OMB
Response to Public Comment on 2009 Part D Applications

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1	***INFORMATION NOT RELEASABLE TO THE PUBLIC UNLESS AUTHO***			
2	*This information has not been publicly disclosed and may be privileged and confidential. It is for internal gover to persons not authorized to receive the information. Unauthorized disclosure may result in prosecution to the fu*			
3	**Comment Number**	**Entity Submitting Comments**	**Subject Matter**	**Summary of Comment**
4	**Substantive Comments**			
5	**Licensure and Solvency**			
6	**1**	HealthPartners	State monitoring	Commenter contends that the attestation asking if the Applicant is under some type of supervision, corrective action plan on special monitoring by the State licensing authority is too broad and "some type" should be deleted.
7	**Pharmacy Access**			
8	**2**	CVS/Caremark	Retail Pharmacy Access	Commenter would like a streamlined approach to allow a PBM to submit one geoaccess national report on behalf of all of its clients.
9	**3**	HealthPartners	Retail Convenient Access Standards	Commenter is seeking clarification in the questions related to waivers of retail convenient access and whether CMS is looking for the number of all prescriptions provided in 2007 or just Part D.
10	**4**	HealthPartners	Home Infusion Pharmacy Access	Commenter would like a measure of "adequate access." Commenter is also asking if there is a statute or guidance that can be referenced.
11	**5**	HealthPartners	LTC Pharmacy Access	Commenter would like a definition of "sufficient access."
12	**Enrollment and Eligibility**			
13	**6**	Coventry	4 Rx data	Commenter is requesting clarifying language on an attestation related to reporting 4 Rx data when the enrollment is generated by CMS.
14	**Coverage Determinations (including Exceptio**			

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15	**7**	CVS/Caremark	Coverage determinations and paper claims	Commenter is requesting that CMS clarify that the time frames for standard coverage determinations applies only to requests for drugs that have not yet been dispensed as well as requests for payment made after and in response to a paper claim adjudication and that the time frame for an initial paper claim adjudication is the 15/30 day time frame regardless of the party that submits the paper claim.

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16				**Claims Processing**
17	**8**	National PACE Association	On-line claims processing	Commenter contends that PACE organizations would be unduly burdened by having to develop and create on-line claims processing systems and that they should have the option to instead have internal procedures in place to ensure accurate and timely payment of all claims submitted by network pharmacies.
18				**DUA Agreement**
19	**9**	CVS/Caremark	Data Use Agreement	Commenter is requesting that CMS revise the DUA agreement to allow the use and disclosure of CMS data as otherwise required by law and, for data that also constitutes PHI, to those uses and disclosures permitted by the HIPAA Privacy Rule and 42 CFR 423.136.

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1	***RIZED BY LAW:***
2	*nment use only and must not be disseminated, distributed, or copied ll extent of the law*
3	**Accept/Deny Change**
4	
5	
6	Accept. Deleted the wording "some type of" from the attestation. CMS is not asking for routine oversight information, but any type of oversight that would be a CAP, supervision or special monitoring.
7	
8	Deny. CMS offered this option during the first two years of the Part D program and since the applicant is ultimately responsible for their own submission, no applicant submitted via their PBM. Additionally at this time, HPMS is contract specific and the automation will not allow for the PBM to upload on behalf of mutliple clients. CMS can look into how to better streamline this process with automation in the future, but PBMs should build this expense into their contracts with their Part D clients.
9	CMS will clarify that it is all prescriptions from all lines of business.
10	Chapter 5 of the Prescription Drug Benefit Manual addresses home infusion adequate access and the reference is provided in the application.
11	Chapter 5 of the Prescription Drug Benefit Manual addresses long-term care access and the reference is provided in the application.
12	
13	Accept. Comment allowed CMS to recognize that this attestation was based on outdated operational guidance. As a result the attestation has been changed to reflect current operational procedures. The revised attestation reads as follows: Applicant ensures a process is in place to transmit plan-generated enrollment transactions that include active 4Rx data, and for CMS-generated enrollments, to transmit active 4Rx data on an update transaction within 3 business days of receipt of the TRR transmitting the enrollments.
14	**ns)**

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15	Deny with clarification. The requirement related to an initial paper claim adjudication time frame only applies to non-network pharmacists who are seeking reimbursement for prescription drugs provided to Part D enrollees. In this situation, an out-of-network pharmacist is seeking reimbursement for costs incurred after providing a prescription drug to an enrollee as though the enrollee were obtaining the prescription at a network pharmacy. This is different from a claim for reimbursement submitted by an enrollee or an enrollee's representative on the enrollee's behalf. Such a request constitutes a request for a coverage determination under 42 CFR §423.566(b)(1) and is subject to the 72-hour adjudication timeframe under §423.568(b). CMS would not be able to implement the commenter's change without a change to regulation, which CMS could do only if there was flexibility to do so under §1860D-4(g) of the Social Security Act. CMS clarified the attestation related to the 15/30 day is in contrast to claims submitted by beneficiaries.

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16	
17	Accept. CMS will put the option back in the application to have internal procedures in place to ensure accurate and timely payment of all claims submitted by network pharmacies.
18	
19	Deny. The suggested revision is not necessary to address the commenter's concerns. The DUA requires sponsors to limit their use of data obtained from CMS information systems to those "directly related to the administration of the Medicare benefits." The administration of the benefits involves compliance with all statutory and regulatory requirements of the Part C and D programs. The regulations for Part C (42 CFR §422.505(h)) and Part D (42 CFR §423.505(h)) requires sponsors to comply with all Federal laws and regulations designed to prevent fraud, waste and abuse, including but not limited to applicable provisions of Federal criminal law and the False Claims Act. Also, sponsors are required by regulation (Part C- 42 CFR §422.118; Part D- 42 CFR §423.136) to establish procedures for complying with all Federal and State laws, including HIPAA, regarding the disclosure of beneficiary health information. Therefore, sponsors' compliance with the statutes and regulations referenced by the commenter is an element of the administration of the Medicare benefits and is not inconsistent with the current terms of the DUA.

Comment Number	Entity Submitting Comments	Subject Matter	Summary of Comment	Accept/Deny Change
Clarification Comments (comments not on substantive information within the application; CMS will clarify directly with commenters)				
1	HealthPartners	Due date	Commenter requested CMS clarify whether the 11:59PM deadline time for submission of the application is local time or Eastern Standard Time.	Accept. CMS will clarify that it is Eastern Standard Time.
2	BCBS RI	General Instructions	Commenter states the CEO/legal authority signature on certifications is duplicative for any new plans being offered under the same contract number.	The applications are for initial contracts. Part D does not have a master application for CMS to reference an existing contract. The commenter is addressing new plans under an existing contract which would not require a new application.
3	BCBS RI	General Instructions	Commenter disagrees that existing MAOs should be required to submit an entire application for any new plans in 2009. Since BCBSRI has an evergreen contract, [their] processes and contracts have already been submitted, and therefore it would be duplicative and burdensome to be required to upload documentation in required pdf or excel format.	CMS is working to develop ways to crosswalk existing sponsors data in HPMS for new applications; however, with the onset of automation we are not able to currently do this. As a result, HPMS is contract specific and sponsors seeking new contracts must complete new applications. However, commenter is addressing new plans under existing contracts which are handled during bid submission. New applications are not needed to add a new plan under an existing contract.
4	BCBS RI	General Instructions	Commenter states existing MAOs should not have to completed sections of the application which have been submitted under evergreen contract.	See comment above, but note, that attestations may change to reflect updated operational policy developments and existing sponsors are responsible for meeting the criteria in the current year's application.
5	BCBS RI	General Instructions	Commenter suggests that existing MAOs be allowed to skip sections that are covered under existing evergreen contract and would not change with the application request (reference made to p. 32 MA-	Deny. The addressed sections of Utilization Management and Medication Therapy Management are not required for PFFS applicants per the regulations at 42 CFR §423.153(e).
6	BCBS RI	General Instructions	Commenter suggests that completing separate applications for an MA-PDP and a PDP is duplicative and burdensome	While CMS agrees that many of the sections are duplicative, there are several sections that are unique depending on the product type and therefore an applicant seeking different products must complete the separate applications
7	BCBS RI	General Instructions	Commenter suggests that unless CMS reduces application requirements, the timeframe [from posting of applications to submission of applications] will be difficult to meet, and CMS	Deny. CMS has provided the same amount of time to complete the Part D applications since the inception of the program. In addition, due to automation, less time will be needed to complete the Part D application.
8	HealthPartners	Financial solvency requirements	Commenter wanted to know where the CMS-published financial solvency and capital adequacy requirements are posted.	This information is included in the corresponding appendix entitled *Financial Solvency Documentation for Applicant Not Licensed as a Risk-bearing Entity in Any State.*

9	HealthPartners	PFFS Pharmacy Access	Commenter contends that an N/A should be added given the types of questions.	Deny. The nature of the questions actually requires either yes or no; n/a would not be an acceptable option.
10	HealthPartners	Retail Pharmacy Access	Commenter wants to know if the Medicare Beneficiary reference file will be updated.	Yes. The file will be updated for the final posting in January.
11	HealthPartners	Retail Pharmacy Access	Commenter wants to know why the N/A option was provided in the table related to whether an applicant is seeking to participate in the territories.	Due to automation, an applicant must provide an answer to every question. N/A is given as an option for those applicants not seeking to expand into the territories at all.