60-Day Comment Response Document

Overview of Comments

CMS received eight comments from Part D sponsors regarding the following reporting sections: Medication Therapy Management, Improving Drug Utilization Reviews, and Coverage Determinations and Redeterminations.

Detailed Summary of Comments

Section	Comment	Commenter's Recommendation	CMS Response	Revised Requirements/ Documents	Revised Burden Estimates
MTM	Appendix B – It appears a data element was removed (v) from the 2023 version and the data elements have shifted. The dependencies for specific areas shifted the data element label as well, but they seem to be off. For example, section 5d states it is counted if Data Element P is within the beneficiaries enrollment period, but it should data element Q. It appears when they shifted all elements and not only the elements that changed beyond element V. This occurs throughout this section.	The commenter believes that RSC 2e. 5d should reference Data Element Q instead of Data Element P. Commenter also believes that all data elements of reference should be verified.	RSC 2e. 5d asks for CMR received date. As per the CY 2022 Reporting Requirements, Data Element P collects the date of CMR receipt and Data Element Q notes the date the initial CMR written summary was provided or sent.	No	No
MTM	Appendix J - 2.e / RSC-6.b - This isn't saying that the data used to determine if a member is eligible for MTM needs to be uploaded, is it?	N/A	In MTM, 2.e RSC-6.b asks that organizations accurately identify data on MTM program participation and uploads it into HPMS, which includes the ingredient cost, dispensing fee, sales tax, and the vaccine administration fee (if applicable) when determining if the total annual cost of a member's covered Part D drugs is likely to equal or exceed the specified annual cost threshold for MTM program eligibility.	No	No
DUR	Included in the list of Data Validation documents in CMS-10305, there appear to be contradictory requirements for DUR reporting. From the 2022 Medicare Part D Reporting Requirements document, under Section IV. Improving Drug Utilization Review, the data requirement is "All data elements must be uploaded to HPMS at the Contract level." From CMS-10305, Appendix B - Data Validation Standards include references to both plan and contract level. • 6.a.iii, 6.b.iii, and 6.c.iii – Rejected opioid claims are counted at the unique plan, … • 7.a.1. and 7.b.1. - Rejected claims are counted at the unique contract,… • 8.a.1. and 8.b.1. - Rejected claims are counted at the unique contract,… Please confirm all rejected claims are counted at the contract level.	Commenter is seeking clarification to DUR reporting between plan- and contract-level reporting.	CMS has updated these conflicting instances to clarify that reporting should be at the contract-level.	Yes	No
CD/RD	2.e / RSC-5.a [Note] says that Data Elements 2.A - 2.F relate to Redeterminations, but it should be 2.A - 2.V.	Commenter recommends that CMS update the Data Elements that relate to Redeterminations in RSC 5.a in Appendix J from Elements 2.A-2.F to 2.A-2.V	CMS agrees. RSC 5.a in Appendix J is updated to reflect Data Elements 2.A-2.V for Redeterminations, as stated in Appendix B.	Yes	No

Section	Comment	Commenter's Recommendation	CMS Response	Revised Requirements/ Documents	Revised Burden Estimates
CD/RD	2.e / RSC-10.l, RSC-11.c, RSC-12.b - These points seem to contradict each other regarding IRE. 10.l says exclude all (which matches CY2022), while 11.c says to include IREs. I can't see all of the data elements called out for 11.c, but if the pattern follows I think it's the same as 10.l. Furthermore, RSC-12.b again states to exclude IREs. So I think it's RSC-11.c that's out of whack.	The commenter believes that RSC 11.c should not include IRE decisions, as it contradicts the exclusion of IRE decisions for RSC 10.l and RSC 12.b.	As per the CY 2022 Reporting Requirements, IRE decisions are not reported for redeterminations. As stated in Appendix B, IRE decisions are excluded from both RSC 10 (total number of redeterminations) and RSC 12 (number of redeterminations by final decision). Comparably, RSC-11 (total number of UM, Formulary, and Tier exception redetermination decisions) includes redetermination requests where the organization failed to issue a timely decision, which were then forwarded to the IRE. RSC 11.c does not include IRE decisions, but it does include redetermination requests that were forwarded to the IRE.	No	No
CD/RD	For non-formulary and Hospice Exceptions where would we bucket these as it is unclear in the guidance as follows: Disposition – Redeterminations (non-exceptions) Disposition – Utilization Management Exception Redeterminations Disposition – Formulary Exception Redeterminations Disposition – Tiering Exception Redeterminations Disposition – At-Risk Redeterminations	N/A	Thank you for your inquiry. Non-formulary exceptions would be reported under the Disposition - Formulary Exceptions Redeterminations category. For hospice requests, if the requested drug is subject to UM, and the person is requesting an exception to the UM requirement it would be reported under the Disposition - Utilization Management Exception Redeterminations. If the only issue is whether the drug should be covered by hospice, it would not be reported as a hospice exception. It would be reported under the Disposition - Redeterminations non-Exceptions category.	No	No
CD/RD	RSC-10e: Organization accurately calculates the total number of redeterminations (Part D only), including the following criteria: e: Includes At-risk determination appeals (beneficiary-specific Point of Sale (POS) edit, prescriber or pharmacy coverage limitation appeals, sharing information for subsequent Part D enrollments) made under a drug management program redeterminations. • Does CMS expect the health plan to issue a written decision at the Point of Sale? • How does sharing information for subsequent Part D enrollment will affect/engage the appeal process?	N/A	Thank you for your inquiry. Please refer to the HPMS memo dated 09/30/21 for guidance on policy questions related to the Part D Drug Management Program - https://www.cms.gov/files/document/cy-2022-part-d-dmp-guidance-memo-september-30-2021.pdf. If you need additional clarification on the drug management program, please send your questions to: PartD_OM@cms.hhs.gov. For reporting purposes, At-risk determination appeals (beneficiary-specific POS edit, or prescriber or pharmacy coverage limitation appeals, sharing information for subsequent Part D enrollments) made under a drug management program should be reported under the Disposition - At Risk Redeterminations category.	No	No
CD/RD	RSC-10: Organization accurately calculates the total number of redeterminations (Part D only), including the following criteria: i: Includes all redetermination decisions that relate to Part B versus Part D coverage (drugs covered under Part B are considered adverse decisions under Part D). a. Point of Sale (POS) claims adjudications (e.g., a rejected claim for a drug indicating a B vs. D PA is required) are not included unless the plan subsequently processed a redetermination. • Point of Sale appeals?	N/A	Redetermination requests that relate to Part B versus Part D coverage are included in this reporting if they are processed under the plan's Part D redetermination process.	No	No