicant sub-contracts with a PBM for its P&T Committee and operates under a Confidentiality Agreement (such that its members are not disclosed to the Part D Applicant) then the Applicant must (1) complete the attached Certification in HPMS, and (2) forward the attached P&T Committee Member Disclosure form to the sub-contracted PBM and direct the PBM to submit the form to CMS by February 18, 2015. The PBM should email the P&T Committee Member Disclosure form to the following email box: PartD_Applications@cms.hhs.gov.
- B.** In the event of any future changes to the membership of the Part D Sponsor's P&T Committee or the PBM's P&T Committee, Part D Sponsors must (or in the case of a confidentiality agreement the Part D Sponsor) assure that the PBM will notify the appropriate CMS account manager (to be assigned at a future date) and make the

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

III. PHARMACY AND THERAPEUTICS COMMITTEE MEMBER DISCLOSURE

PBM must email the following form to PartD_Applications@cms.hhs.gov by February 18, 2015.

Name of Part D Plan or PBM: _____

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

Contact Person: _____

Phone Number: _____

Email: _____

A. Complete the table below.

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

	Practice/Expertise <i>Mark an 'X' in Appropriate Column</i>			Free of Any Conflict of Interest <i>Type Yes or No</i>	
	Practicing Physician	Practicing Pharmacist	Elderly/Disabled Expert	With Your Organization?	With Pharmaceutical Manufacturers?
Full Name of Member					
Start Date and End Date					

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

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

Organization Name	Type of Application	Contract Number(s)

Applicant must upload in HPMS:

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

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

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

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

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

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

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

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

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

Part D Applicant's Contract Number: _____

Authorized Representative Name (printed)

Title

Authorized Representative Signature

Date (MM/DD/YYYY)

APPENDIX XVII – I/T/U Contract Addendum

Note: All Part D sponsors will be required to use the attached revised version of the I/T/U Addendum.

Indian Health Addendum to Medicare Part D Plan Agreement

1. Purpose of Indian Health Addendum; Supersession.

The purpose of this Indian Health Addendum is to apply special terms and conditions to the agreement by and between _____ (herein "Part D Sponsor") and _____ (herein "Provider") for administration of Medicare Prescription Drug Benefit program at pharmacies and dispensaries of Provider authorized by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, and implementing regulations in Parts 403, 411, 417, 422, and 423 of Title 42, Code of Federal Regulations. To the extent that any provision of the Part D Sponsor's agreement or any other addendum thereto is inconsistent with any provision of this Indian Health Addendum, the provisions of this Indian Health Addendum shall supersede all such other provisions.

2. Definitions.

For purposes of the Part D Plan Sponsor's agreement, any other addendum thereto, and this Indian Health Addendum, the following terms and definitions shall apply:

(a) The term "Part D Plan Sponsor" means a nongovernmental entity that is certified under 42 CFR 417.472, 42 CFR Part 423 or 42 CFR Part 422 as meeting the requirements and standards that apply to entities that offer Medicare Part D plans.

(b) The terms "Part D Plan" means prescription drug coverage that is offered under a policy, contract, or plan that has been approved as specified in 42 CFR 423.272, 42 CFR 422.502 or 42 CFR 417.472 and that is offered by a PDP sponsor that has a contract with the Centers for Medicare and Medicaid Services that meets the contract requirements under subpart K of 42 CFR Part 423 or subpart K of 42 CFR Part 422.

(c) The term "Provider" means the Indian Health Service (IHS) and all pharmacies and dispensaries operated by the IHS, or an Indian tribe, tribal organization or urban Indian organization which operates one or more pharmacies or dispensaries, and is identified by name in Section 1 of this Indian Health Addendum.

(d) The term "Centers for Medicare and Medicaid Services" means the agency of that name within the U.S. Department of Health and Human Services.

(e) The term "Indian Health Service" means the agency of that name within the U.S. Department of Health and Human Services established by Sec. 601 of the Indian Health Care Improvement Act ("IHCA"), 25 USC §1661.

(f) The term "Indian tribe" has the meaning given that term in Sec. 4 of the IHCA, 25 USC §1603.

(g) The term "tribal organization" has the meaning given than term in Sec. 4 of the IHCIA, 25 USC §1603.

(h) The term "urban Indian organization" has the meaning given that term in Sec. 4 of the IHCIA, 25 USC §1603.

(i) The term "Indian" has the meaning given to that term in Sec. 4 of the IHCIA, 25 USC §1603.

(j) The term "dispensary" means a clinic where medicine is dispensed by a prescribing provider.

3. Description of Provider.

The Provider identified in Section 1 of this Indian Health Addendum is (check appropriate box):

IHS operated health care facilities located within the geographic area covered by the Provider Agreement, including hospitals, health centers and one or more pharmacies or dispensaries ("IHS Provider"). Where an IHS Provider operates more than one pharmacy or dispensary all such pharmacies and dispensaries are covered by this Addendum.

An Indian tribe that operates a health program, including one or more pharmacies or dispensaries, under a contract or compact with the Indian Health Service issued pursuant to the Indian Self-Determination and Education Assistance Act, 25 USC §450 *et seq.*

A tribal organization authorized by one or more Indian tribes to operate a health program, including one or more pharmacies or dispensaries, under a contract or compact with the Indian Health Service issued pursuant to the Indian Self-Determination and Education Assistance Act, 25 USC §450 *et seq.*

An urban Indian organization that operates a health program, including one or more pharmacies or dispensaries, under a grant from the Indian Health Service issued pursuant to Title V of the IHCIA.

4. Deductibles; Annual Out-of-Pocket Threshold.

The cost of pharmaceuticals provided at a pharmacy or dispensary of Provider or paid for by the Provider through a referral to a retail pharmacy shall count toward the deductible and the annual out-of-pocket threshold applicable to an IHS beneficiary enrolled in a Part D Plan.

5. Persons eligible for services of Provider.

(a) The parties agree that the IHS Provider is limited to serving eligible IHS beneficiaries pursuant to 42 CFR Part 136 and section 813(a) and (b) of the IHCIA, 25 USC §1680(a) and (b), who are also eligible for Medicare Part D services pursuant to Title XVIII, Part D of the Social Security Act and 42 CFR Part 423. The IHS Provider

may provide services to non-IHS eligible persons only under certain circumstances set forth in IHCIA section 813(c) and in emergencies under section 813(d) of the IHCIA.

(b) The parties agree that the persons eligible for services of the Provider who is an Indian tribe or a tribal organization or a Provider who is an urban Indian organization shall be governed by the following authorities:

- (1) Title XVIII, Part D of the Social Security Act and 42 CFR Part 423;
- (2) IHCIA sections 813, 25 USC §1680c;
- (3) 42 CFR Part 136; and
- (4) The terms of the contract, compact or grant issued to the Provider by the IHS for operation of a health program.

(c) No clause, term or condition of the Part D Plan Sponsor's agreement or any addendum thereto shall be construed to change, reduce, expand or alter the eligibility of persons for services of the Provider under the Part D Plan that is inconsistent with the authorities identified in subsection (a) or (b).

6. Applicability of other Federal laws.

Federal laws and regulations affecting a Provider include but are not limited to the following:

- (a) An IHS provider:
 - (1) The Anti-Deficiency Act 31 U.S.C. § 1341;
 - (2) The Indian Self Determination and Education Assistance Act ("ISDEAA"); 25 USC § 450 *et seq.*;
 - (3) The Federal Tort Claims Act ("FTCA"), 28 U.S.C. § 2671-2680;
 - (4) The Federal Medical Care Recovery Act, 42 U.S.C. §§ 2651-2653;
 - (5) The Federal Privacy Act of 1974 ("Privacy Act"), 5 U.S.C. § 552a, 45 CFR Part 5b;
 - (6) Confidentiality of Alcohol and Drug Abuse Patient Records, 42 CFR Part 2;
 - (7) The Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), 45 CFR Parts 160 and 164; and
 - (8) The IHCIA, 25 U.S.C. § 1601 *et seq.*
- (b) A Provider who is an Indian tribe or a tribal organization:
 - (1) The ISDEAA, 25 USC §450 *et seq.*;
 - (2) The IHCIA, 25 USC §1601, *et seq.*;
 - (3) The FTCA, 28 USC §§2671-2680;
 - (4) The Privacy Act, 5 USC §552a and regulations at 45 CFR Part 5b;

- (5) The HIPAA and regulations at 45 CFR parts 160 and 164; and
- (6) Sec. 206(e)(3) of the IH CIA, 25 USC § 1624e(e)(3), regarding recovery from tortfeasors.

(c) A Provider who is an urban Indian organization:

- (1) The IH CIA, 25 USC §1601, *et seq.*;
- (2) The Privacy Act, 5 USC §552a and regulations at 45 CFR Part 5b;
- (3) The HIPAA and regulations at 45 CFR parts 160 and 164; and
- (4) Sec. 206(e)(3) of the IH CIA, 25 USC §1621e(e)(3), regarding recovery from tortfeasors, as made applicable to urban Indian organizations by Sec. 206(i) of the IH CIA.

7. Non-taxable entity.

To the extent the Provider is a non-taxable entity, the Provider shall not be required by a Part D Plan Sponsor to collect or remit any Federal, State, or local tax.

8. Insurance and indemnification.

(a) As an IHS provider, FTCA coverage obviates the requirement that IHS carry private malpractice insurance as the United States consents to be sued in place of federal employees for any damages to property or for personal injury or death caused by the negligence or wrongful act or omission of federal employees acting within the scope of their employment. 28 U.S.C. § 2671-2680. Nothing in the Part D Plan Sponsor's Agreement shall be interpreted to authorize or obligate any IHS employee to perform any act outside the scope of his/her employment. The IHS Provider shall not be required to acquire insurance, provide indemnification, or guarantee that the Plan will be held harmless from liability.

(b) A Provider which is an Indian tribe or a tribal organization shall not be required to obtain or maintain professional liability insurance to the extent such Provider is covered by the Federal Tort Claims Act (FTCA) pursuant to Federal law (Pub.L. 101-512, Title III, §314, as amended by Pub.L. 103-138, Title III, §308 (codified at 25 USC §450 F note); and regulations at 25 CFR Part 900, Subpt. M. To the extent a Provider that is an urban Indian organization is covered by the FTCA pursuant to section 224(g)-(n) of the Public Health Service Act, as amended by the Federally Supported Health Centers Assistance Act, Pub.L. 104-73, (codified at 42 USC §233(g)-(n)) and regulations at 42 CFR Part 6, such Provider shall not be required to obtain or maintain professional liability insurance. Further, nothing in the Part D Plan Sponsor's agreement or any addendum thereto shall be interpreted to authorize or obligate Provider or any employee of such Provider to operate outside of the scope of employment of such employee, and Provider shall not be required to indemnify the Part D Plan Sponsor.

9. Licensure.

(a) States may not regulate the activities of IHS-operated pharmacies nor require that the IHS pharmacists be licensed in the State where they are providing services, whether the IHS employee is working at an IHS-operated facility or has been assigned to a pharmacy or dispensary of a tribe, tribal organization, or urban Indian organization. The parties agree that during the term of the Part D Plan Sponsor's Agreement, IHS pharmacists shall hold state licenses in accordance with applicable federal law, and that the IHS facilities where the pharmacies and dispensaries are located shall be accredited in accordance with federal statutes and regulations. During the term of the Part D Plan Sponsor's Agreement, the parties agree to use the IHS facility's Drug Enforcement Agency (DEA) number consistent with federal law.

(b) Federal law (Sec. 221 of the IHClA) provides that a pharmacist employed directly by a Provider that is an Indian tribe or tribal organization is exempt from the licensing requirements of the state in which the tribal health program is located, provided the pharmacist is licensed in any state. Federal law (Sec. 408 of the IHClA) further provides that a health program operated by an Indian tribe or tribal organization shall be deemed to have met a requirement for a license under state or local law if such program meets all the applicable standards for such licensure, regardless of whether the entity obtains a license or other documentation under such state or local law. The parties agree that these federal laws apply to the Part D Plan Sponsor's Agreement and any addenda thereto. This provision shall not be interpreted to alter the requirement that a pharmacy hold a license from the Drug Enforcement Agency.

(c) To the extent that any directly hired employee of an urban Indian Provider is exempt from State regulation, such employee shall be deemed qualified to perform services under the Part D Plan Sponsor's agreement and all addenda thereto, provided such employee is licensed to practice pharmacy in any State. Federal law (Sec. 408 of the IHClA) provides that a health program operated by an urban Indian organization shall be deemed to have met a requirement for a license under state or local law if such program meets all the applicable standards for such licensure, regardless of whether the entity obtains a license or other documentation under such state or local law. This provision shall not be interpreted to alter the requirement that a pharmacy hold a license from the Drug Enforcement Agency.

10. Provider eligibility for payments.

To the extent that the Provider is exempt from State licensing requirements, the Provider shall not be required to hold a State license to receive any payments under the Part D Plan Sponsor's agreement and any addendum thereto.

11. Dispute Resolution.

a. For IHS Provider. In the event of any dispute arising under the Participating Part D Plan Sponsor's Agreement or any addendum thereto, the parties agree to meet and confer in good faith to resolve any such disputes. The laws of the United States shall apply to any problem or dispute hereunder that cannot be resolved by and

between the parties in good faith. Notwithstanding any provision in the Part D Plan Sponsor's Agreement or any addendum thereto to the contrary, IHS shall not be required to submit any disputes between the parties to binding arbitration.

b. For Tribal and Urban Providers. In the event of any dispute arising under the Participating Part D Plan Sponsor's Agreement or any addendum thereto, the parties agree to meet and confer in good faith to resolve any such disputes. Any dispute hereunder that cannot be resolved by and between the parties in good faith shall be submitted to the dispute resolution procedure pursuant to the Participating Part D Plan Sponsor's Agreement.

12. Governing Law.

The Part D Plan Sponsor's agreement and all addenda thereto shall be governed and construed in accordance with Federal law of the United States. In the event of a conflict between such agreement and all addenda thereto and Federal law, Federal law shall prevail. Nothing in the Part D Plan Sponsor's agreement or any addendum thereto shall subject an Indian tribe, tribal organization, or urban Indian organization to State law to any greater extent than State law is already applicable.

13. Pharmacy/Dispensary Participation.

The Part D Plan Sponsor's agreement and all addenda thereto apply to all pharmacies and dispensaries operated by the Provider, as listed on the attached Schedule ----- to this Indian Health Addendum. A pharmacy is required to use a National Provider Identifier (NPI) number.

14. Acquisition of Pharmaceuticals.

Nothing in the Part D Plan Sponsor's agreement and all addenda thereto shall affect the Provider's acquisition of pharmaceuticals from any source, including the Federal Supply Schedule and participation in the Drug Pricing Program of Section 340B of the Public Health Service Act. Nor shall anything in such agreement and all addenda thereto require the Provider to acquire drugs from the Part D Plan Sponsor or from any other source.

15. Drug Utilization Review/Generic Equivalent Substitution.

Where the Provider lacks the capacity to comply with the information technology requirements for drug utilization review and/or generic equivalent substitution set forth in the Part D Plan Sponsor's agreement, the Provider and Part D Plan Sponsor agree that the Provider shall comply with the Part D Plan Sponsor's drug utilization review and/or generic equivalent substitution policies and procedures through an alternative method. Nothing in this paragraph shall be interpreted as waiving the applicability of the drug utilization review and/or generic equivalent substitution policies and procedures adopted by Part D sponsor in accordance with 42 C.F.R. §§ 423.153(b) and (c), as

approved by CMS, to covered Part D drugs dispensed by the Provider to enrollees in the Part D Plan[s]. As specified at 42 C.F.R. §423.132(c)(3), the requirements related to notification of price differentials is waived for the Provider .

16. Claims.

The Provider may submit claims to the Part D Plan by telecommunication through an electronic billing system or by calling a toll-free number for non-electronic claims; in the case of the latter, Provider shall submit a confirmation paper claim.

17. Payment Rate.

Claims from the provider shall be paid at rates that are reasonable and appropriate.

18. Information, Outreach, and Enrollment Materials.

(a) All materials for information, outreach, or enrollment prepared for the Part D Plan shall be supplied by the Part D Plan Sponsor to Provider in paper and electronic format at no cost to the Provider.

(b) All marketing or informational material listing a provider as a pharmacy must refer to the special eligibility requirements necessary for service to be provided, consistent with the eligibility requirements as described in this Indian health addendum in paragraphs 5(a) for IHS providers and 5(b) for tribal and urban providers.

19. Hours of Service.

The hours of service of the pharmacies or dispensaries of Provider shall be established by Provider. At the request of the Part D Plan Sponsor, Provider shall provide written notification of its hours of service.

20. Endorsement

An endorsement of a non-Federal entity, event, product, service, or enterprise may be neither stated nor implied by the IHS provider or IHS employees in their official capacities and titles. Such agency names and positions may not be used to suggest official endorsement or preferential treatment of any non-Federal entity under this agreement.

21. Sovereign Immunity

Nothing in the Part D Plan Sponsor's Agreement or in any addendum thereto shall constitute a waiver of federal or tribal sovereign immunity.

Signature of Authorized Representative

Printed Name of Authorized Representative

Title of Authorized Representative

APPENDIX XVIII – Compliance Program Crosswalk

<p>INSTRUCTIONS: Applicants must complete and upload in HPMS the following chart, which contains the required elements for a Compliance Plan. Applicant must identify <u>specifically</u> (i.e., the .pdf page number) where in its compliance plan the following elements are located.</p>	
Compliance Plan Elements	Page and paragraph where element located
A. Applicant’s legal entity name	
B. Explicit statement indicating that the compliance plan applies to Medicare Part D (and Part C if an MA-PD applicant)	
C. Written policies, procedures, and standards of conduct must include the following components in 42 CFR §423.504(b)(4)(vi)(A):	
1. Articulate the applicant’s commitment to comply with <u>all applicable Federal and State standards</u> .	
2. Describe compliance expectations as embodied in the standards of conduct.	
3. Describe the implementation and operation of the compliance program.	
4. Provide guidance to employees and others on dealing with potential compliance issues.	
5. Identify how to communicate compliance issues to appropriate compliance personnel.	
6. Describe how potential compliance issues will be investigated and resolved by the applicant.	
7. Include a policy of non-intimidation and non-retaliation for good faith participation in the compliance program, including, but not limited to, reporting potential issues, investigating issues, conducting self-evaluations, audits and remedial actions, and reporting to appropriate officials.	
D. Measures that prevent, detect, and correct fraud, waste, and abuse. (42 CFR § 423.504(b)(4)(vi))	

<p>E. Measures that prevent, detect, and correct noncompliance with CMS' program requirements. (42 CFR § 423.504(b)(4)(vi))</p>	
<p>F. Designate a compliance officer and a compliance committee who report directly to and are accountable to applicant's chief executive or senior management and include the following three components in 42 CFR §423.504(b)(4)(vi)(B):</p>	
<p>1. The compliance officer, vested with the day-to-day operations of the compliance program, <u>must be an employee</u> of the applicant, parent organization or corporate affiliate. The compliance officer may not be an employee of the applicant's first tier, downstream or related entity.</p>	
<p>2. The compliance officer and the compliance committee must periodically report directly to the governing body of the applicant on the activities and status of the compliance program, including issues identified, investigated, and resolved by the compliance program.</p>	
<p>3. The governing body of the applicant must be knowledgeable about the content and operation of the compliance program and must exercise reasonable oversight with respect to the implementation and effectiveness of the compliance programs.</p>	
<p>G. Establish, implement and provide effective training and education for employees including the chief executive and senior administrators or managers, governing body members, first tier, downstream, and related entities must include the following components in 42 CFR § 423.504(b) (4)(vi)(C):</p>	
<p>1. Training and education must occur at least annually and must be part of the orientation for new employees, including the chief executive and senior administrators or managers; governing body members; and first tier, downstream and related entities,</p>	
<p>2. An indication that first tier, downstream, and related entities who have met the fraud, waste, and abuse certification requirements through enrollment into the Medicare program or accreditation as a Durable Medical Equipment, Prosthetics, Orthotics, and supplies (DMEPOS) are deemed to have met the training and educational requirements for fraud, waste, and abuse.</p>	

H. Establish and implement effective lines of communication, ensuring confidentiality, as described in in 42 CFR § 423.504(b) (4)(vi)(D):	
1. The compliance officer, members of the compliance committee, the applicant's employees, managers and governing body.	
2. The applicant's first tier, downstream, and related entities.	
3. The lines of communication (e.g, free telephone hotlines) must be accessible to all, including first tier, downstream, and related entities.	
4. Include a method for anonymous and confidential good faith reporting of potential compliance issues, as they are identified.	
I. Well-publicized disciplinary standards and implementation of procedures, which encourage good faith participation in the compliance program by all individuals. These standards must include the following policies per 42 CFR § 423.504(b) (4)(vi)(E):	
1. Expectations for reporting compliance issues and assisting in their resolution.	
2. Identify non-compliant or unethical behavior.	
3. Provide for timely, consistent, and effective enforcement of the standards when noncompliance or unethical behavior is determined.	
J. Establish and implement an effective system for routine monitoring and identification of compliance risks. The system should include: internal monitoring and audits and, as appropriate, external audits, to evaluate the applicant, including first tier entities', compliance with CMS requirements and the overall effectiveness of the compliance program. 42 CFR § 423.504(b) (4)(vi)(F)	
K. Establish and implement procedures and a system for promptly responding to compliance issues as they are raised, investigating potential compliance problems identified in the course of self-evaluations and audits, correcting such problems promptly and thoroughly to reduce the potential for recurrence, and ensure ongoing compliance with CMS requirements. The procedures must include the following components per 42 CFR § 423.504(b) (4)(vi)(G):	

1. If the applicant discovers evidence of misconduct related to payment or delivery of items or services under the contract, it must conduct a timely, reasonable inquiry into that conduct.	
2. The applicant must conduct appropriate corrective actions (e.g., repayment of overpayments and disciplinary actions against responsible individuals) in response to a potential violation of item 1, above.	
3. The applicant should have procedures to voluntarily self-report potential fraud or misconduct related to the Medicare program to CMS or its designee.	