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Summary of Substantive and Technical Changes for All Part D Application Revisions from 2011 Version of Part D Application to 2012 Draft Version

SUBSTANTIVE CHANGES						
Clarification	**Purpose of the Clarification**	**Application**				
		PDP	**MA-PD**	**Cost**	**PACE**	**Change in Burden**
GENERAL INFORMATION and INSTRUCTIONS						
1. Revise general instructions to indicate compliance with attestations is at the point of the application due date. **Further clarified this requirement.**	Changes the timeframe for compliance with the general attestations to be at the time of application submission instead of at the time of entering into a contract with CMS. This is to ensure that applying organizations have the infrastructure and system capabilities required to become Part D sponsors.	2.4.1; Throughout the application **2.4.1**	2.4.1; Throughout the application **2.4.1**	2.4.1; Throughout the application **2.4.1**	Throughout the application **2.4.1**	N/A
2. Revised retail pharmacy access section.	CMS is streamlining the process for reviewing retail pharmacy access by requiring less documentation from the applicants. This section summarizes at a high level the change, including clarifying information about service areas in HPMS compared to access reports provided by the applicants. **CMS provides additional information regarding the methodology used in retail access geo-coding.**	2.8.1	2.8.1	2.8.1	N/A	N/A
3. Revised "Summary of Sponsor Role and Responsibilities".	**Added language regarding discounts for applicable brand drugs to the responsibilities for administering the Part D benefit**	**1.5**	**1.5**	**1.5**	**N/A**	**N/A**
APPLICANT EXPERIENCE, CONTRACTS, LICENSURE AND FINANCIAL STABILITY						
MANAGEMENT AND OPERATIONS						
4. Amend the instructions for submitting information	In an effort to improve the documentation provided under this	3.1.1B	3.1.1B	3.1.1B	N/A	N/A

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about the organization history and structure.	section, CMS has deleted the general instructions and provided a new template for Applicants to complete. This provides applicants with definitive questions to answer related to the organization's history and structure.					
5. Amend the table for identifying the first tier, downstream and related entities that perform key Part D functions on behalf of the Applicant.	Added a column for the applicant to identify if the first tier, downstream, or related entity is an offshore subcontractor.	3.1.1C	3.1.1C	3.1.1C	Management and Operations	Increase
6. Added new contract language required between applicants and their first tier, downstream or related entities that perform key Part D functions on the Applicant's behalf.	New provisions were added to reflect statutory changes from the enactment of Patient Protection and Affordable Care Act. Specifically new contract language is required for network pharmacies to submit claims on behalf of enrollees and new language is required for specific PBM transparency reporting requirements.	3.1.1D	3.1.1D	3.1.1D	Management and Operations	Increase
EXPERIENCE AND CAPABILITIES						
7. Delete the table of attestations.	The specific attestations in this table are duplicative to the First tier, Downstream and Related Entities Function Chart completed in 3.1.1C of the application.	3.1.2	3.1.2	3.1.2	N/A	Decrease
BUSINESS INTEGRITY						
8. Delete the requirement to upload all past and pending investigations,	The information is no longer required at the time of the application since it is not used in the determination of whether an	3.1.4B	3.1.3B	3.1.3B	Business Integrity	Decrease

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legal actions or matters subject to arbitration over the past three years related to payments from government entities for healthcare and/or prescription drug services.	organization is qualified as a Part D sponsor.					
HPMS PART D CONTACTS						
9. Updated the list of required Part D contacts. **Additional contact added.**	Based on CMS guidance issued during the 2010 Contract Year, added the new contact for DIR**, and Reconciliation Contact.**	3.1.5A	3.1.4A	3.1.4A	HPMS Part D Contacts	N/A
10. Prohibit the use of PO Boxes within the mailing address of the Part D contacts.	Organizations applying to participate as a Part D sponsor must have a physical location, therefore, PO Boxes are not acceptable.	3.1.5A	3.1.4A	3.1.4A	HPMS Part D Contacts	N/A
BENEFIT DESIGN						
FORMULARY//PHARMACY AND THERAPEUTICS (P&T) COMMITTEE						
11. Update attestation language addressing the Medicare populations eligible for transitions.	Pursuant to CMS-4085-F, (preamble page 167 and 423.120(B)(3)) this revision clarifies that transition policies are for new enrollees, newly eligible Medicare enrollees from other coverage, individuals who switch from one plan to another after the start of the contract year, and current enrollees remaining in the plan who are affected by formulary changes between contract years.	3.2.1A6	3.2.1A6	3.2.1A6	Formulary/Pharmacy and Therapeutics Committee	N/A
12. Update attestations related	Based on a March 2010 HPMS memo,	3.2.1A8	3.2.1A8	3.2.1A8	Formulary/Pha	N/A

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to documentation of the transition policy.	organizations must provide CMS the transition policies.				rmacy and Therapeutics Committee	
13. Adds a new attestation to address a P&T committee requirement.	As a result of CMS-4085-F a new attestation was added that requires P&T committees to review and approve all clinical criteria.	3.2.1B6	3.2.1B6	3.2.1B6	Formulary/Pharmacy and Therapeutics Committee	Increase
QUALITY ASSURANCE AND PATIENT SAFETY						
14. Adds a new attestation related to waste in LTC facilities.	Adds a new attestation to reflect Section 3310 of the **Affordable Care Act**. The statute requires Part D sponsors to utilize dispensing techniques to reduce waste in LTC facilities.	3.2.3A4	3.2.3A4	3.2.3A4	N/A	Increase
MEDICATION THERAPY MANAGEMENT (MTM)						
15. Update and clarify MTM attestations to reflect the issuance of CMS-4085-F.	Prior to the issuance of CMS-4085-F, the amount a beneficiary was likely to incur to be considered for MTM services was determined by the Secretary annually. The regulation sets the amount at $3,000 and accounts for inflation. Further, attestation language was updated in relation to beneficiaries that may be targeted for enrollment.	3.2.4	3.2.4	3.2.4	N/A	N/A
BIDS						
16. Clarify an existing attestation related to	Based on CMS-4085-F, clarified that CMS will look at meaningful differences	3.2.6A1	N/A	N/A	N/A	N/A

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meaningful differences. **Additional clarification provided.**	in benefit packages and plan costs when evaluating bids.					
17. Added a new attestation related to uniform benefits.	Based on CMS-4085-F, added an attestation that Applicants offer plans with uniform benefits to its beneficiaries.	3.2.6A3	N/A	N/A	N/A	Increase
GENERAL PHARMACY ACCESS						
18. Delete 4 attestations.	The deleted attestations addressed required contractual provisions in the pharmacy contract templates. These were duplicative of the provisions provided in the appendices containing all of the required pharmacy contract provisions.	3.4A3-A6	3.5A3-A6	3.3A3-A6	N/A	Decrease
RETAIL PHARMACY ACCESS						
19. Delete the attestation referencing the Medicare Beneficiary Count File.	Removed the attestation that required Part D sponsors to use the Beneficiary Count Data file provided to complete the retail pharmacy access reports. See, item 19 for the removal of the retail access reports.	3.4.1A3	3.5.1A3	3.3.1A3	N/A	Decrease
20. Delete the requirement to upload a retail pharmacy access report.	CMS is automating the retail pharmacy access analysis based on the service area provided by the applicant and the retail pharmacy list. There will no longer be a need for an applicant to submit an access report to CMS.	3.4.1B and Appendix entitled Retail Pharmacy Network Access Instructions	3.5.1B and Appendix entitled Retail Pharmacy Network Access Instructions	3.3.1B and Appendix entitled Retail Pharmacy Network Access Instructions	N/A	Decrease
21. Deleted Puerto Rico from the list of territories eligible	Part D sponsors can demonstrate convenient access in Puerto Rico, and	3.4.1D	3.5.1E	3.3.1E	N/A	Decrease

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for a waiver of convenient access.	therefore Part D sponsors operating in this territory are not eligible for the waiver.					
ENROLLMENT						
22. Added a new attestation related allowing a beneficiary to have a 12-month absence from a Part D sponsor's service area.	CMS-4085-F amended 42 CFR 423.44 to allow beneficiaries to have a 12 month absence from their service area before a sponsor begins disenrollment procedures.	3.5A25	N/A	N/A	N/A	Increase
COORDINATION OF BENEFITS						
23. Amend an existing attestation to reflect ADAPs and IHS as third party payers that sponsors must coordinate benefits with.	Pursuant to ~~PPACA~~ **the Affordable Care Act** Section 3314, ADAPs and IHS are recognized as third party payers.	3.10A3	3.11A3	3.9A3	Coordination of Benefits	N/A
24. Adds a new attestation setting a time limit for third-party payers to coordinate benefits.	CMS-4085-F amends 423.466 to provide third-party payers no more than three years from the date a prescription is filled to coordinate benefits with the Part D sponsor.	3.10A14	3.11A14	3.9A14	Coordination of Benefits	Increase
TrOOP						
25. Added a new attestation that ADAPs and IHS count toward TrOOP.	Pursuant to ~~PPACA~~ **the Affordable Care Act** Section 3314, ADAPs and IHS count towards TrOOP.	3.11A16	3.12A15	3.10A15	TrOOP	Increase
MARKETING/BENEFICIARY COMMUNICATION						
26. Added a new attestation related to disclosing information related to	CMS-4085-F amends 423.128 to require Part D sponsors disclose, upon CMS' request, information concerning	3.13A5	3.14A5	3.12A5	N/A	Increase

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performance and contract compliance deficiencies.	the Applicant's performance and contractual compliance deficiencies.					
COMPLIANCE PLAN						
27. Delete attestation table.	Attestations are duplicative of provisions required with the actual compliance plan submission.	3.15A	3.16A	3.14A	Compliance Plan	Decrease
28. Update the compliance plan crosswalk.	Updated the provisions in the compliance plan crosswalk to reflect the new regulatory language from CMS-4085-F.	3.15C	3.16C	3.14C	Compliance Plan	N/A
REPORTING REQUIREMENTS						
29. Add an attestation related to data validation.	Regulations require Part D sponsors to attest that the reporting requirements data has undergone data validation**, including yearly independent audit**.	3.16A3	3.17A3	3.15A3	N/A	Increase
30. Add an attestation related to PBM transparency.	Pursuant to ~~PPACA~~ **the Affordable Care Act** Section 6005, add a general attestation related to specific reporting requirements for Part D sponsors and their PBMs.	3.16A19	3.17A16	3.15A18	N/A	Increase
CLAIMS PROCESSING						
31. Added new attestation related to unique Part D identifiers.	CMS-4085-F requires Applicants to use unique Part D identifiers for each individual Part D member.	3.22A12	3.23A12	3.21A12	Claims Processing	Increase
32. Added a new attestation related to adjustments and issuances of refunds or recoveries.	CMS-4085-F amends 423.464 and 466 that requires the adjustments be made within 45 days of sponsor's receipt of information necessitating the adjustment.	3.22A13	3.23A13	3.21A13	Claims Processing	Increase
APPENDICES						

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33. Delete the requirement for an initial applicant to complete the DUA agreement.	This document is collected as part of the contracting process for initial applicants.	3.18B	N/A	N/A	N/A	Decrease
34. Add new appendix as a template for Applicant's organization background and structure.	Consistent with changes to the Management and Operations section of the application, a new template was created to request specific information about the applicant's background and structure.	3.1.1B and Appendix	3.1.1B and Appendix	3.1.1B and Appendix III	N/A	N/A
35. Delete reference to National Council for Prescription Drug Programs (NCPDP) provider number and replaced with the required National Provider Identifier (NPI) number.	**Consistent with the January 23, 2004 final rule (69 FR 3434*), HIPAA Administrative Simplification: Standard Unique Health Identifier for Health Care Providers***	**Appendix XIV – I/T/U Addendum**	**Appendix XI – I/T/U Addendum**	**Appendix XI – I/T/U Addendum**	**N/A**	**N/A**

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GENERAL INFORMATION and INSTRUCTIONS					
1. Updated background information. **Additional change made.**	Added language describing the passage of the Patient Protection and Affordable Care Act as amended by the Health Care and Education Reconciliation Act of 2010 **(together, "the Affordable Care Act").**	1.2	1.2	1.2	General Information
2. Updated dates, websites, (language where appropriate), regulatory, Prescription Drug Benefit Manual citations, and reference file names as needed. **Additional changes made throughout the document.**	Updated dates, websites, (language where appropriate), references to statutes, regulations, Part D guidance, reference file names and URLs. **Changed abbreviation for the Patient Protection and Affordable Care Act as amended by the Health Care and Education Reconciliation Act of 2010 from "PPACA" to "the Affordable Care Act". Updated websites' URLs as appropriate.**	**Throughout document**	**Throughout document**	**Throughout document**	**Throughout document**
3. Made grammatical changes throughout the document. **Additional changes made throughout the document.**	In an effort to make the language tense consistent throughout the application, grammatical changes were made.	Throughout document	Throughout document	Throughout document	Throughout document
4. Clarified attestation language throughout the document.	Language was edited in attestations throughout the document to better clarify CMS policy.	Throughout document	Throughout document	Throughout document	Throughout document
5. Clarified Part D application technical assistance manuals.	**Added description of the two technical assistance manuals available to Part D applicants: *Basic Contract Management User's Manual* and the *Online Application User's Manual*, both available in HPMS.**	**2.2**	**2.2**	**2.2**	**N/A**

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6. Updated contact for application technical assistance.	**New contact is Linda Anders.**	**2.4.8**	**2.4.8**	**2.4.5**	
7. Updated name for the Medicare Plan Finder.	**Changed name from “Medicare Prescription Drug Plan Finder” to “Medicare Plan Finder.”**	**Throughout document**	**Throughout document**	**Throughout document**	**N/A**
EXECUTED CONTRACTS, FULLY EXTECUTED LETTERS OF AGREEMENT, ADMINISTRATIVE SERVICES AGREEMENTS, OR INTERCOMPANY AGREEMENTS WITH EACH FIRST TIER, DOWNSTREAM AND RELATED ENTITIES					
8. Clarified CMS’ expectations.	**Provided expectation that each contract meets all requirements when read on its own.**	**3.1.1.D**	**3.1.1.D**	**3.1.1.D**	**Management and Operations**
TROOP					
9. Deleted two attestations related to TrOOP related Part D contacts.	Deleted the attestations because they were duplicative of information collected in the HPMS Contacts section of the application.	3.11A12 3.11A13	3.12A12 3.12A13	3.10A12 3.10A13	TrOOP
MEDICARE SECONDARY PAYER					
10. Deleted an attestation related to workers’ compensation Medicare set asides.	Based on the prior attestation in the table, this attestation is duplicative of CMS policy.	3.12A7	3.13A7	3.11A7	Medicare Secondary Payer
MARKETING/BENEFICIARY COMMUNICATION					
11. Changed the date when the ANOC/SB must be received by beneficiaries. **Changed “two weeks” to “15 days” per updated guidance.**	Based on the **Affordable Care Act**, the annual enrollment period for 2012 will begin October 15th. Beneficiaries must receive the ANOC/SB no later than **15 days** ~~two weeks~~ prior to the start of the annual election period. As a result, the October 31st date has been changed in the attestation.	3.13A12	3.14A12	3.12A12	
HIPAA					
12. Consolidated two attestations into one.	Consolidated the attestations requiring Applicants comply with the Standards for Privacy of Individually Identifiable Health	3.18A1 and A2	3.19A1 and A2	3.17A1 and A2	HIPAA

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	Information and Security Standards.				
13. Deleted an attestation related to privacy and security provisions from ARRA.	The regulations from HiTech implementing the privacy and security provisions of ARRA amend sections 160 and 164 of HIPAA, which is addressed in another attestation in this section of the application.	3.18A11	3.19A11	3.17A11	HIPAA
APPENDICES					
14. Updated the contract crosswalks to reflect language requirements based on new regulation or statute.	Based on ~~PPACA~~ **the Affordable Care Act** and CMS-4085-F, new provisions are required between the Part D sponsor and its first tier, downstream, and related entities. Each crosswalk was updated to reflect these new requirements and are also reflected within the respective sections of the application.	Appendices VIII-XII	Appendices IV-IX	Appendices IV-IX	N/A

NOTE 1: Nothing in the technical changes table increases burden on the applicant.
NOTE 2: The Service Area Expansion Application is a condensed version of the initial application.
NOTE 3: Red Bolded language represents changes made following the 60-day comment period.