High-Level Summary of All Part D Application Revisions from 2008 Solicitation for the 2009 Solicitation

Clarification	Purpose of the Clarification	Application		
		PDP	MA-PD	Cost
GENERAL INFORMATION and INSTRUCTIONS				
1. Added regulatory and Prescription Drug Benefit Manual references for each attestation section; Changed instructions to provide attachments as uploads in HPMS; and amended the instructions related to not accepting any hard copy and CD submissions.	• Included references to Part D guidance. • The application will be completed entirely in HPMS, so prior instructions about how to submit attachments have been changed to how to upload documents into HPMS.	Throughout document	Throughout document	Throughout document
2. Technical change to the instructions to provide that attachments not being uploaded in an excel format will be uploaded in pdf format.	All uploads will be required to be in either excel, a CMS provided template or pdf format to be properly uploaded in HPMS.	Throughout document	Throughout document	Throughout document
APPLICANT EXPERIENCE, CONTRACTS, LICENSURE AND FINANCIAL STABILITY				
3. Amend attestations related to licensure waivers.	• MMA changes the licensure waiver authority for year three of the program and the attestations were amended to reflect statutory authority. • Language was modified from referencing licensure in <u>any</u> state to licensure in <u>each</u> state.	3.1.3B	N/A	N/A
BENEFIT DESIGN				
4. Added new attestations related to formulary.	Added attestations to highlight several aspects of previously existing formulary guidance related to six classes of drugs that CMS wanted to highlight to initial applicants.	3.2.1A	3.2.1A	3.2.1A
5. Added new attestations related to bundling home infusion drugs as part of a supplemental benefit.	Based on the 2008 Call Letter, existing policy clarified how certain Part D sponsors may bundle Part D home infusion drugs as part of the supplemental benefit and how this should be reported on a formulary and the information relayed to beneficiaries.	N/A	3.2.1D	3.2.1D

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6. Added an attestation related to guidance on vaccine administration.	Legislation passed in 2007 requires the shift of vaccine administration from Part B to Part D. This guidance implements this legislative change.	3.2.1B	3.2.1B	3.2.1B
7. Deleted a new attestation related to the CAHPS survey.	Based on comments received during the 60-day posting of the Draft 2009 application, this attestation has been deleted since guidance has not been issued related to any follow-up requirements for Part D sponsors in relation to the CAHPS survey thus the attestation has been removed.	3.2.3A5	3.2.3A5	3.2.3A5
8. Adds a new attestation, which limits the number of bids up to the parent organization.	Based on the 2008 Call Letter, CMS is implementing a policy that provides parent organizations of multiple Part D sponsors to limit the number of benefit offerings to no more than 2 basic benefit plans throughout all subsidiaries.	3.2.6A3	N/A	N/A
PHARMACY ACCESS				
9. Added new attestations related to Private Fee For Service Part D sponsors.	Based on the 2008 Call Letter, these new attestations address on line billing and paper claims.	N/A	3.4A	N/A
10. Added clarifying language to a mail order attestation related to a level-playing field with retail and providing of extended day supply.	• Added clarifying language that is part of Chapter 5 of the Prescription Drug Benefit Manual to ensure applicants understand the policy with providing extended day supply of medications via mail order or at retail • New language ensures that the availability of an extended day supply at retail does not increase the costs to the government and that cost-sharing for an extended day supply never exceeds what the enrollee would have paid had he/she filled the prescription in multiple 30-day supply increments at retail pharmacy	3.4.3A3	3.5.3A3	3.3.3A3

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	rates.			
11. Clarified language in long-term care attestations.	▪ Clarified existing language references to long term care pharmacies throughout this table and where appropriate included specific references to Chapter 5 of the Prescription Drug Benefit Manual, which incorporated previously separate guidance. ▪ This allowed CMS to delete references to any of the separate guidance.	3.4.5	3.5.5	3.3.5
12. Added instructions to provide applicants the choice of software vendors to complete the pharmacy access network reports.	Based on comments received during the 60-day posting of the Draft 2009 Part D application, added detailed instructions to use either Quest Analytics or GeoNetworks software to produce the required pharmacy network access reports.	3.4.1B	3.5.1B	3.3.1B
ENROLLMENT AND ELIGIBILITY				
13. Added 2 attestations related to involuntary disenrollments.	Based on the 2008 Call Letter and HPMS guidance, attestations were added to address involuntary disenrollments when beneficiaries fail to pay premiums.	3.5A19 3.5A20	3.6A9 3.6A10	3.4A9 3.4A10
14. Changed language in attestation related to 4Rx data.	Based on a change in the Plan Communications User Guide and HPMS Guidance, the process for processing 4Rx data has changed from 3 days before the end of the month preceding the effective date of enrollment to being part of the enrollment transaction with CMS.	3.5A18	3.6A8	3.4A8
COMPLAINTS TRACKING				
15. Added clarifying language related to applicants' requirement to monitor and document complaints in CTM.	▪ Added language that applicants must monitor and document complaints in CTM in accordance with CMS standard operating procedures for sponsors. ▪ Previous language required applicants to monitor and document resolutions	3.6A2	3.7A2	3.5A2

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	for complaints associated with their contracts in HPMS. Language was added so that the monitoring and documenting of resolutions are in accordance with CMS standard operating procedures.			
COVERAGE DETERMINATIONS (INCLUDING EXCEPTIONS) AND APPEALS				
16. Reorganized and clarified language of existing attestations. Added new attestations to further highlight key aspects of coverage determination and appeals policy.	Attestation language was clarified and the order was redone for a better flow of understanding for the applicants.	3.9	3.10	3.8
COORDINATION OF BENEFITS				
17. Added new attestations related to plan-to-plan reconciliation and reconciliation when another payer paid as primary instead of the Part D sponsor.	Addresses applicant's responsibility to reconcile payments with other Part D sponsors (where appropriate) and other payers that should not pay for Part D drugs as primary.	3.10A13 3.10A14	3.11A11 3.11A12	3.9A11 3.9A12
TRUE OUT-OF-POCKET COSTS (TrOOP)				
18. Added two attestations related to processing of TrOOP-related data.	Attestations highlight applicant's system requirements necessary to appropriately process TrOOP-related data in a timely fashion.	3.11A14 3.11A15	3.12A15 3.12A16	3.10A15 3.10A16
MARKETING/BENEFICIARY COMMUNICATION				
19. Added a new bullet within an existing attestation related to beneficiary call centers.	Highlights the guideline for returning a beneficiary call when the call goes appropriately to a voice mailbox. Also changed the 80% of calls answered within 30 seconds to average wait time being two minutes or less.	3.13A5	3.14A5	3.12A5
20. Added new attestation specific to marketing of formularies.	Based on current practices, this attestation highlights to applicants that they may only market a CMS-approved formulary.	3.13A7	3.14A7	3.12A7
21. Added a new attestation addressing the release of prescription drug event data for research and other purposes.	Based on the forthcoming data regulation, this attestation highlights that Applicants must notify enrollees that prescription drug event data may	3.13A11	3.14A11	3.12A11

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	be released by CMS for research and other purposes. CMS will delete this attestation if the proposed rule does not receive OMB approval.			
PROVIDER COMMUNICATIONS				
22. Clarified attestation related to pharmacist and provider call centers.	Clarified that if a network pharmacy is open 24 hours then the call center must be available 24 hours. Also clarified that the average wait time must be two minutes or less.	3.14A1	3.15A1	3.13A1
REPORTING REQUIREMENTS				
23. Added new attestation related to reporting direct and indirect remuneration dollars for payment reconciliation.	Based on CMS guidance, this reporting requirement was highlighted to address payment reconciliation with DIR data.	3.16A17	3.17A17	3.15A17
DATA EXCHANGE BETWEEN PART D SPONSOR AND CMS				
24. Deleted an attestation related to enrollment transactions and replaced it with new attestations that more specifically highlight system requirements.	The new attestations focus more appropriately on testing, lifecycle memos and disaster and recovery plans for systems.	3.17	3.18	3.16
HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996 AND RELATED CMS REQUIREMENTS				
25. Reordered and added new attestations related to data security, off shore contracting, and the National Provider Identifier.	Added new attestations based on the 2008 Call Letter and implementation of the National Provider Identifier.	3.18	3.19	3.17
26. Amended and deleted attestations related to offshore subcontracting.	Consolidated and revised attestations related to offshore subcontracts to be less burdensome for Applicants so that they will submit attestations at an appropriately designated time instead of receiving CMS prior approval under specified conditions.	3.18	3.19	3.17
27. Added new section to have Applicants complete an appendix for data use agreements.	The Data Use Agreement will require initial applicants to agree to only use the data received through the Part D program for Part D purposes.	Appendix XI	N/A	N/A

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	▪ Existing sponsors have completed the data use agreement through the contracting process. ▪ Deleted the Appendix from the MA-PD and Cost applications as the information will be collected through the Part C applications.			
PREMIUM BILLING				
28. Added a new section to highlight requirements of Applicants related to premium withhold and billing issues.	▪ Based on existing CMS guidance, these attestations were added to the application to highlight premium billing and withholding concerns and when beneficiaries need to be reimbursed.	3.22	3.24	3.21
APPENDICES				
29. Deleted Banking Information Form appendix.	Appendix is not part of the application review and is not completed in HPMS so it has been removed from the application.	Appendix I	Appendix I	Appendix I
30. Updated language throughout Application to Request Federal Waiver of State Licensure Requirement for Prescription Drug Plan.	Updated language to address automation of the Part D application. Clarified language related to the dates of submission for the waiver application in conjunction with the Part D application.	Appendix II	N/A	N/A
31. Deleted Certification of Monthly Enrollment and Payment Data Relating to CMS Payment to a Part D Sponsor.	Appendix is not part of the application review and is not completed in HPMS so it has been removed from the application.	Appendix III	Appendix III	Appendix III
32. Deleted Certification by Prescription Drug Plan Organization that Subcontracts Meet the Requirements of Section 3.1.2D.	Deleted certification because it is duplicative of statements addressed in the 4.0 Certification.	Appendix V	Appendix IV	Appendix IV
33. Clarified language for the Retail Network Pharmacy Access appendix.	Clarified the instructions for developing the retail network pharmacy access reports. Added in language specific to using the Quest Analytics software to produce the network pharmacy access reports.	Appendix XIII	Appendix XII	Appendix XII