60-Day PRA Comments on CY2016 Part D Reporting Requirements - CMS-10185

Reporting Section	Description of Issue or Question	Commenter's Recommendations	CMS Response
Coverage Determinations and Redeterminations	Elements A -E: Data for elements A-E contain many multiples of the member POS experience. A significant number of events reported under the current specifications are due to attempts to put a transmission through the system. These events differ only by a system-assigned claim/claim-sequence number or transmission times that are minutes/seconds apart.	Recommends CMS defines a unique transaction, i.e., unique point-of-sale (POS) event. This would be a unique combination of member-pharmacy-drug-date (but not time). If CMS intends to capture a unique POS experience, specifications can be limited to a transaction type of bill, excluding reverse and re-bill. CMS could consult with industry experts at NCPDP concerning the definition of a unique transaction in terms of the member POS experience and define it in terms of D.0 fields, such as fill date, prescription number, product ID, memberID, dispenserID.	CMS will consider such changes in the future. At this time however, we will not revise the data collected.
Coverage Determinations and Redeterminations	General comment: Define if and where (which data element) “direct member reimbursement” (DMR) and “paper clams” determinations should be reported: o DMR requests received without regard to determination status o DMR and “paper claims” determinations for drugs with utilization management edits o DMR and “paper claims” determinations without utilization management edits	Recommends CMS defines if and where DMR determinations should be reported.	CMS agrees and will provide additional technical clarifications regarding direct member reimbursements.

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Coverage Determinations and Redeterminations	Resolve the specification contraction that asks that all Coverage Determinations be reported, but says to exclude Excluded Drugs. According to Chapter 18, after the member has received his Notice of Inquiry he may request a coverage determination. The SO will handle such request as a coverage determination per Chapter 18.	Recommend CMS clarifies that all Coverage Determinations be reported, but says to exclude Excluded Drugs. According to Chapter 18.	CMS agrees this exclusion could be further clarified in the technical specifications.
Coverage Determinations and Redeterminations	Element L-S: Specify if Hospice coverage determinations should or should not be reported as Exceptions.	Recommend CMS specifies if Hospice coverage determinations should or should not be reported as Exceptions.	CMS agrees and will provide additional technical clarifications about coverage determinations for beneficiaries enrolled in hospice.
Coverage Determinations and Redeterminations	General comment: Report rejections, de-duplicated, to greatly reduce the volume of data that needs to be put forward for Data Validation.	Recommend Sponsors reports rejections, de-duplicated, as above.	CMS disagrees, as information about multiple transactions for a single claim is important for monitoring beneficiary access to their medications.
Coverage Determinations and Redeterminations	General comment: Discontinue quarterly reporting. Go to annual reporting. For purposes of Data Validation, as needed to reduce file size, large contracts that can supply their Element A transactions broken into quarters.	Recommend CMS discontinues quarterly reporting and go to annual reporting.	Sponsors already report these data on an annual basis. At this time, no changes will be made.
Coverage Determinations and Redeterminations	Element B-E: Combine PA and ST rejections to reflect industry practice.	Recommend CMS combines PA and ST rejections to reflect industry practice.	CMS disagrees with this recommendation, as these data are aligned with Part D formulary requirements. We will continue to collect separate reporting for prior authorization (PA) and step therapy rejections.

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Coverage Determinations and Redeterminations	Element L-S: Remove the specification to exclude Excluded Drugs. That way, all completed coverage determinations can be reported without a specific additional step to find and remove those that were completed Exception Requests related to Excluded Drugs.	Recommend CMS removes the specification to exclude Excluded Drugs.	CMS disagrees with the recommendation. Data should be limited to non-excluded drugs in order for CMS to compare data across all plans, regardless of benefit designs.
Coverage Determinations and Redeterminations	Element L-S: Discontinue partially favorable. Most SOs do not recognize the existence of this type of event. For those that do, these rare events can be combined with adverse.	Recommend CMS discontinues partially favorable.	CMS appreciates this comment, but will continue to collect partially favorable data. Discontinuation of this element would lead to inconsistencies with categorizing these types of decisions.
Disenrollment	Elements E-G: "Given that good cause requests are submitted to CMS for approval, would this data be currently available to CMS? Element E:. Of the total reported in D, the number of disenrolled individuals who submitted a timely request for reinstatement for Good Cause.** F. Of the total reported in E, the number of favorable Good Cause determinations.** G. Of the total reported in F, the number of individuals reinstated.**	Recommend CMS not include these reporting elements, as the data seem to be currently available to CMS.	CMS disagrees with the recommendation. These elements are not duplicative of other data available to CMS. There are two paragraphs from the 2016 Call Letter (pages 76-77), where we explain the transfer of this responsibility from CMS to plans. CMS intends to assign the responsibility to conduct good cause reviews to MAOs, Part D plan sponsors and cost plans for CY 2016 and will expect that they perform the work from start to finish (i.e., intake, research, decision, notification, and effectuation). We will provide guidance regarding the application of the good cause criteria and related activities in our enrollment manuals (Chapter 2 and Chapter 17, Subchapter D, of the Medicare Managed Care Manual and Chapter 3 of the Medicare Prescription Drug Benefit Manual). Our expectation is that plans will develop their own internal processes for reviews, based on our

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			guidance, and carry out the majority of this workload without involving CMS. CMS will develop an oversight protocol for any activities assigned to plans that are currently carried out by CMS to verify that plans appropriately apply the regulatory standards associated with the good cause process. As part of this oversight, CMS will retain the authority to review both favorable and unfavorable decisions to make certain that results are fair and sound, and based on regulatory standards for reinstatement. CMS will transfer this responsibility to plans starting January 1, 2016, such that plans will be responsible for the intake and processing of good cause reinstatement requests for individuals disenrolled effective December 31, 2015, and later.
Grievances	General comment: Plans that are Fully Integrated Dual Eligible Special Needs plan (FIDE SNP) and the Part D technical specifications (including the data validation standards provided to data validation auditors) do not include differences found in FIDE SNP grievance requirements that may exist under the Medicaid state contract approved for the DNSP plan (e.g. state contract approved by CMS may have a different timeframe).	Recommend CMS incorporates language in the Part D Reporting Requirements Technical Specifications to include accommodation of FIDE SNP or MMP plans that may be subject to different timeframes due to the nature of dual eligible plan requirements.	CMS agrees with this comment. Medicare/Medicaid Plans (MMPs) should refer to the Medicare-Medicaid Financial Alignment Model Reporting Requirements for additional reporting guidance. We have revised the introduction in our Reporting Requirements document to explicitly state some MMP measures may have specific timelines that may be different.

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Grievances	General comments: • Supply a set of definitions, with examples, for each category • A text correction is needed to remove D. Notes 4. This specification language is inconsistent with Chapter 18. • A text correction is needed to remove B. Edits and Validation checks, "excluding expedited grievances".	Recommendations for CMS: 1. Supply a set of definitions with examples. 2. Clarify Note 4. 3. Remove incorrect text in B. Edits and Validation checks, "excluding expedited grievances". 4. Discontinue quarterly figures. Report timeliness only for the total grievances category.	These comments are out of scope for the data collection instrument, and are focused on technical specifications. CMS provides the following responses: 1. A set of definitions with examples is not needed for each grievance category. Technical specifications already include reference to Chapter 18, Sections 10 and 20 of the Prescription Drug Benefit Manual; we will also add that Sponsors can also refer 20.2.4.2 for examples of grievances, and definitions 2. We will clarify note 4 of the technical specifications with the following information: Sponsors should report expedited grievances in two elements: First, in the total number of expedited grievances. Second, in the appropriate grievance category. For example, if an enrollee files an expedited grievance because the plan denied their request for an expedited coverage determination, that grievance should be reported both as an "Expedited Grievance" and also as a "Coverage Determination and Redetermination Process" grievance. For this example, sponsors should report under element P. 3. The text listed in B. Edits and Validation checks is correct, but CMS will consider how to further clarify. For example, the total number of grievances (data element B) should be the sum of the

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			grievances by category (e.g. data elements F, H, J, etc). Since grievances processed as expedited grievances would also be counted in a grievance category, Sponsors should not double-count expedited grievances when verifying the number of total grievances has been reported correctly. 4. CMS disagrees, and will continue collecting on an annual basis, quarterly snapshots. It is important for CMS to continue monitoring for timeliness of grievances by category.
LTC	General comment: Expunge the words "Service Area" throughout the specifications, because you have repeatedly clarified that you want reporting on the basis of the national network. For some contracts, a service-area limitation significantly limits the volumes reported at elements D and E.	Recommend CMS expunges the words "Service Area" throughout the specifications.	N/A – This reporting section was suspended effective August 2015. The data collected are no longer needed, due to other data available through the Prescription Drug Event (PDE) data. This reporting section has been removed from the draft 2016 Part D Reporting Requirements for the 30-day comment period.
LTC	Element D: Specify if element D should be limited to patient residence code of 03. Inclusion of patient residence code 04-assisted living significantly increases the volume at element D.	Recommend CMS specifies if element D should be limited to patient residence code of 03.	N/A – This reporting section was suspended effective August 2015. The data collected are no longer needed, due to other data available through the Prescription Drug Event (PDE) data. This reporting section has been removed from the draft 2016 Part D Reporting Requirements for the 30-day comment period.
MTM	General comment about 2015 TS: The second sentence should be stricken from the specifications because it is contradicted by the preceding sentence, by CMS enrollment processes, and by the DV standards. *8. For Date of MTM program opt-out*	Recommend CMS revises the Technical Specifications (TS) document.	This comment does not impact the data collection, but CMS will consider how to further clarify this issue in the technical specifications document.

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	(element K) and Reason participant opted-out of MTM program (element L), sponsors should not count and report a member as having disenrolled from the plan with an opt-out date of 12/31 simply because it is the end of the year and the beneficiary will no longer be enrolled in the plan for the following year. A 12/31 disenrollment date should only be counted and reported if the member truly disenrolled from the plan on 12/31.		
MTM	General comment: Reduce the number of fields by limiting the reporting to beneficiaries who meet the CMS criteria	Recommend CMS reduces the number of fields by limiting the reporting to beneficiaries who meet the CMS criteria.	CMS disagrees with the recommendation. The information about beneficiaries enrolled in the sponsors' MTM program who met the sponsors' expanded eligibility criteria is needed to comprehensively analyze the Part D MTM programs. For example, to analyze outcomes of MTM programs, the analysis must control for who received MTM services (whether based on CMS' specifications or other plan-specific targeting criteria) or not.
MTM	General Comment: The Gentran (and Connect:Direct) submission/validation processes took weeks and rejections were not provided clear messaging to issues CMS identified based on the files submitted.	Recommend CMS create an alternative method to have the submission and acceptance process for Gentran (and direct:connect) be more efficient? None of the other Part D measures go through a 'validation' process and furthermore, a submission activity report capability is available in HPMS.	CMS believes this comment is out of scope for the proposed data collection. Due to the sensitive nature of the data being submitted for this measure, sponsors must use Gentran to submit beneficiary level data that cannot be submitted via HPMS. The response files also must reside on the Gentran server since this is the mechanism for which the data are uploaded. We have measures in place to be sure that responses are provided timely for future submission timeframes. CMS will look to improve communication when this situation occurs.

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MTM	General Comment: The file naming convention was inaccurate from the January 2015 memo and was not corrected until the end of the submission window period.	Recommend correction of the naming convention for future submissions.	CMS believes this comment is out of scope for the proposed data collection. CMS agrees the naming convention was incorrect in the January 2015 memo. Any user calling the HPMS help desk was provided the correct naming convention to submit their uploads and an updated HPMS memo was distributed to sponsors with the correct naming convention. CMS will put additional safeguards in place to prevent this issue in the future.
MTM	General Comment: We are concerned with the process for reporting in Gentran (and direct:connect), under the current guidance reports are considered timely only if CMS opens and verifies (validates) the report was received. Is there an alternative method to have the submission and acceptance process for Gentran (and direct:connect) be more efficient? None of the other Part D measures go through a 'validation' process and furthermore, a submission activity report capability is available in HPMS.	Recommend CMS create an alternative method to have the submission and acceptance process for Gentran (and direct:connect) be more efficient? None of the other Part D measures go through a 'validation' process and furthermore, a submission activity report capability is available in HPMS.	CMS disagrees with the recommendation. The Gentran submission is required to protect the personally identifiable information (PII) data contained therein. The validation is to assure that the sponsors are submitting all associated contracts or plans and that the format matches the technical specifications. If we remove all validations, we run the risk of receiving invalid data.
MTM	General Comment: The CMS-IT helpdesk resource responses (and response times) were severely slow and many times during the last few weeks of reporting, unresponsive (in that a caller could not get into a call queue and would be on hold for hours) and in some cases had to work with the IT desk for weeks to get resolution. Could CMS provide a notification process of known issues to plan sponsors via HPMS memo or email.	Recommend CMS provides a notification process of known issues to plan sponsors via HPMS memo or email.	CMS believes this comment is out of scope for the proposed data collection. CMS will look to improve communication when this situation occurs. CMS understands this technical comment and will be working to improve response times.

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MTM	General Comment: Could CMS utilize HPMS rather than Gentran (or direct:connect) to report MTMP?	Recommend CMS utilizes HPMS rather than Gentran (or direct:connect) to report MTMP data.	CMS disagrees due to the fact that MTM submission includes PII and beneficiary level data cannot be submitted via HPMS. Therefore, these data are submitted through Gentran.
General	• Expunge the words “Service Area” throughout the specifications. This will greatly simplify programming. • Round numbers up.	1. Recommend CMS expunges the words “Service Area” throughout the specifications. 2. Recommend CMS round numbers up.	1. This comment does not impact the data collection instrument. CMS has clarified the issues around “service area” in the technical specifications. 2. N/A since the LTC reporting section has been suspended.
General	Could CMS provide additional guidance for plans that have fully integrated dual eligible beneficiaries to accommodate differences impacting reporting requirements?	Recommend CMS provide additional guidance for plans that have fully integrated dual eligible beneficiaries to accommodate differences impacting reporting requirements.	CMS agrees with this comment. Medicare/Medicaid Plans (MMPs) should refer to the Medicare-Medicaid Financial Alignment Model Reporting Requirements for additional reporting guidance. We have revised the introduction in our Reporting Requirements document to explicitly state some MMP measures may have specific timelines that may be different.
General	If guidance is released and there are issues identified afterwards, or even with the guidance itself, please send out corrections to the plans. The CMS helpdesk identified numerous issues with 2014 reporting, once we were able to get in contact with them, but additional guidance was not released to clarify the issues for all plans.	Recommend CMS send out corrections to the plans if guidance is released and there are issues identified afterwards.	CMS believes this comment is out of scope for the proposed data collection. CMS however, does agree communication can be improved if technical issues occur during a data submission window. CMS will look to improve communication when this situation occurs.

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General	Could plans actively seek out clarifications and guidance regarding the Technical Specifications? Perhaps responses would be tracked somewhere (FAQ) on an on-going basis as sponsors may have similar questions and it would be helpful to information share.	Recommend CMS create an ongoing (FAQ) document as sponsors may have similar questions and it would be helpful to share information.	CMS believes this comment is out of scope for the proposed data collection. CMS agrees and does consider questions/suggestions received to make updates to Reporting Requirement and the Technical Specifications. CMS will look to improve communication when this situation occurs.
General	What does CMS intend to do with this information?	n/a	Data collected via Medicare Part D Reporting Requirements are an integral resource for oversight, monitoring, compliance and auditing activities necessary to ensure quality provision of the Medicare Prescription Drug Benefit to beneficiaries.