High-Level Summary of All Part D Application Revisions from 2009 Version of Part D Application to 2010 Version

Clarification	Purpose of the Clarification	Application					
		PDP	MA-PD	Cost	800 series (PDP and Cost)	Directs (PDP and MA-PD)	PACE
GENERAL INFORMATION and INSTRUCTIONS							
1. Updated dates (language where appropriate) and regulatory and Prescription Drug Benefit Manual references for each attestation section.	Updated dates (language where appropriate) and references to statutes, regulations and Part D guidance.	Throughout document	Throughout document	Throughout document	Throughout document	Throughout document	Throughout document
2. Clarified instructions related to the application submission and correction process.	Clarified instructions related to the courtesy opportunity to cure deficiencies, the Notice of Intent to Deny process to cure deficiencies, and the retail pharmacy access review process.	Instructions	Instructions	Instructions	Instructions	Instructions	Instructions
APPLICANT EXPERIENCE, CONTRACTS, LICENSURE AND FINANCIAL STABILITY							
3. Clarified contractual requirements related to the MMA and Compliance regulations.	▪ Deleted the reference to abiding by all applicable State laws and regulations as the MMA regulations only refer to Federal laws and regulations. ▪ Two of the contractual provisions were clarified to properly reflect CMS authority under the compliance regulation related to CMS or its designee's access to books and records related to the Part D program.	3.1.1D8 3.1.1D11 3.1.1D13	3.1.1D8 3.1.1D11 3.1.1D13	3.1.1D8 3.1.1D11 3.1.1D13	N/A	N/A	Mgmt & Operations
4. Added contractual requirements to reflect the enactment of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA)	Based on sections 171 and 173 of MIPPA all Part D sponsors are required to include contractual provisions that relate to prompt payment and notice of reimbursement standard updates.	3.1.1D17 3.1.1D18	3.1.1D17 3.1.1D18	3.1.1D17 3.1.1D18	N/A	N/A	Mgmt & Operations
BIDS							
5. Deleted attestation related to submitting meaningful and distinct bids.	The attestation is only applicable to stand-alone PDPs and should not be applied to other types of Part D sponsors.	N/A	3.2.6	3.2.6	N/A	N/A	N/A

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		PDP	MA-PD	Cost	800 series (PDP and Cost)	Directs (PDP and MA-PD)	PACE
APPENDICES							
6. Updated language throughout Application to Request Federal Waiver of State Licensure Requirement for Prescription Drug Plan.	Clarified language related to the dates of submission for the waiver application in conjunction with the Part D application.	Appendix I	N/A	N/A	N/A	N/A	N/A
7. Clarified language in contract templates to properly address the MMA and compliance regulations.	▪ Deleted the reference to abiding by all applicable State laws and regulations as the MMA regulations only refer to Federal laws and regulations ▪ Language was clarified to properly reflect CMS authority under the compliance regulation related to CMS or its designee's access to books and records related to the Part D program.	Appendices III-VIII	Appendices II-VII	Appendices II-VII	N/A	N/A	Mgmt & Operations
8. Added language to address the enactment of MIPPA.	Based on section 171 of MIPPA all Part D sponsors are required to include contractual provisions that relate to prompt payment with its PBM, retail, home infusion, and ITU pharmacies.	Appendices III, IV, VI, VIII	Appendices II, III, V, VII	Appendices II, III, V, VII	N/A	N/A	Mgmt & Operations
9. Added language to address the enactment of MIPPA.	Based on section 173 of MIPPA all Part D sponsors are required to include contractual provisions that relate to notice of reimbursement standard updates.	Appendices III-VIII	Appendices II-VII	Appendices II-VII	N/A	N/A	Mgmt & Operations
10. Added language to address the finalization of a home infusion contractual requirement based on the Policy and Technical Regulation.	Based on the final approval in April 2008 of the Policy and Technical correction regulation, all Part D sponsors are required to include a contractual provision related to the delivery of home infusion drugs within 24 hours of discharge.	Appendix VI	Appendix V	Appendix V	N/A	N/A	N/A
11. Added language to address the enactment of MIPPA.	Based on section 172 of MIPPA all Part D sponsors are required to include contractual provisions with long-term care pharmacies	Appendix VII	Appendix VI	Appendix VI	N/A	N/A	Mgmt & Operations

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		PDP	MA-PD	Cost	800 series (PDP and Cost)	Directs (PDP and MA-PD)	PACE
	that related to timeframes for claims submission.						