

A	B	C	D	E	F	
1	<b>60-Day Comment Response Document</b>					
2	<b>Overview of Comments</b>	CMS received various comments from Part D sponsors, PBMs and other associations. We received 8 comments regarding the following reporting sections: Improving Drug Utilization Review Controls, Coverage Determinations and Redeterminations, Grievances, and Medication Therapy Management.				
3	<b>Detailed Summary of Comments</b>					
4	<b>Section</b>	<b>Comment</b>	<b>Committer's Recommendation</b>	<b>CMS Response</b>	<b>Revised Requirements/Documents</b>	<b>Revised Burden Estimates</b>
5	DUR	In the recently released 60 day Data Validation Audit comment period, the referenced Appendix B Crosswalk for DUR Reporting under the CY2022 DV (2021 Reporting Requirements) has a few sections listed as N/A deleted however in the 2021 Record File Layout it does not show as an N/A but rather a different element than what was listed in 2020. Please confirm is the N/A not required for the data validation audit but remains required for the Part D Reporting?	N/A	Please note that the N/A or deletion applies to the data validation check rather than the data elements themselves listed in the DUR Record File Layout.	No	No
6	Grievances	Appendix B, page 4, section REPORTING SECTION CRITERIA (for 2021 reported data), GRIEVANCES (PART C) (for 2021 REPORTED DATA).7. For clarification the CY2021 Part D Reporting Requirements Technical Specifications are not required the distribution of the elements by category. The language for this 2022 document makes mention of categories. (Organization accurately calculates the number of grievances by category for which it provided timely notification of the decision, including the following criteria)	N/A	For Part C Grievances, RSC 7 in Appendix B and Appendix J has been updated as per the Reporting Requirements to read as follows:  "Organization accurately calculates the number of grievances for which it provided timely notification of the decision, including the following criteria."  This language has also been updated in Exhibit 14, page 16 of the DV Procedure Manual.	Yes	No
7	CD/RD	Appendix B: Data Validation Standards, page 24, item 6a and page 25, item 10a: There is a discrepancy between the CY2021 Part D Reporting Requirements Technical Specifications and the Attachment B: Data Validation Standards Document specifically, for the Coverage Determinations and Redeterminations Reporting. In accordance with the Medicare Part D Plan Reporting Requirements: Technical Specifications Document Contract Year 2021 updated in January 2021, states that for the coverage determination and redetermination reports the data should be reported based on the date the enrollee/enrollee's representative is notified in writing of the coverage determination and redetermination decisions. However, in the Attachment B: Data Validation Standards states that the data should be reported based on the date of decision that occurs during the reporting period, regardless of when the request for coverage determination was received. Please clarify which is the correct date that the data should be reported for the year 2021.	N/A	For CDR, RSC 6a, RSC 10 a, as well as RSC 7 a, have been updated in Appendix B and J, as per Reporting Requirements to read as follows:  RSC 6a: Includes all coverage determinations (fully favorable, partially favorable, and adverse), including exceptions, with a date of decision that occurs during the reporting period. Date of the final decision is based on the date the enrollee/enrollee's representative is notified in writing of the coverage determination decision.  RSC 7a: Includes all decisions made (fully favorable, partially favorable, and adverse) with a date of decision that occurs during the reporting period. Date of the final decision is based on the date the enrollee/enrollee's representative is notified in writing of the exception decision.  RSC 10 a: Includes all redetermination final decisions for Part D drugs with a date of final decision that occurs during the reporting period. Date of the final decision is based on the date the enrollee/enrollee's representative is notified in writing of the redetermination decision.	Yes	No

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4	CD/RD	Will CMS update the Data Validation documents for Part D Coverage Determinations & Redeterminations to reflect what it states in the 2021 Part D Reporting Requirements, which is to report by notification date? Or, should sponsors expect an update for the 2021 Reporting Requirements?	N/A	For CDR, RSC 6a, 7a, and 10a have been updated in Appendix B and J, as per Reporting Requirements to read as follows:  RSC 6a: Includes all coverage determinations (fully favorable, partially favorable, and adverse), including exceptions, with a date of decision that occurs during the reporting period. Date of the final decision is based on the date the enrollee/enrollee's representative is notified in writing of the coverage determination decision.  RSC 7a: Includes all decisions made (fully favorable, partially favorable, and adverse) with a date of decision that occurs during the reporting period. Date of the final decision is based on the date the enrollee/enrollee's representative is notified in writing of the exception decision.  RSC 10 a: Includes all redetermination final decisions for Part D drugs with a date of final decision that occurs during the reporting period. Date of the final decision is based on the date the enrollee/enrollee's representative is notified in writing of the redetermination decision.	Yes	No
8	CD/RD	In our review of the 2022 Medicare Part C and D Reporting Requirements Data Validation Procedure Manual, Appendix B we found a discrepancy on page 24. To improve consistency, we ask for CMS to update sections 6 and 7, Coverage Determinations, to match the section E Notes 2. Coverage Determinations and Exceptions, bullet 3, on p. 19 of the 2021 Medicare Part D Plan Reporting Requirements: Technical Specifications.	N/A	For CDR, RSC 6a, 7a, as well as 10a have been updated in Appendix B and J, as per Reporting Requirements to read as follows:  RSC 6a: Includes all coverage determinations (fully favorable, partially favorable, and adverse), including exceptions, with a date of decision that occurs during the reporting period. Date of the final decision is based on the date the enrollee/enrollee's representative is notified in writing of the coverage determination decision.  RSC 7a: Includes all decisions made (fully favorable, partially favorable, and adverse) with a date of decision that occurs during the reporting period. Date of the final decision is based on the date the enrollee/enrollee's representative is notified in writing of the exception decision.  RSC 10 a: Includes all redetermination final decisions for Part D drugs with a date of final decision that occurs during the reporting period. Date of the final decision is based on the date the enrollee/enrollee's representative is notified in writing of the redetermination decision.	Yes	No
9	CD/RD	In our review of the Medicare Part C and D Reporting Requirements Data Validation Procedure Manual, Appendix B we found a discrepancy on p. 25. To improve consistency, we ask for CMS to update section 10.ato match section E.3. on p. 20, Redeterminations of the 2021 Medicare Part D Plan Reporting Requirements: Technical Specifications.	N/A	For CDR, RSC 6a, 7a, as well as 10a have been updated in Appendix B and J, as per Reporting Requirements to read as follows:  RSC 6a: Includes all coverage determinations (fully favorable, partially favorable, and adverse), including exceptions, with a date of decision that occurs during the reporting period. Date of the final decision is based on the date the enrollee/enrollee's representative is notified in writing of the coverage determination decision.  RSC 7a: Includes all decisions made (fully favorable, partially favorable, and adverse) with a date of decision that occurs during the reporting period. Date of the final decision is based on the date the enrollee/enrollee's representative is notified in writing of the exception decision.  RSC 10 a: Includes all redetermination final decisions for Part D drugs with a date of final decision that occurs during the reporting period. Date of the final decision is based on the date the enrollee/enrollee's representative is notified in writing of the redetermination decision.	Yes	No
10						

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	Section	Comment	Commenter's Recommendation	CMS Response	Revised Requirements/Documents	Revised Burden Estimates
4						
11	DUR	We would request that CMS add additional language to element CC to emphasize that the request for coverage determination or appeal be directly linked to element Z. We would propose the following language be added to the Appendix J RSC-8.biii "RSC-8 biii: Includes all coverage determination or appeals requests subject to the opioid naive edit specific to same drug and date".	N/A	The CY 2021 Part D Reporting Requirements lay out the link between Data Elements Z and CC.  RSC-8 biii has been updated in Appendix J and Appendix B as follows:  "Includes all coverage determination or appeal requests subject to the opioid naive edit."  As Note #5 in DUR Technical Specifications addresses rejected claims and the specifications include aspects beyond drug and date, such as quantity, strength and dosage form; we took out the part about being "specific to same drug and date".	Yes	No
12	MTM	UHC asks CMS to confirm the process to populate the data for Elements I, J and K, (Appendix B: Data Validation Standards, 3, Part D Data Validation Standards, Medication Therapy Management (MTM) Programs) in the scenario below. We understand that Element K will not be validated in the 2022 Data Validation audit. Element I. Date of MTM program enrollment. Element J. Date met the specified targeting criteria per CMS – Part D requirements in § 423.153(d)(2). Required if met the specified targeting criteria per CMS – Part D requirements (May be same as date of MTM program enrollment). Element K. Targeting criteria met. Required if met the specified targeting criteria per CMS – Part D requirements in § 423.153(d)(2) (Multiple chronic diseases/multiple Part D drugs/cost threshold, (Drug management program at-risk beneficiary1, Both)).	Member meets Medication Therapy Management (MTM) program targeting criteria on 1/5/22 based on having multiple chronic diseases/multiple Part D drugs/cost threshold. Later in the year, on 4/5/22, the member is identified as a Drug Management Program At Risk Beneficiary (DMP-ARB). Given the member meets two reporting categories, please confirm the reporting for this member should be as follows: • Element I = 1/5/22 (date member met MTM program criteria) • Element J = 4/5/22 (date the member meets both MTM program and DMP-ARB criteria) • Element K = "Both"	This question is outside of the scope of this PRA.  This PRA is for the 2022 DV of CY 2021 reporting data, not CY 2022 reporting data. Please reference the CY 2021 Medicare Part D Reporting Requirements which is located at <a href="https://www.cms.gov/files/document/cy2021-part-d-reporting-requirements-120920.pdf">https://www.cms.gov/files/document/cy2021-part-d-reporting-requirements-120920.pdf</a> .  Specifically refer to the Section II. Medication Therapy Management Programs and footnotes 1 and 2 that identify where items are not applicable for January 1 – December 31, 2021 reporting period.	No	No