30-Day Comment Response Document

Overview of Comments

CMS received various comments from Part D sponsors, PBMs and other associations. We received 13 comments regarding the following reporting sections: Enrollment and Disenrollment, Improving Drug Utilization Review Controls, Coverage Determinations and Redeterminations, Medication Therapy Management and Employer/Union-Sponsored Group Health Plan Sponsors.

Detailed Summary of Comments

Section	Comment	Commenter's Recommendation	CMS Response	Revised Requirements/Documents	Revised Burden Estimates
Enrollment and Disenrollment	Element D: The 2021 element D for enrollments indicated, “the number of enrollment requests denied due to the sponsor’s determination of the applicant’s ineligibility to elect the plan.” This 2022 version now states, “the number of enrollment requests denied due to the sponsor’s determination that the applicant was not eligible for an election period.” We would like clarification if this means element D should only include election period denials and no other upfront denial reasons such as for outside the service area and element F is for all other denials.	N/A	The commenter is incorrect. The 2021 Element D for enrollments indicates the following: "Of the total reported in A, the number of enrollment requests denied due to the sponsor’s determination of the applicant’s ineligibility to elect the plan (i.e. individual not eligible for an election period)." For 2022, Element D is as follows: "D. Of the total reported in A, the number of enrollment requests denied due to the sponsor’s determination that the applicant was not eligible for an election period." The activity to be reported for Element D has not changed from 2021 to 2022. We can confirm that Element D should only include enrollment denials based on lack of eligibility for an election period. We can also confirm that enrollment Element F is not "for all other denials," as the commenter states. Element F should only include denials due to the applicant or his/her authorized/legal representative not providing the information required to complete the enrollment request within established timeframes, as follows: "F. Of the total reported in C, the number of enrollment requests denied due to the applicant or his/her authorized/legal representative not providing the information required to complete the enrollment request within established timeframes."	No	No

Section	Comment	Commenter's Recommendation	CMS Response	Revised Requirements/Documents	Revised Burden Estimates
CD/RD	For the Redetermination section, please provide guidance on how to report RD DMR's not related to an exception? For example, which of the new reporting sections would we report RD DMR's related to cost sharing appeals or Self-Administered Drugs where the coverage determination was denied for no proof of payment and the member is now providing documentation of payment?	N/A	Thank you for your inquiry. If the enrollee is appealing the initial DMR denial and it is not an exception request, the DMR would be reported under the total number of Redeterminations processed (2A) as well as Dispositions- Redetermination (non exceptions); D, E, or F - whichever is applicable to the case.	No	No
EGWP	We would like CMS to insert clarification on why the following paragraph from this section was removed: "NOTE: This reporting requirement applies only to individual PDPs and "800 series" PDPs offered to employers. MA-PD plans already report these data as part of the Part C reporting requirements and are therefore exempt from this Part D reporting section." Please insert clarification on whether this means CMS expects MAPD plans to now follow the Part D Reporting Requirements for this specific section as of 2022 going forward and not the Part C Reporting Requirements.	N/A	The statement was removed for 2020 Part D reporting, it is not a change for 2022. Please refer to the HPMS email sent on 11/24/20 that stated effective for 2020 reporting, all "800 series" PDPs offered to employers are required to report data for this reporting section.	No	No
MTM	On page 8, data element K is defined as, "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 beneficiary; Both; None)." o Comments: We requests clarity on the date that should be reported to CMS in an example where a beneficiary is identified as MTMP eligible via both the eligibility criteria utilized by the plan sponsor and at-risk beneficiary designation through the plan sponsor's Drug Management Program. Like other requirements within Part D reporting, we otherwise plans to report the earliest date of whichever targeting criteria eligibility is met first.	N/A	Sponsors should report the date the beneficiary first met either set of the targeting criteria. CMS will update the technical specifications pending OMB approval of the final CY 2022 Reporting Requirements.	No	No

Section	Comment	Commenter's Recommendation	CMS Response	Revised Requirements/Documents	Revised Burden Estimates
MTM	On page 8, for data elements Y and Z, the reporting requirements reference communications “sent” to beneficiary. o Comments: We asks that CMS clarify the definition of “sent” and if that includes hand delivery of MTM Program materials from the MTM service provider and/or returned mail.	N/A	The CY 2021 Reporting Requirements technical specifications state "For reporting annual CMR with written summary in CMS standardized format, the beneficiary must receive the CMR written summary. Therefore, returned mail does not count as a received CMR." In addition, "sent" refers to hand delivery as well as secure electronic or postal mail. CMS will update the technical specifications pending OMB approval of the final CY 2022 Reporting Requirements.	No	No
MTM	We seek confirmation regarding how to populate the data for Elements H, I and J, (Section II. Medication Therapy Management Program) in the scenario below. Member meets 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 DMP-ARB. Given the member meets two reporting categories, please confirm the reporting for this member should be as follows: • Element H = 1/5/22 (date member met MTM program criteria) • Element I = “Both” • Element J = 4/5/22 (date the member meets both MTM program and DMP-ARB criteria)	N/A	Sponsors should report the date the beneficiary first met either set of the targeting criteria. CMS will update the technical specifications pending OMB approval of the final CY 2022 Reporting Requirements.	No	No
DUR	Please clarify the intent of data element DD - Of the total reported in element AA, the number of unique beneficiaries for whom up to a 7 day supply (covered by the plan) was dispensed by the pharmacy. Does element DD represent: 1. a member with a rejected claim due to the naive edit and another opioid claim filled up to a 7 day supply, or 2. a member with a rejected claim due to the naive edit that was overridden and had a subsequent fill of up to a 7 day supply	N/A	Neither. The intent of element DD is to report the number of unique beneficiaries with a claim rejected because of the opioid naïve 7 day supply edit and, in response to that edit, the pharmacy dispensed up to 7 days instead of the full duration included in the prescription. Dispensing up to 7 days is generally expected if the claim is not overridden (allowing more than 7 days dispensed and covered by the plan), unless the enrollee refuses the partial fill or chooses to pay cash for the full prescription.	No	No

Section	Comment	Commenter's Recommendation	CMS Response	Revised Requirements/Documents	Revised Burden Estimates
DUR	We believe the new proposed DUR Reporting elements X, Y, BB and CC provide limited to no value in the reporting because currently there is no way for the pharmacist to distinguish an override for an exemption versus override for member being opioid naive because the pharmacist currently uses the same code for either override.	N/A	As described in the opioid safety edit FAQs (link below), "Sponsors should instruct pharmacists on how to communicate to the plan that the enrollee is excluded (e.g., through a transaction response code or by contacting the pharmacy help desk) to override the edit or to avoid the beneficiary or their prescriber from having to request a coverage determination on this particular fill. Plans are expected to accept this information in real-time so the claim can adjudicate." The NCPDP released updated telecommunication standards guidance that supports the Part D opioid safety edits which can capture the information in the proposed elements. For more information on the NCPDP standards, refer to the following document: https://www.ncpdp.org/NCPDP/media/pdf/VersionD-Questions.pdf. For more information on opioid safety edit guidance, refer to https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.	No	No
DUR	What would be considered an exception for a pharmacist allowing a claim to pay at POS? How would that be identified?	N/A	Reasons for a pharmacist override may vary depending on the edit, e.g., prescriber attestation for care coordination edit, or recent claims history demonstrating a beneficiary is not opioid naive for the 7 day supply edit. We will consider clarifying in the Technical Specifications. In the meantime, refer to the current opioid safety edit guidance for detailed information about beneficiary exemptions applicable to all opioid safety edits: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization. Additionally, NCPDP guidance contains a number of response codes related to these edits: https://www.ncpdp.org/NCPDP/media/pdf/VersionD-Questions.pdf	No	No
DUR	Element F: The number of claim rejections overridden by the pharmacy due to an exemption. Question - Please provide more detail on what is considered and "exemption".	N/A	We will consider clarifying in the Technical Specifications. In the meantime, refer to the current opioid safety edit guidance for detailed information about beneficiary exemptions: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization. Additionally, NCPDP guidance contains a number of response codes related to these edits: https://www.ncpdp.org/NCPDP/media/pdf/VersionD-Questions.pdf	No	No

Section	Comment	Commenter's Recommendation	CMS Response	Revised Requirements/Documents	Revised Burden Estimates
DUR	Element F: In the Opioid Care Coordination Safety Edit at 90 MME, the new element F they are requesting the number of claim rejections overridden by a pharmacy due to an exemption. Since this is a soft edit and its solved at POS it never gets to CD to be approved as an exception. What CMS is referring to when they say overridden by an exemption? That is was approved by CD or pharmacy override without consulting prescriber due to other reason?	N/A	While the care coordination edit may be resolved at POS, CMS disagrees that it will always be resolved without the need for a coverage determination. Element F refers to the number of claim rejections overridden by the pharmacy due to an exemption; that is, the enrollee is exempt because they are a resident of a long-term care facility, are in hospice care or receiving palliative or end-of-life care, have sickle cell disease, or are being treated for active cancer related pain. We will consider clarifying in the Technical Specifications. In the meantime, refer to the current opioid safety edit guidance for detailed information about beneficiary exemptions: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization. Additionally, NCPDP guidance contains a number of response codes related to these edits: https://www.ncpdp.org/NCPDP/media/pdf/VersionD-Questions.pdf.	No	No
DUR	Element E. The number of claim rejections overridden by the pharmacy within 24 hours of the initial claim rejection Question: Can CMS clarify the timeframe for if/when a claim would become an "initial claim rejection" again? For example, if a claim was processed for a particular member on January 1st, rejected for the Care Coordination Safety Edit, and then another claim was processed on April 1st and also rejected for this edit, would they be considered 2 separate "initial claim rejections"? Or is CMS considering the "initial claim rejection" to be counted once per year, upon the first occurrence?	N/A	Yes, based on the example you describe, these would be different initial claim rejections. We will consider additional clarification in the Technical Specifications.	No	No

Section	Comment	Commenter's Recommendation	CMS Response	Revised Requirements/Documents	Revised Burden Estimates
DUR	Element J. The number of unique beneficiaries with at least one claim rejection overridden by the pharmacy within 24 hours of the initial claim rejection Question: In the example above, should the beneficiary be counted only if the January 1st claim (first incidence) was overridden by the pharmacy within 24 hours? Or should the April 1st claim also be reviewed and taken into account?	N/A	For Element J, report the beneficiary the first time they meet the conditions. We will consider clarifying in Technical Specifications. With regard to additional claims after a care coordination override, refer to A18-19 in the Frequently Asked Questions (FAQs) about Formulary-Level Opioid Point-of-Sale (POS) Safety Edits. We expect sponsors to implement reasonable logic to remove the likelihood of redundant or duplicative coordination edits from triggering multiple times and necessitating repeated pharmacist-prescriber consultations (e.g., after they receive the prescriber attestation via a coverage determination request or confirmation from the pharmacy that the prescriber was consulted). We encourage the use of 90 MME message-only alerts similar to sponsors' care coordination edit parameters once the care coordination edit has been resolved; that is, has been overridden at the POS or no longer triggers as the result of a coverage determination or appeal.	No	No