60-Day Comment Response Document

CMS received various comments from Part D sponsors, PBMs and other associations. We received 27 comments regarding the following reporting sections: Enrollment/Disenrollment, Employer/Union-Sponsored Group Health Plan Sponsors, Medication Therapy Management, Improving Drug Utilization Review Controls and Coverage Determinations and Redeterminations. CMS also received two out of scope comments.

Detailed Summary of Comments

Section	Comment	Commenter's Recommendation	CMS Response	Revised Requirements/Documents	Revised Burden Estimates
Enrollment	The previous 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 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. There is no substantive change in the criteria for this element from 2021 to 2022. Current Element D states: *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).* Proposed Element 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.* Element D should include denials based on lack of election period eligibility only. Element F should include the number of cases reported for Element C which were eventually denied because the applicant or his/her authorized representative/legal representative failed to provide the information required to complete the enrollment request within established timeframes.	No	No
Enrollment	The previous element K for enrollments stated "the number of enrollment requests effectuated by sales persons." It now says, "the number of enrollment requests received from an applicant through an agent broker." We would like clarification whether that means this should only include applications received from 3rd party brokers or if this also includes internal plan sales agents.	N/A	As proposed, Element K should include enrollment requests received from an applicant through an agent or broker, including sales agents employed by the plan.	No	No

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Enrollment	CY2021: Enrollment K: Of the total reported in A, the number of enrollment requests effectuated by sales persons. CY2022: Enrollment K: Of the total reported in A, the number of enrollment requests received from an applicant through an agent broker. Is “agent broker” the same as a sales rep/person? We have an internal sales team and external brokers. Are we only reporting the brokers in this field? Or does this include the sales team and brokers?	N/A	As proposed, Element K should include enrollment requests received from an applicant through an agent or broker, including sales agents employed by the plan.	No	No
Enrollment	We have agents that use our CRM system to submit the enrollments electronically. Usually either on an iPad or Laptop. We have always captured these as Electronic since that is how we interpreted the guidance. This is under I, "Of the total reported in A, the number of electronic enrollment requests received via an electronic device or secure internet website (if sponsor offers this mechanism". Would this instead fall under K "Of the total reported in A, the number of enrollment requests received from an applicant through an agent broker"?	N/A	Elements I and K are not mutually exclusive. An enrollment request can be counted in both elements if it meets the criteria for both elements.	No	No
Enrollment	If the agent doesn’t submit the application via an electronic device but rather faxes in an app, would that be captured as Paper under G, "Of the total reported in A, the number of paper enrollment requests received" or under K, "Of the total reported in A, the number of enrollment requests received from an applicant through an agent broker"?	N/A	An enrollment request that is reported as a paper, telephonic or electronic enrollment request (Elements G, H or I, respectively) should also be reported in Element K (enrollment requests received from an applicant through an agent or broker) if the enrollment request meets the criteria for Element K.	No	No

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MTM	For Data Element Z, 'Welcome Letter' is listed as an option for the method of delivery. Can you please define 'Welcome Letter'? Is this referring to the invitation/offer communications sent to members who meet our MTMP targeting criteria?"	N/A	In the February 2020 proposed rule (85 FR 9002), CMS proposed to implement two sections of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act which amended the Part D MTM requirements. Section 6103 of the SUPPORT Act requires Part D plans to provide all MTM targeted individuals with information about the safe disposal of controlled substances, including information on drug takeback programs, in-home disposal, and cost-effective means for disposal. CMS proposed requiring plans to include this information in a CMR, TMR, or other follow-up service. The addition of other MTM correspondences or services as a means of distribution of safe disposal information was a result of public comments that indicated plan sponsors wanted to provide this information sooner than a CMR or TMR. MTM program welcome or enrollment letters and CMR offers were suggested as additional ways the safe disposal information could be disseminated. In CMS' final rule (86 FR 5899), “Medicare and Medicaid Programs; Contract Year 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Program, and Programs of All-inclusive Care for the Elderly” (CMS 4190-F2), published on January 19, 2021, CMS finalized § 423.153(d)(1)(vii)(E) with modifications to allow plans to meet the safe-disposal educational requirement through use of a CMR, TMR, or other MTM correspondence or service, such as an MTM welcome letter.	No	No
MTM	Our Medicare Advantage organization seeks clarification from CMS regarding how to populate Elements I and J of the Medication Therapy Management Plan Reporting. If a member is enrolled into MTM due to plan-specific criteria (Some sponsors also offer enrollment in the MTM program to an expanded population of beneficiaries who do not meet the targeting criteria under §423.153(d)(2).): Would Element I (Targeting criteria met) be populated with “None” or is there a choice of “N/A”? Would Element J (Date met the specified targeting criteria per CMS – Part D requirements in §423.153(d)(2)) be populated with “N/A” or left blank?	N/A	Per the CY 2022 Part D Reporting Requirements Element I: "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)." The options for Element J are Multiple chronic diseases/multiple Part D drugs/cost threshold, Drug management program at-risk beneficiary, Both, or None. Please reference the field description column for Elements I and J in the CY 2022 MTM Record Layout when it becomes available.	No	No

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CD/RD	For Section V. Coverage Determinations Redeterminations, and Reopenings, under At-Risk Redeterminations, we ask CMS to define in the reporting requirements and/or technical specifications what would fall under this At-Risk Redetermination category. Clarification in the reporting requirements and/or technical specifications as to whether this would be a combination of all redeterminations or only exception redetermination requests would be helpful for achieving the goal of accurate and comparable reporting. Also, is an "at-risk" redetermination based on the drug, type of drug, protected drug class, preauthorization criteria or some other criteria?	Although we would suggest not distinguishing between at-risk versus non-at-risk redeterminations, additional background on the purpose behind this reporting distinction could be helpful as well.	Thank you for your suggestion. Clarification regarding At-Risk Determinations will be clarified in the Reporting Requirements as well as the Technical Specifications. Sponsors must also report data relating to redeterminations of at-risk determinations made under a plan sponsor's drug management program pursuant to the rules at 42 CFR §423.153(f), including the number of requests and the disposition. At-risk redeterminations may involve decisions about: • Being identified as an at-risk beneficiary for prescription drug misuse or abuse; • Having a limitation, or the continuation of a limitation, on access to coverage for frequently abused drugs (i.e., an enrollee specific point-of-sale (POS) edit or the selection of a prescriber and/or pharmacy for purposes of lock-in); • Sharing information for subsequent Part D plan enrollments.	No	No
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 your for you 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).	No	No
EGWP	"We would like clarification on why CMS removed the following paragraph from section VI "Employer/Union Sponsored Group Health Plan Sponsors: 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. We would like to understand if this means CMS expects MAPD plans to now follow the Part D Reporting Requirements for this specific section as of 2022 going forward."	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

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DUR	Regarding the updates for the DUR reporting there are requests being made that are not currently captured by Part D Sponsors. For example, the proposal includes capturing the number of claim rejections overridden by the pharmacy due to a beneficiary exemption. Today pharmacies are just placing codes to override claims and are not providing this granular level of detail for a Part D Sponsor to capture. It would require a large amount of network recontracting to require our pharmacies to provide this type of information on their overrides, to the amount of our entire network. This granular level of override will be overly burdensome to capture on a consistent basis as well since pharmacies are not used to providing detail to these overrides; rather they are used to providing a singular code for overrides. This could cause additional rejections at the point of sale and beneficiary dissatisfaction, as well as potential for beneficiaries to go without their medication due to a pharmacy not submitting proper codes, etc. This additional reporting requirement could be a roadblock for beneficiaries and pharmacies a like to provide needed medication.	N/A	Thank you for your comment. The NCPDP publishes telecommunication standards which can capture the information in the proposed elements. For more information, refer to the following document: https://www.ncpdp.org/NCPDP/media/pdf/VersionD-Questions.pdf.	No	No
DUR	We ask CMS to add clarifying language to the reporting requirements and/or technical specifications on what is considered an “exemption” for data elements F, S, and X.	If the reference to an excepted beneficiary refers to the beneficiary categories at 42CFR 423.100, we recommend that CMS add a link to the regulation, so that plans, pharmacies, and others can easily reference the most up-to date list (since it has changed and may continue to do so). Alternatively, CMS could, on an annual basis, add the list to the specifications from the regulation text.	We will consider clarifying in the Technical Specifications. In the meantime, refer to the current opioid safety edit guidance for the definitions of an exemption or exclusion: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization	No	No

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DUR	We ask CMS to add clarifying language to the reporting requirements and/or technical specifications on what is considered an "exemption" for data elements F, S, and X.	If the reference to an excepted beneficiary refers to the beneficiary categories at 42CFR 423.100, we recommend that CMS add a link to the regulation, so that plans, pharmacies, and others can easily reference the most up-to date list (since it has changed and may continue to do so). Alternatively, CMS could, on an annual basis, add the list to the specifications from the regulation text.	We will consider clarifying in the Technical Specifications. In the meantime, refer to the current opioid safety edit guidance for the definitions of an exemption or exclusion: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization	No	No
DUR	For element U, would the favorable coverage determination be a coverage determination that fell within the same quarter as the rejected claim edit? What would happen if the rejected claim occurred on the last day of quarter 1 and the coverage determination was approved during quarter 2?	N/A	Refer to the CY 2021 Technical Specifications, General, #8: If a claim override, paid claim, coverage determination or appeal request, or favorable coverage determination or appeal was initiated after the current reporting period, but was the result of a claim rejection during the calendar year and within the current reporting period, it may be reported for the current reporting period. It should not be reported again in the following reporting period.	No	No
DUR	For element U, are the favorable coverage determination and the rejected claim edit linked at the National Drug Code (NDC) level for the purposes of including in the reporting?	N/A	As described in the CY 2021 Technical Specifications, Cumulative hard MME edit/opioid naïve days supply safety edit, #2: The coverage determination or appeal should be associated with a cumulative opioid hard MME edit claim rejection. A favorable determination may result in the original or a modified (e.g., different daily dose, quantity, etc.) opioid prescription or a different opioid being covered. We intend to update the Technical Specifications accordingly for CY 2022.	No	No

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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
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

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DUR	Element K: The number of unique beneficiaries with at least one claim rejection overridden by the pharmacy due to an exemption. Element L: Of the total not in element K, the number of unique beneficiaries with at least one claim rejection overridden by the pharmacy as a result of prescriber consultation.	Healthfirst recommends that CMS not include elements K or L. CMS does not require dispensing pharmacists to include special documentation for these overrides and only one Result of Service Code may be entered per reject reason. Pharmacists may be overriding Opioid Care Coordination edits “with prescriber approval,” rather than using specific exemption overrides. For these reasons we question the value in collecting the volume of claims overridden by the pharmacy for a specific reason, given that pharmacists may not be using specific exemption overrides for this edit.	Thank you for your comment. The NCPDP publishes telecommunication standards which can capture the information in the proposed elements. For more information, refer to the following document: https://www.ncpdp.org/NCPDP/media/pdf/VersionD-Questions.pdf.	No	No

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DUR	Element X: The number of rejected claims overridden by the pharmacy due to an exemption. Element Y: The number of rejected claims overridden by the pharmacy because the beneficiary was not opioid naïve. Element BB: The number of unique beneficiaries with at least one rejected claim overridden by the pharmacy due to an exemption. Element CC: The number of unique beneficiaries with at least one rejected claim overridden by the pharmacy because the beneficiary was not opioid-naive.	Healthfirst recommends that CMS combine elements X and Y into a single element: The number of rejected claims overridden by the pharmacy. We also recommend the CMS combine elements BB and CC into a single element: The number of unique beneficiaries with at least one rejected claim overridden by the pharmacy. Hard rejects, like the opioid naïve safety edit, may only be overridden by a pharmacist using a Submission Clarification Code (SCC). "Beneficiary is not opioid naïve" overrides cannot be distinguished from exemption overrides, as SCC values to clarify the reason for an opioid naïve edit override do not exist. For this reason, we recommend CMS combine elements X and Y and elements BB and CC.	Thank you for your comment. The NCPDP publishes telecommunication standards which can capture the information in the proposed elements. For more information, refer to the following document: https://www.ncpdp.org/NCPDP/media/pdf/VersionD-Questions.pdf.	No	No
DUR	Element G states: Of the total not in element F, the number of claim rejections overridden by the pharmacy as a result of prescriber consultation. We will be including the following override in the element G count: • Prescriber consulted, dispensed, with prescriber approval Is this the correct override to include in the Element G count? Are there any other overrides that should be included in the element G count and what overrides are they?	N/A	We will consider clarifying in the Technical Specifications. In the meantime, refer to the current opioid safety edit guidance for the definitions of an exemption or exclusion: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization	No	No

Section	Comment	Commenter's Recommendation	CMS Response	Revised Requirements/Documents	Revised Burden Estimates
DUR	Element S states: Of the total reported in element R, the number of unique beneficiaries with at least one claim rejection overridden by the pharmacy due to an exemption. We will be including the following overrides in the element S count: • Prescriber consulted, dispensed, palliative care • Prescriber consulted, dispensed, cancer treatment • Pharmacist consulted other source, dispensed, palliative care • Pharmacist consulted other source, dispensed, cancer treatment Is this a complete list of the overrides to include in the Element S count? If it is not, which other overrides should be included? Should any of the above overrides not be included?	N/A	We will consider clarifying in the Technical Specifications. In the meantime, refer to the current opioid safety edit guidance for the definitions of an exemption or exclusion: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization	No	No
DUR	Element X states: The number of rejected claims overridden by the pharmacy due to an exemption. We will be including the following overrides in the element X count: • Prescriber consulted, dispensed, palliative care • Prescriber consulted, dispensed, cancer treatment • Pharmacist consulted other source, dispensed, palliative care • Pharmacist consulted other source, dispensed, cancer treatment Is this a complete list of the overrides to include in the Element X count? If it is not, which other overrides should be included? Should any of the above overrides not be included?	N/A	We will consider clarifying in the Technical Specifications. In the meantime, refer to the current opioid safety edit guidance for the definitions of an exemption or exclusion: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization	No	No

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DUR	Element Y states: The number of rejected claims overridden by the pharmacy because the beneficiary was not opioid naïve. We will be including the following overrides in the element Y count: • Prescriber consulted, dispensed, patient is not opioid naive • Pharmacist consulted other source, dispensed, patient is not opioid naive Is this a complete list of the overrides to include in the Element Y count? If it is not, which other overrides should be included? Should any of the above overrides not be included?	N/A	We will consider clarifying in the Technical Specifications. In the meantime, refer to the current opioid safety edit guidance for the definitions of an exemption or exclusion: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization	No	No
DUR	Element Z states: Of the total not in elements X or Y, the number of rejected claims for which up to a 7 day supply (covered by the plan) was dispensed by the pharmacy. We will be including the following in the element Z count: • Claims which were paid without a pharmacy override or a favorable or partially favorable coverage determination for up to a 7 day supply Is this a complete list of what should be included in the Element Z count? If it is not, which other claims should be included?	N/A	Yes, based on the examples you describe, these would be reported in Element Z.	No	No
DUR	Element F, K, S, and X - The number of claim rejections overridden by the pharmacy due to an exemption o What is classified as an exemption?	N/A	We will consider clarifying in the Technical Specifications. In the meantime, refer to the current opioid safety edit guidance for more information about exemptions: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization	No	No
DUR	Element T - Of the total reported in element R and not in element S, the number of unique beneficiaries who requested a coverage determination for the prescription(s) subject to the edit. o So CMS wants us exclude CD for claims that were overridden at POS?	N/A	Yes, based on the example you describe, CDs for claims overridden at POS would be excluded for Element T.	No	No

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DUR	Element EE – The number of unique beneficiaries with an opioid naïve days supply edit claim rejection who requested a coverage determination for the prescription(s) subject to the edit. o For this element we do not need to exclude members with a POS override or got a paid claim due to reduced supply?	N/A	Beneficiaries with a POS override or who received a paid claim due to a reduced supply would be excluded for Element EE.	No	No
DV	Will the Part D excluded drugs be excluded from the DV count as in the past?	N/A	This comment is out of scope of this PRA collection.	No	No
PPM	We recognize this as an important first step in the process of standard pharmacy performance metrics being applied across the industry. We appreciate CMS hearing the issues raised bypass comments in the Part D space and for willingly taking the first step in situational awareness around the discrepancies in the application of performance measures by plans/PBMs to pharmacies within the various PBM networks.	The measure developer or entity responsible for development of the measure; □ How the measure was validated and tested; □ If the plan/PBM is using the measure in accordance with published measure specifications which have been validated and tested; □ If the plan/PBM is using the measure according to licensing agreements with measure stewards; □ Adjustments or modifications to measure steward specifications; □ Source of data used to calculate the measure; □ The minimum number of patients required in the denominator to reliably calculate the measure; □ The platform, e.g., EQuIPP, and measurement period used in calculating the measure. □ Thresholds for incentives or other cut points related to	This comment is out of scope of this PRA collection.	No	No