Summary of Substantive and Technical Changes for All Part D Application Revisions from 2010 Version of Part D Application to 2011 Draft Version

SUBSTANTIVE CHANGES						
Clarification	**Purpose of the Clarification**	**Application**				
		PDP	**MA-PD**	**Cost**	**PACE**	**Change in Burden**
GENERAL INFORMATION and INSTRUCTIONS						
1. Deleted the July 15th date from the Schedule.	The July 15th date, by which an applicant must have an affirmative determination on their application to offer the Part D benefit the following contract year, was removed. In prior years, the CMS Hearing Officer did not follow this date in order to ensure denied applicants received due process in a timely manner.	1.4	1.4	1.4	N/A	N/A
2. Added providing information for plan finder as a Part D Sponsor role and responsibility.	Updated the roles and responsibilities of Part D sponsors by including a reference to providing accurate drug pricing and pharmacy network data for the Medicare Prescription Drug Plan Finder.	1.5 and 1.6.3	1.5 and 1.6.3	1.5 and 1.6.3	N/A	N/A
3. Added language related to CMS' Best Available Evidence policy.	Added language in the section related to eligibility for the low-income subsidy program to explain the Best Available Evidence policy and CMS expectations. The policy was put into regulation since the last application revisions.	1.6.5	1.6.5	1.6.5	N/A	N/A
4. Specified steps an Applicant must take when having technical difficulties uploading materials in HPMS.	Requires Applicants to notify the HPMS help desk when experiencing technical difficulties with uploading required materials prior to the submission deadline to establish a record with CMS.	Instructions; 2.4.1 and 2.4.8	Instructions; 2.4.1 and 2.4.8	Instructions; 2.4.1 and 2.4.5	N/A	N/A

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5. Add references to "gross covered prescription drug costs."	Added references to gross covered prescription drug costs as appropriate throughout the document. References are in relation to maintenance and tracking with Applicant's systems.	Throughout document	Throughout document	Throughout document	Throughout document	N/A
6. Added language and examples from 2010 Call Letter related to what constitutes a valid application submission.	Provide some examples as to what would constitute an invalid application submission.	Instructions; 2.4.1	Instructions; 2.4.1	Instructions 2.4.1	N/A	N/A
7. Clarified communication process between CMS and Applicants.	Clarified language to indicate all communications from CMS related to the Part D applications will be issued through HPMS. CMS will no longer send Notices of Intent to Deny, Denials or Approvals in hard copy.	Instructions; 2.4.1	Instructions; 2.4.1	Instructions; 2.4.1	N/A	N/A
8. Added a section related to auto-enrollment of dual eligible individuals in MA-PD plans.	Added language to explain how auto-or facilitated enrollments work for MA-PD plans, specifically when an organization may enroll an eligible individual into an MA-PD plan or under certain circumstances into a PDP.	N/A	2.4.6	N/A	N/A	N/A
9. Added a section on how to withdraw an application.	Provided an instructional section specifying how an organization can withdraw an application. Further clarified the withdrawal instructions by indicating the date CMS will recognize the request and an additional email box to send the request for certain application types (MA-PD).	2.4.7	2.4.7	2.4.4	N/A	N/A
10. Revised the section that	Clarified the discussion of how CMS	2.8.2	2.8.2	2.8.2	N/A	N/A

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discusses how CMS will measure HI pharmacy access.	uses the home infusion pharmacy list that Applicants submit to determine adequate access. Also provides the link to a reference file that provides the number of pharmacies necessary to meet adequate access.					
11. Revised the section that discusses how CMS will measure LTC pharmacy access.	Replaces the discussion about LTC ratios with a discussion that the pharmacy list will be used to ensure applicants meet LTC standards once they become Part D sponsors and have enrollees residing in LTC facilities.	2.8.3	2.8.3	2.8.3	N/A	N/A
12. Streamlined the 800-series and Direct applications into the appropriate individual market applications.	Condensed the 800-series and Direct certification/attestation pages into appendices within the individual market applications to streamline the process for applicants seeking to participate in the employer Part D market.	Instructions; 2.4.2, 2.4.3, 2.9, Appendices I-III	Instructions; 2.4.2, 2.4.3, 2.9, Appendices II and III	Instructions; 2.4.2, 2.9, and Appendix II	N/A	N/A
13. Added a clarifying instruction related to the timeframe that an application is valid.	Added a clarifying instruction related to the standard contract with Part D sponsors explaining that approved applications are valid for the forthcoming contract year. The clarification was added so that organizations would clearly understand that if an application is approved but a contract is not signed for the forthcoming contract year, the organization will need to reapply for any future years.	2.10	2.10	2.10	N/A	N/A
14. Added a waiver of	Based on PACE waiver authority, the	N/A	N/A	N/A	Instructions	N/A

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electronic prescribing for PACE applicants.	Part D requirements for electronic prescribing have been waived.					
APPLICANT EXPERIENCE, CONTRACTS, LICENSURE AND FINANCIAL STABILITY						
MANAGEMENT AND OPERATIONS						
15. Added an attestation related to following laws, regulations and CMS instructions.	Application requires first tier, downstream or related entities to abide by all federal laws, regulations and CMS instructions but not the actual applicant. This attestation corrects that.	3.1.1A2	3.1.1A2	3.1.1A2	N/A	N/A
16. Added a key Part D function related to enrollment processing.	CMS has required Part D sponsors to identify the entity responsible for performing enrollment processing since 2008. Incorporating this function into the chart makes the application consistent with current operations.	3.1.1C	3.1.1C	3.1.1C	N/A	N/A
17. Deleted a provision related to long-term care claims processing.	Removed the provision requiring agreements for entities maintaining the LTC network to include this provision.	3.1.1D20	3.1.1D20	3.1.1D20	Management and Operations	N/A
18. Added a new section related to prescription drug pricing standard reimbursements.	Based on the passage of MIPAA, added a section for Applicants to identify in HPMS the methodology and source for the drug pricing standard for reimbursements to pharmacies.	3.1.1F	3.1.1.F	3.1.1.F	Management and Operations	N/A
EXPERIENCE AND CAPABILITIES						
19. Added an attestation related to the key Part D function of enrollment processing (related to #13)	CMS has required Part D sponsors to identify the entity responsible for performing enrollment processing since 2008. Added this attestation to correspond with existing requirement.	3.1.2A10	3.1.2A10	3.1.2A10	N/A	N/A
LICENSURE AND SOLVENCY						

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20. Clarified the due date (to CMS) of an Application to Request a Federal Waiver of State Licensure Requirement for a PDP.	Previous language in the attestation referred to submission of the Waiver Application being due within the requisite time period. The language was deleted since the Waiver Application is due at the same time as the application.	3.1.3B3	N/A	N/A	N/A	N/A
HPMS PART D CONTACTS						
21. Added a note to request specific extensions and email addresses when appropriate and explain where to find the definitions for each contact.	• Based on existing data within this section of HPMS, CMS wanted to clarify that specific phone numbers or general phone numbers with specific extensions must be provided. • Further general email addresses are not permitted. • Provides the location for applicants to find the CMS definition for each Part D contact.	3.1.5A	3.1.4A	3.1.4A	HPMS Part D Contacts	N/A
22. Updated the contacts that are required and deleted the contacts that are optional.	• Deleted the Pharmacy Benefit Manager Contact. • Added the Plan Directory Contact for Public Website • Added Financial Reporting Contact • Added the Best Available Evidence Contact • Added Automated TrOOP Balance Transfer Contact • Added Agent/Broker Compensation Data Contact • Added Complaints Tracking Module Contact	3.1.5A	3.1.4A	3.1.4A	HPMS Part D Contacts	N/A

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	• Added Part D Reporting Requirements Contact • Added Fraud Investigations Contact					
BENEFIT DESIGN						
FORMULARY//PHARMACY AND THERAPEUTICS (P&T) COMMITTEE						
23. Added attestation requiring Applicants to link all associated contracts with the appropriate formulary submission.	Consistent with the 2010 Call Letter added an attestation requiring applicants to ensure that all associated contracts are linked to the proper formulary to ensure formularies are submitted correctly.	3.2.1A2	3.2.1A2	3.2.1A2	Formulary / P&T Committee	N/A
24. Clarified the formulary resources that the Applicant will follow.	Added a reference to the HPMS Formulary Submission Module and Reports Technical Manual to the documents that Applicants will follow.	3.2.1A3	3.2.1A3	3.2.1A3	Formulary / P&T Committee	N/A
25. Changed references of "six categories of clinical concern" to "protected classes."	Consistent with MIPPA and the 2010 Call Letter, attestations were changed to refer to "protected classes of drugs" instead of "six categories of clinical concern."	3.2.1A5	3.2.1A5	3.2.1A5	Formulary / P&T Committee	N/A
26. Changed attestation to require applicants to attest to transition policy requirements in HPMS rather than submit documentation.	Applicants and existing sponsors now complete a set of attestations in HPMS related to transition policies rather than submit their individual organization's policies to CMS.	3.2.1A7	3.2.1A7	3.2.1A7	Formulary / P&T Committee	N/A
27. Added a new attestation that an organization will submit its transition policy to CMS upon request.	Based on the revised attestation above, CMS requires applicants to provide their organization's transition policy upon request.	3.2.1A8	3.2.1A8	3.2.1A8	Formulary / P&T Committee	N/A

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28. Clarified an attestation related to how applicants identify the home infused Part D drugs that will be offered as part of a supplemental benefit under Part C.	Requires applicants covering home infused covered Part D drugs as part of a supplemental benefit under Part C to submit a supplemental formulary file to CMS.	N/A	3.2.1D5	3.2.1D5	N/A	N/A
UTILIZATION MANAGEMENT STANDARDS						
29. Added a new attestation related to submitting UM criteria for each drug identified on formulary flat file with prior authorization or step therapy.	Consistent with the 2010 Call Letter added an attestation on the proper way to submit UM criteria for formulary drugs that have prior authorization or step therapy.	3.2.2A5	3.2.2A5	3.2.2A5	N/A	N/A
QUALITY ASSURANCE AND PATIENT SAFETY						
30. Expanded the attestation related to quality assurance and patient safety.	Based on the issuance of Chapter 7 of the Prescription Drug Benefit Manual, expanded the general attestation related to quality assurance and patient safety. List the measures and reporting systems that should be included in concurrent drug utilization review.	3.2.3A1	3.2.3A1	3.2.3A1	N/A	N/A
MEDICATION THERAPY MANAGEMENT (MTM)						

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31. Updated and clarified the attestations related to MTM.	Based on the issuance of Chapter 7 of the Prescription Drug Benefit Manual and the 2010 Call Letter updated several attestations related to MTM. This includes, but not limited to: • Correcting the annual cost amount; • Clarifying MTM enrollment policy; and • Highlighting CMS expectations for administering the MTM program.	3.2.4A3-A10	3.2.4A3-A10	3.2.4A3-A10	N/A	N/A
ELECTRONIC PRESCRIPTION PROGRAM and HEALTH INFORMATION TECHNOLOGY STANDARDS						
32. Added two attestations related to complying with electronic prescription program requirements.	• Added an attestation for applicants to agree to support and comply with electronic prescription standards. • Added an attestation for applicants to agree to establish and maintain an electronic drug program that complies with Part D standards.	3.2.5A1-A2	3.2.5A1-A2	3.2.5A1-A2	N/A	N/A
33. Added an attestation related to obtaining and reporting prescription origin codes on PDE submissions.	Added an attestation that requires applicants to use the proper coding on their PDE submissions.	3.2.5A3	3.2.5A3	3.2.5A3	N/A	N/A
34. Added an attestation related to health information technology (HIT).	Added an attestation that requires Part D sponsors to comply with HIT requirements as referenced in the American Recovery and Reinvestment	3.2.5A4	3.2.5A4	3.2.5A4	Health Information Technology	N/A

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	Act of 2009.					
35. Made attestations related to electronic prescribing optional for PACE organizations.	Made the following of the electronic prescription program rules conditional for PACE organizations similar to how formularies are treated. If the PACE organization uses e-prescribing then they must attest to meeting CMS requirements.	N/A	N/A	N/A	Electronic Prescription Program	Decrease
GENERAL PHARMACY ACCESS						
36. Deleted a reference related to LTC pharmacies notifying beneficiaries of the lowest-priced, generically equivalent drug.	Deleted the note in the general attestation since this is operationally not workable in the LTC setting.	3.4A6	3.5A6	3.3A6	N/A	N/A
OUT OF NETWORK (OON) ACCESS						
37. Deleted the reference to "a physician's office' as an example of routine OON that is acceptable.	Deleting the reference makes the attestation consistent with Chapter 5 of the Prescription Drug Benefit Manual.	3.4.2A1	3.5.2A1	3.3.2A1	N/A	N/A
38. Added an attestation related to limiting the amount of medication that is permissible to be dispensed through an OON pharmacy.	Consistent with Chapter 5, the attestation specifies that organizations will not routinely permit more than one month's supply of medication through an OON pharmacy.	3.4.2A4	3.5.2A4	3.3.2A4	N/A	N/A
MAIL ORDER PHARMACY						
39. Changed the reference of 30-day supply to one-month supply.	Changing the reference to a one-month supply addresses 31-day months.	3.4.3A3	3.5.3A3	3.3.3A3	N/A	N/A

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HOME INFUSION PHARMACY						
40. Added language referring Applicants to a reference file for home infusion adequate access.	Added the reference to a new file indicating the number of pharmacies by service area that constitutes adequate access.	3.4.4A1	3.5.4A1	3.3.4A1	N/A	N/A
41. Clarified an attestation that network contracts will address Part D drugs administered in the home setting.	Expands the attestation to include administered and delivered in the home setting to be consistent with the requirements set forth in regulation and Chapter 5.	3.4.4A2	3.5.4A2	3.3.4A2	N/A	N/A
42. Added an attestation related to the delivery of home infusion drugs within 24 hours of discharge.	This requirement was part of MIPAA and was included in the contractual provision changes for the last application. Adding the attestation makes the section consistent with other required provisions specific to home infusion.	3.4.4A6	3.5.4A6	3.3.4A6	N/A	N/A
LONG TERM CARE PHARMACY						
43. Added several attestations to ensure that Applicants will meet the LTC convenient access standard once they have enrollees residing in any LTC facility.	Add attestations to highlight CMS' expectation about contracting with LTC pharmacies that serve LTC facilities where the organization has beneficiaries residing.	3.4.5A5 and 3.4.5A7-11	3.5.5A5 and 3.5.5A7-11	3.3.5A5 and 3.3.5A7-11	N/A	N/A
SPECIALTY PHARMACY						
44. Clarified that additional education or counseling alone does not qualify a drug for limited distribution	Clarified an existing attestation related to when a Part D sponsor may restrict access to a Part D drug through a specialty pharmacy. Specifies that a	3.4.7A1	3.5.7A1	3.3.7A1	N/A	N/A

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through a specialty pharmacy.	drug that requires additional education or counseling alone does not qualify a drug to be restricted to specialty pharmacies.					
ENROLLMENT AND ELIGIBILITY						
45. Added attestation related to Applicants following CMS' Best Available Evidence (BAE) policy.	Added a new attestation to reflect Chapter 13 and newer regulations at 42 CFR 423.586 for Applicants to follow the BAE policy.	3.5A18	3.6A8	3.4A8	N/A	N/A
46. Add attestation requiring sponsors to accept enrollments via the on-line enrollment center and download these daily.	The 2010 Call Letter requires certain Part D sponsors to accept all enrollments submitted through the on-line enrollment center and to download them daily.	3.5A22	3.6A12	N/A	N/A	N/A
47. Added attestation requiring sponsors to quality check files and reports received from CMS against internal data to identify discrepancies and reconcile.	Added this attestation so that Part D sponsors know they must verify data received from CMS to identify any possible discrepancies.	3.5A23	3.6A14	3.4A13	N/A	N/A
48. Added attestation related to completing reconciliation of enrollment membership and payment data and submits the CEO certification of enrollment data for payment.	Identifies the 45-day schedule for submitting the monthly CEO certification of enrollment data for payment.	3.5A24	3.6A15	3.4A14	N/A	N/A
COMPLAINTS TRACKING						
49. Added attestations related	Expects at least 95% of urgent	3.6A2-A3	3.7A2-A3	3.5A2-A3	Complaints	N/A

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to the resolution of urgent cases and complaints without a designated issue level in CTM.	complaints and complaints without a designated issue level to be resolved in accordance with CMS issued guidance.				Tracking	
PLAN FINDER						
50. Added an attestation related to responding to quality assurance outlier notifications from CMS.	Added an attestation that failure to respond to a quality assurance outlier email from CMS may result in suppression of plan finder data from the website.	3.7A4	3.8A4	3.6A4	N/A	N/A
COVERAGE DETERMINATIONS						
51. Attestations were amended to reflect the ability of prescribers other than physicians to request coverage determinations on behalf of beneficiaries.	Expanded attestations to reflect the ability of other prescribers to submit supporting statements for coverage determinations and the need for the sponsor to respond appropriately and timely to other prescribers.	3.9A4 3.9A5	3.10A4 3.10A5	3.8A4 3.8A5	N/A	N/A
52. Added an attestation requiring notice of standard determinations regarding reimbursement to be no later than 14 calendar days after receipt of the request.	This attestation was added to be consistent with the 2010 Call Letter related to enrollee notifications regarding reimbursement or received reimbursement, when appropriate.	3.9A8	3.10A8	3.8A8	N/A	N/A
53. Clarified an attestation related to the tiering of drugs covered based on a formulary exception.	• Consistent with the 2010 Call Letter clarified an attestation related to the ability to have a second level of cost sharing for generics that are based on formulary exceptions for generic drugs.	3.9A16	3.10A16	3.8A16	N/A	N/A

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	• Deletes language that prohibited applicants from assigning drugs to a high cost specialty tier if the level of cost sharing for that tier exceeds 25%.					
COORDINATION OF BENEFITS						
54. Add attestation requiring Part D sponsors to receive COB files from CMS and update systems at least weekly.	Reflects guidance in Chapter 14 of the Prescription Drug Benefit Manual.	3.10A7	3.11A7	3.9A7	N/A	N/A
TrOOP						
55. Revised attestation language to incorporate the use of the Automated TrOOP Balance Transfer (ATBT) process.	Consistent with the 2010 Call Letter and Chapter 14, incorporated the ATBT process into the attestations. Identifies when sponsors must send data manually, provide an ATBT contact, and have systems capability to receive and respond to the TrOOP related data.	3.11A13-A16	3.12A13-A16	3.10A13-16	N/A	N/A
MEDICARE SECONDARY PAYER						
56. Added an attestation related to making conditional primary payment in certain situations.	Based on the 2010 Call Letter and Chapter 14, added an attestation that in situations involving workers' compensation, Black Lung, No-Fault, or Liability coverage applicants should make conditional primary payment and recover mistaken payments.	3.12A6	3.13A6	3.11A6	Medicare Secondary Payer	N/A
57. Clarified attestation related to workers' compensation Medicare set-asides.	Consistent with the 2010 Call Letter and Chapter 14, revised an attestation to have the applicant establish the	3.12A7	3.13A7	3.11A7	Medicare Secondary Payer	N/A

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	appropriate point-of-sale edits to deny payment and reject claims for the included drugs.					
MARKETING/BENEFICIARY COMMUNICATION						
58. Added an attestation related to marketing materials being available in other languages.	Consistent with Chapter 2 of the Prescription Drug Benefit Manual, added an attestation that marketing materials must be made available in any language that is the primary language of more than 10% of an Applicant's plan's geographic service area.	3.13A5	3.14A5	3.12A5	N/A	N/A
59. Added information that must be shown on Part D sponsor's internet website.	Requires Part D sponsors to provide information on their website that describes prior authorization criteria, step therapy requirements, and quantity limits. Attestation language has been clarified to delete financial information that is not required on the Part D sponsors' websites.	3.13A7	3.14A7	3.12A7	N/A	N/A
60. Added attestations related to agents/brokers.	Based on MIPPA, added two attestations dealing with agents/brokers. Specifically: • Requires Applicants to provide initial and renewal compensation to agents or brokers for the sale of a PDP consistent with CMS requirements; and • Requires Applicants ensure that brokers and agents selling	3.13A13 3.13A14	N/A	3.12A13 3.12A14	N/A	N/A

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	Medicare products are trained and tested in the specifics of the plans.					
REPORTING REQUIREMENTS						
61. Added attestation requiring that reporting requirement data has been audited internally for accuracy.	Corresponds to the Reporting Requirements Instructions that data has been internally audited prior to submission to CMS.	3.16A2	3.17A2	3.15A2	N/A	N/A
62. Deleted the attestations related to rebate reporting.	• The rebate reporting requirements are incorporated in the general attestation requiring the applicant to comply with the Reporting Requirements. • In addition the LTC rebate attestation stopped being collected by CMS during the 2008 contract year.	3.16A13-16	3.17A13-16	3.15A13-26	N/A	Decrease
DATA EXCHANGE						
63. Clarified language related to the timing to submit enrollment, disenrollment and change transactions to CMS.	Changed the language for the timing to submit enrollment, disenrollment and change transactions from “monthly” to “within the timeframes provided by CMS.”	3.17A4	N/A	N/A	Data Exchange Between PACE Organizations and CMS	N/A
HIPAA						
64. Clarified language related to securing portable media.	Clarified the attestation related to securing portable media. Changed the wording to make it clear that portable media must be secure regardless of whether it is inside or outside of the	3.18A4	3.19A4	3.17A4	HIPAA	N/A

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	organization.					
65. Added a new attestation requiring applicants to abide by new privacy and security provisions and forthcoming CMS guidance.	Consistent with the American Recovery and Reinvestment Act, requires applicants to abide by new privacy and security provisions and future CMS guidance related to business associates that obtain or create protected health information.	3.18A11	3.19A11	3.17A11	HIPAA	N/A
PRESCRIPTION DRUG EVENT (PDE) RECORDS						
66. Added a new section to address basic expectations related to PDE records.	Added several attestations to ensure that Applicants are aware of basic requirements related to PDE. The attestations touch upon the following: • Guidance materials • Timely submissions • Format of data submissions	3.21A1-A6	3.22A1-A6	3.20A1-A6	Prescription Drug Event Records	Increase
CLAIMS PROCESSING						
67. Clarified attestations related to paper claims processing.	Clarified an attestation to distinguish non-electronic claims submission from network pharmacies from requests for reimbursement from beneficiaries.	3.22A2 3.22A4	3.23A2 3.23A4	3.21A2 3.21A4	Claims Processing	N/A
68. Clarified the names for the organizations that serve as the resource for pricing files.	Deleted the specific names of MediSpan and First Data Bank since there are other organizations that publish pricing information.	3.22A3	3.23A3	3.21A3	Claims Processing	N/A
69. Clarified an attestation related to claims data retrieval processes.	• Deleted references to encounter data since that is a concept specific to Medicare Advantage. • Added reference to file claims adjustments including records or	3.22A6	3.23A6	3.21A6	Claims Processing	N/A

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Summary of Substantive and Technical Changes for All Part D Application Revisions from 2010 Version of Part D Application to 2011 Draft Version

SUBSTANTIVE CHANGES						
Clarification	**Purpose of the Clarification**	**Application**				
		PDP	**MA-PD**	**Cost**	**PACE**	**Change in Burden**
	reimbursements and recoveries which are applicable to Part D.					
70. Deleted attestations that are repetitive based on clarified attestations.	Based on how the above mentioned attestations were edited, duplicative attestations were deleted from this section.	3.22A7-A8	3.23A7-A8	3.21A7-A8	Claims Processing	N/A
71. Changed an attestation to ensure that applicants use HIPPA compliant transactions.	Changed the wording of an attestation to ensure that applicants use HIPPA compliant transactions where applicable.	3.22A8	3.23A8	3.21A8	Claims Processing	N/A
72. Added a new attestation to address the updating of systems to ensure excluded providers are not paid.	Requires applicants to agree that systems receive regular updates to Part D claims are not paid when such claims have been prescribed by sanctioned (excluded) providers.	3.22A11	3.23A11	3.21A11	Claims Processing	N/A
CAHPS						
73. Add a new section (attestations) that the Part D sponsor will pay for CAHPS data collection costs once enrollment is more than 600.	Consistent with the 2010 Call Letter, two attestations were created that require: • Part D sponsors to pay for CAHPS data collection when enrollment reaches a certain point; and • Requires applicants to follow forthcoming CMS guidance that will address the process for organizations to contract with approved CAHPS survey vendors.	3.24	3.25	3.23	N/A	Increase
APPENDICES						
74. Incorporated the ITU required addendum into	The IHS and TTAG have requested that CMS amend the ITU addendum to	Appendix XV	Appendix XI	Appendix XI	N/A	N/A

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SUBSTANTIVE CHANGES						
Clarification	**Purpose of the Clarification**	**Application**				
		PDP	**MA-PD**	**Cost**	**PACE**	**Change in Burden**
the application as a reference document with IHS and TTAG requested changes.	clarify existing provisions, specifically related to arbitration. The addendum will be required by all new applicants and any existing sponsors as they re-contract with ITU pharmacies.					
75. Amended retail pharmacy access instructions to address 508 compliant software.	Per HHS guidance, deleted instructions for non-508 compliant software. Explained that CMS can only provide instructions and technical support for compliant software, but can still accept the access reports generated from non-508 compliant software.	Appendix XIII	Appendix X	Appendix X	N/A	N/A

Note: The Part D Service Area Expansion (SAE) application is an abbreviated version of the PDP and MA-PD applications. Corresponding changes and updates were made as appropriate. The one substantive change for the SAE application is that existing Part D Sponsors seeking to only expand employer service areas will need to complete the pharmacy access attestations.

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TECHNICAL CHANGES					
Clarification	**Purpose of the Clarification**	**Application**			
		PDP	**MA-PD**	**Cost**	**PACE**
GENERAL INFORMATION and INSTRUCTIONS					
1. Updated dates (language where appropriate), regulatory, Prescription Drug Benefit Manual citations, and reference file names as needed.	Updated dates (language where appropriate), references to statutes, regulations, Part D guidance, reference file names and URLs.	Throughout document	Throughout document	Throughout document	Throughout document
2. Made grammatical changes 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
3. Clarified language related to CMS monitoring and Part D Program oversight.	Clarified that CMS publishes the results of our monitoring on the appropriate websites, such as the Medicare Prescription Drug Plan Finder.	1.6.2	1.6.2	1.6.2	N/A
4. Clarified language related to General Enrollment Processing and Enrollment and Payment.	Updated language to reflect that CMS has developed enrollment systems, processes, payments.	1.6.6 and 2.6.2	1.6.6 and 2.6.2	1.6.6 and 2.6.2	N/A
5. Clarified language explaining the payment to Part D sponsors.	Clarified language related to the payment to Part D sponsors. Specifically, clarify low income	1.6.7	1.6.7	1.6.7	N/A

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TECHNICAL CHANGES					
Clarification	**Purpose of the Clarification**	**Application**			
		PDP	**MA-PD**	**Cost**	**PACE**
	subsidies to mean low income cost sharing and premiums.				
6. 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. This includes clarification on the timing for correct retail pharmacy access submissions.	Instructions; 2.4.1 2.8.1	Instructions; 2.4.1 2.8.1	Instructions; 2.4.1 2.8.1	N/A
7. Deleted the redundant reference to “business” day for payment.	To clarify the section related to when payments will be wired to sponsor accounts, the first occurrence of the word “business” was deleted from the first sentence.	2.6.3	2.6.3	2.6.3	N/A
8. Added a section explaining CMS expectations for pharmacy access to Indian Tribe and Tribal Organization, and Urban Indian Organizations (I/T/Us)	Consistent with the explanations provided for retail, home infusion and long-term care pharmacy access, a paragraph was added to explain expectations for ITU pharmacy access.	2.8.4	2.8.4	2.8.4	N/A
APPLICANT EXPERIENCE, CONTRACTS, LICENSURE AND FINANCIAL STABILITY					
MANAGEMENT AND OPERATIONS					
9. Clarified attestation that	Clarified existing attestation that had	3.1.1A1	3.1.1A1	3.1.1A1	N/A

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TECHNICAL CHANGES					
Clarification	**Purpose of the Clarification**	**Application**			
		PDP	**MA-PD**	**Cost**	**PACE**
applicant seeks to enter into a contract or addendum with CMS.	the applicant agreeing to abide by the terms of the contract with CMS. The new wording has the applicant attesting to their intent.				
10. Clarified the instructions for submission of the organizational chart and placement of Part D operations.	Based on past submissions, clarified the language to clearly indicate Applicants must provide an organizational chart for the legal entity seeking to become a Part D sponsor and the placement of Part D operations within that legal entity.	3.1.1B	3.1.1B	3.1.1B	N/A
11. Delete the phrase subcontractor and replace it with first tier, downstream, and related entities.	Based on the December 2007 regulations, references to subcontractor are replaced with first tier, downstream, and related entities.	Throughout document	Throughout document	Throughout document	Throughout document
12. Separated and clarified the language for the provision related to standard source of reimbursement into two provisions.	To assist applicants in clearly identifying necessary contractual provisions, we divided an existing required provision related to the standard source of reimbursement into two provisions and clarified the language (source and updates).	3.1.1D19	3.1.1D19	3.1.1D19	Management and Operations
13. Added administrative service agreements into the types of	Many applicants enter into administrative service agreements in	3.1.1D 3.1.1E	3.1.1D 3.1.1E	3.1.1D 3.1.1E	Management and

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TECHNICAL CHANGES

Clarification	Purpose of the Clarification	Application			
		PDP	MA-PD	Cost	PACE
agreements that must be provided and identified regulatory citations for required provisions.	addition to contracts with other organizations to provide key Part D functions.				Operations
EXPERIENCE AND CAPABILITIES					
14. Clarified an attestation related to tracking an enrollee's benefit in real time.	Added language "as applicable" since not all tracking of an enrollee's benefit can be completed in real time.	3.1.2A3	3.1.2A3	3.1.2A3	N/A
15. Identified regulatory citations, where appropriate, for required provisions.	Added the regulatory citations for the required contractual provisions as a point of reference for Applicants.	3.1.1D	3.1.1D	3.1.1D	Management and Operations
UTILIZATION MANAGEMENT STANDARDS					
16. Clarified language in attestation related to utilization of prescribed medications.	Clarified general language in the attestation that addresses applicants to maintain policies and procedures related to over- and under-utilization.	3.2.2A1	3.2.2A1	3.2.2A1	N/A
GENERAL PHARMACY ACCESS					
17. Clarified the instructions for submitting the ITU pharmacy contract template.	Clarified the instructions so that it is clear to applicants, the ITU pharmacy contract template is only required if there is an ITU pharmacy within the pending service area.	3.4B	3.5B	3.3B	N/A
RETAIL PHARMACY					

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TECHNICAL CHANGES

Clarification	Purpose of the Clarification	Application			
		PDP	MA-PD	Cost	PACE
18. Changed the year reference for the tables associated with pharmacy access waivers.	Changed from 2008 to 2009 the reference year in the tables related to waiver of retail convenient access and waiver of any willing pharmacy requirements.	N/A	3.5.1G 3.5.1H	3.3.1G 3.3.1H	N/A
I/T/U PHARMACY					
19. Clarified language related to postal carriers.	The existing attestation specified U.S. postage mail receipt of delivery to demonstrate proof a contract was offered. This expands that proof to "other carrier's" receipt of delivery.	3.4.6A3	3.5.6A3	3.3.6A3	N/A
20. Clarified instructions for submitting an ITU list.	Based on prior years' experience, we clarified the instructions for submitting the ITU list to more clearly indicate that applicants must use the reference file provided by CMS exactly.	3.4.6B	3.5.6B	3.3.6B	N/A
SPECIALTY PHARMACY					
21. Changed the word "attention" to "handling."	Consistent with Chapter 5, changing the phrase "special attention" to "special handling" more clearly references industry terminology.	3.4.7A3	3.5.7A3	3.3.7A3	N/A
ENROLLMENT & ELIGIBILITY					
22. Clarified language in several	Language was updated in several	3.5A8	3.6A2	3.4A2	N/A

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TECHNICAL CHANGES

Clarification	Purpose of the Clarification	Application			
		PDP	MA-PD	Cost	PACE
attestations.	attestations to maintain consistency with Enrollment Guidance (PDPs-Chapter 3 & MA-PDs and Cost-Chapter 4). Meanings were unchanged.	3.5A10-13 3.5A16	3.6A16-A17	3.4A15-A16	
23. Add change transactions to the list of transactions that Part D sponsors must submit to CMS within required timeframes.	Part D sponsors are required currently to submit change transactions within specified CMS timeframes. Adding the language makes the attestation consistent with current policy and operations.	3.5A6	N/A	3.4A12	N/A
COMPLAINTS TRACKING					
24. Replaced reference of business days to calendar days.	Reflects the language in Chapter 7 of the Prescription Drug Benefit Manual that Part D sponsors have 2 calendar days to resolve immediate need cases instead of 2 business days.	3.6A1	3.7A1	3.5A1	Complaints Tracking
COORDINATION OF BENEFITS					
25. Clarified attestation language.	Consistent with Chapter 14 of the Prescription Drug Benefit Manual, updated language in several attestations. Meanings were unchanged.	3.10A2 3.10A6 3.10A13	3.11A2 3.11A6 3.11A13	3.9A2 3.9A6 3.9A13	Coordination of Benefits
TROOP					

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TECHNICAL CHANGES

Clarification	Purpose of the Clarification	Application			
		PDP	MA-PD	Cost	PACE
26. Clarified attestation language.	Consistent with the 2010 Call Letter and Chapter 14 of the Prescription Drug Benefit Manual, updated language in several attestations. Meanings were unchanged.	3.11A2 3.11A6 3.11A7 3.11A9 3.11A10	3.12A2 3.12A6 3.12A7 3.12A9 3.12A10	3.10A2 3.10A6 3.10A7 3.10A9 3.10A10	TrOOP
MARKETING/BENEFICIARY COMMUNICATION					
27. Clarified attestation related to call center hours.	Consistent with Chapter 2, revised wording related to call center hours. Specifically: • Clarified hours on Saturdays, Sundays and holidays after March 2nd; • Changed the reference of wait time to hold time; and • Changed the reference of abandonment rate to disconnect rate.	3.13A6	3.14A6	3.12A6	N/A
PROVIDER COMMUNICATIONS					
28. Clarified attestation related to call center hours.	Consistent with Chapter 2, revised wording related to call center hours. Specifically: • Changed the reference of wait time to hold time; and • Added the reference to the	3.14A1	3.15A1	3.13A1	N/A

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TECHNICAL CHANGES					
Clarification	**Purpose of the Clarification**	**Application**			
		PDP	**MA-PD**	**Cost**	**PACE**
	disconnect rate.				
29. Clarified references in attestations related to coverage determinations.	Consistent with Chapter 18, revised language in several attestations to replace references of "exceptions" with "coverage determinations (including exceptions)".	3.14A2-A3	3.15A2-A3	3.13A2-A3	N/A
COMPLIANCE PLAN					
30. Changed the tense of the wording for the compliance plan attestations.	• Changed the wording of the attestations to make them read in the affirmative. • Added additional language to reiterate that the Medicare Compliance Officer must be an employee of the Applicant.	3.15A-C	3.16A-C	3.14A-C	Compliance Plan
HIPAA					
31. Clarified how an applicant will submit offshore subcontract information.	Makes the attestation clear that applicants will submit offshore subcontractor information via HPMS.	3.18A10	3.19A10	3.17A10	HIPAA
APPENDICES					
32. Added regulatory provision citations to each of the contract/template crosswalks and clarified instructions.	• To assist applicants in drafting contracts and contract templates correctly, the crosswalks have been revised to include the regulatory citation for each	Appendices VI-XI	Appendices III-VIII	Appendices III-VIII	Crosswalks of Requirement in Subcontracts

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Clarification	**Purpose of the Clarification**	**Application**			
		PDP	**MA-PD**	**Cost**	**PACE**
	provision, where appropriate. • To further assist CMS in locating the required provisions within the contracts and contract templates, the instructions were clarified to specify applicants should provide the exact page numbers of the .pdf files.				
33. Clarified instructions and updated reference file documents throughout retail pharmacy network access instructions.	• Changed the point of contact applicants may use when they have questions on completing the retail pharmacy network access portion of the application. • Clarified the instructions for both Quest Analytics and GeoNetworks software, including updating the names or reference files and examples of reports.	Appendix XIII	Appendix X	Appendix X	N/A

NOTE: Nothing in the technical changes table increases burden on the applicant.