30-Day Comment Response Document

Overview of Comments

CMS received various comments from Part D sponsors, PBMs and other associations. We received 35 comments regarding the following reporting sections: Enrollment and Disenrollment, Improving Drug Utilization Review Controls, Coverage Determinations and Redeterminations, Grievances and Medication Therapy Management.

Detailed Summary of Comments

Section	Comment	Commenter's Recommendation
Enrollment and Disenrollment	L. Of the total reported in A, the number of enrollment transactions submitted usingthe Speacial Election Period (SEP) Election Period code "S" related toinvoluntary loss of creditable prescription drug coverage or lack of adequatenotification regarding the creditable status of drug coverage provided by an entity required to give such notice.	We recommend correcting the spelling of the word "Special".
Enrollment and Disenrollment	Element K	For Enrollment element K, we recommend CMS add in verbiage that states, “as defined in the Medicare Communications and Marketing Guidelines”.
Enrollment and Disenrollment	Element I	For Enrollment element I, we recommend CMS includes clarification as to whether this includes enrollments via third-party websites.

Enrollment and Disenrollment	In Enrollment element B and Disenrollment elements B the language that clarified that no additional information was required from the applicant (or his/her representative) has been removed.	We recommend CMS re-insert this language to these elements for clarity.
Enrollment and Disenrollment	For Disenrollment element C, the language that clarified that additional information was required from the applicant (or his/her representative) has been removed.	We recommend CMS re-insert this language to this element for clarity.
Grievances	Sponsors should: Report data based on when the enrollee/appointed representative is notified (orally or written) of the the grievance decision.	We recommend removing the extra instance of the word "the".
MTM	The first part of the Medicare Advantage (MA) and Part D rule for 2021 did not contain finalized guidance on MTMPs, or information on the safe disposal of prescription drugs, and we expect to see the second part of the rule released later in 2021 applicable for 2022. Therefore, we request that CMS remove these data elements from the Plan Year 2021 Medicare Part D Reporting Requirements. Finally, we are concerned that the MTMP may not be the program best suited to address the needs of ARBs. The addition of beneficiaries at-risk of opioid abuse to MTMPs has the potential to increase costs and administrative burdens, and may not be the most effective and efficient way to achieve positive outcomes for beneficiaries. Mandatory Drug Management Programs (DMPs) are an important and necessary tool to combat the opioid epidemic. As CMS takes steps to make these programs mandatory starting in 2022, we ask that the agency provide more clarity and guidance around the requirements for DMPs, particularly related to the specific criteria for identifying potentially at-risk beneficiaries.	We ask CMS to remove the reporting requirements for at-risk beneficiaries (ARBs) in the Medication Therapy Management Program (MTMP), and the provision of information on safe disposal of medications.

MTM	In the Medication Therapy Management reporting section, CMS has included element K for reporting beneficiaries who meet targeting criteria via multiple diseases/multiple Part D drugs/cost threshold vs. beneficiaries who meet targeting criteria via a Drug Management Program at-risk beneficiary determination or both. CMS has also included element AA for reporting the number of communications sent to beneficiary regarding safe disposal of medications. Inclusion in MTM programs for at-risk beneficiaries and requirement to send communications regarding safe disposal of medications in the MTM program have not been finalized in regulations at this time. Additionally in Final Rule CMS-4190-F, CMS stated that if this regulation is finalized later in 2020, it would not be applicable until 1/1/2022.	As such we request that CMS remove elements K and AA from the Plan Year 2021 Medicare Part D Reporting Requirements.

MTM	Are new elements K and AA required for Contract Year 2021 Medicare Part D Reporting? If yes, should Part D sponsors assume that the proposed details in Section III.B. of the Proposed Rule should be relied upon for the inclusion of elements K and AA of the Reporting Requirements? Is there additional detail that we should expect for either 2021 or 2022?	Depending on the answers to the above questions, Envision suggests that the new elements K and AA either be removed from the 2021 MTM program annual reporting requirements or made optional and included in the 2022 MTM program annual reporting requirements after additional or final guidance has been provided. This will allow for adequate time to include these new requirements within program processes. MTM software configuration will be required and as such an appropriate amount of time is needed in order to incorporate these elements into platforms for documentation and reporting.

MTM	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 beneficiary, Both) AA. Number of communications sent to beneficiary regarding safe disposal of medications. Required if met the specific targeting criteria per CMS – Part D requirements.	CMS has included reporting requirements for at risk beneficiaries (ARBs) referred to the Medication Therapy Management Program (MTMP) and provision of information on safe disposal of medications in the 2021 Medicare Part D Reporting Requirements published May 18, 2020. In the 2021 Final Rule, CMS noted that "CMS plans to make any provisions adopted in the subsequent, second final rule, although effective on or before January 1, 2021, applicable no earlier than January 1, 2022."To date, a Final Rule providing the details for implementing these requirements has not been published. Because the referral of ARBs to the plan's MTMP and the provision of information on the safe disposal of medications will not be applicable until January 1, 2022 (for Plan Year 2022), we request that CMS remove these data elements from the Plan Year 2021 Medicare Part D Reporting Requirements.

MTM	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 beneficiary, Both). This was in the Proposed Final Rule (CMS-4190-P), but CMS has not released Final Rule Part 2 yet. Will ARBs we required to be enrolled in MTM for the 2021 plan year?	N/A
MTM	AA. Number of communications sent to beneficiary regarding safe disposal of medications. Required if met the specific targeting criteria per CMS – Part D requirements. This was in the Proposed Final Rule (CMS-4190-P), but CMS has not released Final Rule Part 2 yet. Would inclusion of this information in a Welcome Letter (i.e., a written initial offer of the CMR) meet the intent of this proposal. While it is not a “follow-up service,” it would be provided to all members and would be available to members as soon as they become eligible, many at the beginning of the plan year.	N/A

MTM	Proposed Final Rule (CMS-4190E. Eligibility for Medication Therapy Management Programs (MTMPs) (§ 423.153) 2. Information on Safe Disposal of Prescription Drugs that are Controlled Substances for MTM Enrollees. Would inclusion of this information in a Welcome Letter (i.e., a written initial offer of the CMR) meet the intent of this proposal. While it is not a “follow-up service,” it would be provided to all members and would be available to members as soon as they become eligible, many at the beginning of the plan year.	N/A
MTM	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 beneficiary, Both). Element AA - Number of communications sent to beneficiary regarding safe disposal of medications. Required if met the specific targeting criteria per CMS – Part D requirements.	We would request that further guidance be shared as to how each of the below data elements be represented in Medicare Part D Reporting when the program revisions represented through this data will not be active. For example, if it is not required to disseminate safe disposal information to beneficiaries starting 1/1/2021, how should element AA be populated to meet the reporting requirements for CY2021?

MTM	On page 8, data element F is defined as, “Met the specified targeting criteria per CMS – Part D requirements. (Y (yes) or N (no)).”	We request clarity on the designation that should be selected for this element when a beneficiary qualifies for MTM services as a part the Drug Management Program. Should this designation be reserved for only beneficiaries that meet the current MTM criteria selected by the plan sponsor (not including at-risk beneficiaries identified via a Drug Management Program)?
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).”	We appreciate the modification CMS has inserted, however, unless CMS intends to leverage this added visibility, we would suggest that element K be updated to reflect the targeting criteria that is met first by the beneficiary reduce administration burden.
MTM	On page 9, data element AA is defined as, “Number of communications sent to beneficiary regarding safe disposal of medications. Required if met the specific targeting criteria per CMS – Part D requirements.”	OutcomesMTM asks that CMS clarify whether the information must be shared via a document or if a verbal conversation between the beneficiary and an MTM provider would count as a communication provided to the beneficiary for the purposes of Part D MTMP Annual Reporting.

MTM	Element K: Element K of the proposed Part D MTM reporting requirements directs plans to identify how a beneficiary had met their MTM program criteria, including via their designation as an at-risk beneficiary ("ARB") within the MA plan's Drug Management Program (DMP). The proposal to expand MTM eligibility criteria to include ARBs was proposed in Section E. "Eligibility for Medication Therapy Management Programs (MTMPs)" of the 2021 and 2022 MA/Part D Proposed Rule but, as noted above, not finalized. The inclusion of ARBs in the MTM eligibility criteria was similarly not addressed in the May 22, 2020 HPMS memo titled "2021 Medication Therapy Management Program Information and Submission Instructions."	We urge CMS to clarify this apparent discrepancy.
MTM	Element AA: Element AA of the proposed Part D MTM reporting requirements directs plans to identify the "number of communications sent to beneficiary regarding safe disposal of medications," a directive that appears to be related to a provision in the 2021 and 2022 MA/Part D Proposed Rule, which had proposed a requirement Part D Sponsors provide this information to all beneficiaries enrolled in their MTM programs at least annually. As noted above, this provision was not addressed in the 2021 MA/Part D Final Rule, and therefore does not appear to be applicable to the CY2021 MTM program.	We request CMS issue clarifying guidance to address this concern.

MTM	As of today's date, the second final rule providing detailed information on how to implement and satisfy the new reporting requirements for the CY 2021 MTM program has not been provided (inclusion of At Risk Beneficiaries, and provision of safe disposal of medications). In addition, the most recent final rule indicated these changes will not be applicable until 1/1/2022. How should plans report on this data in 2021 without guidance on how to implement appropriately to meet regulatory requirements? How should plans report on data that is not applicable until the following program year?	N/A
MTM	The following comment is related to MTM Element K - Text of the criteria met: Do the full values need to be entered? For example: For “Current” MTM criteria, should “Multiple chronic diseases/multiple Part D drugs/cost threshold” be entered? For “New” MTM criteria, should “Drug management program at-risk beneficiary” be entered? For “Both” MTM criteria, should “Both” be entered?	N/A

MTM	In Section II. Medicare Therapy Management Programs, Element K states, “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).” In this field will we be required to list the targeting criteria met or will this require another field description indicator? We were also hoping to clarify the Drug Management Program criteria of this Element. If a member is identified as an “at risk beneficiary” but they are not currently enrolled in the Drug Management Program are we to include them in the MTMP? Currently, we include all beneficiaries who meet the CMS – Part D requirements § 423.153(d)(2) criteria but this does not specify an “at risk beneficiary” who meets no other targeting criteria.	N/A

MTM	Reporting Requirements for ARB	Healthfirst requests that CMS remove the reporting requirements for ARB (at risk beneficiaries) referred to the Medication Therapy Management Program (MTMP) and the provision of information on safe disposal of medications from the 2021 Medicare Part D reporting requirements, published May 18th, 2020. CMS noted that they plan to adopt these provisions in the second final rule, applicable no earlier than January 1, 2022. As no Final Rule with implementation details has yet been published and will not be applicable until Plan Year 2022, we request removal of these data elements.

MTM	Regarding new “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 beneficiary, Both)”, please confirm that we would be reporting out the targeting criteria that was met on reported “Element J: Date met the specified targeting criteria per CMS – Part D requirements in 423.153(d)(2)”. Regarding new “Element AA: Number of communications sent to beneficiary regarding safe disposal of medications. Required if met the specific targeting criteria per CMS – Part D requirements”, if a communication is returned, i.e. returned letter, should that communication still be counted?	N/A

MTM	UHC opposes the updates to Element K and the addition of Element AA in the Medicare Part D Reporting Requirements, Section II. Medication Therapy Management Programs. CMS indicated in its recent final rule (CMS-4190-F, published in the Federal Register on June 2, 2020 at FR 33796-33911) that it would address requirements related to "Eligibility for Medication Therapy Management Programs (MTMPs) (§ 423.153) and Information on the Safe Disposal of Prescription Drugs" later in 2020 and that "any provisions adopted in the subsequent, second final rule, although effective on or before January 1, 2021, [would] be applicable no earlier than January 1, 2022." Since these requirements are not yet finalized, we did not account for them in our 2021 MTMP submission and plans should not be expected to report on these items in 2021.	UHC urges CMS to remove proposed changes to Element K (pg. 8) – "…drug management program at-risk beneficiaries, Both" and also remove Element AA (pg. 9) – "Number of communications sent to beneficiary regarding safe disposal of medications. Required if met the specific targeting criteria per CMS – Part D requirements." We recommend that CMS reintroduce these elements once they are finalized in rulemaking for the 2022 program year. CMS will also need to update the Health Plan Management System (HPMS) application template to include a selection for drug management program at-risk beneficiaries.

DUR	Elemnt AA: If a member received an opioid naïve reject for Oxycontin 15 and receives favorable CD, but switches to Fentanyl without filling Oxycontin, and receives a paid claim for the Fentanyl (Never received paid Oxycontin, no reject on Fentanyl.). Would this be counted as Elements AA & BB? Would the same logic apply to a therapy change within the same HICL?	N/A
DUR	Element EE: Is it the expectation that the paid claim pursuant to a favorable coverage determination is directly related to the reject for that claim prior to CD? A member attempts to fill Rx #1234567 for Oxycontin 10mg and it is rejected. Later, that member receives a favorable coverage determination for Oxycontin. The member then returns to the pharmacy and fills Rx #7654321 for Oxycodone ER 10mg (paid claim as it shares a HICL with the approved Oxycontin). Would this be considered element EE?	N/A

DUR	For all elements that include “favorable coverage determination or appeal”, is this only related to CD or RD that yields a favorable decision in terms of the opioid naïve day supply safety edit? If a claim rejected for a UM edit AND the opioid naïve edit, but the CD or RD was requested and submitted only for the UM edit, would a favorable decision for the UM edit (but no decision on the opioid naïve edit, as it was not requested) be included in this reporting?	N/A

DUR	Element E: Please clarify how the following scenario should be counted. If a member has 3 care coordination rejections for the same (or different) drug for different dates of service but only has 1 subsequent paid claim via pharmacist override, would that count as: o Element C = 3 o Element D = 1 o Element E = 1	N/A

DUR	If a claims is successfully processed at POS but then subsequently reversed, does CMS want those claims to count for elements such as E, H, N etc.?	N/A
DUR	When CMS says successfully processed at POS “other than” through favorable coverage determination or appeal, such as pharmacist communication and/or plan override, does that mean for example: o Care Coordination edit – claim pays because pharmacy reduced the quantity on the claim and no longer triggers the greater than 90 MME edit or DOS of paid claim is later so that there is no overlap in active opioid claims thus also not triggering care coordination edit. o Hard MME edit – claim pays because pharmacy reduced the quantity or DOS is later so there is no overlap in active opioid claims thus no Hard edit is triggered. o Opioid Naïve – claim pays because pharmacy reduces day supply to 7 or less.	N/A

Coverage Determinations and Redeterminations	In the following paragraph there appears to be a couple typos: Title 42, Part 423, Subpart U describes requirements for reopenings of coverage determinations and redeterminations. Sponsors should also include reopened coverage determination and redetermination data i, based on the date the enrollee/enrollee's representative is notified in writing of the revised decision. A reopening may or may not change the disposition of the case.	We request that CMS review the paragraph and if CMS agrees with the typos, that CMS correct the typos.
Coverage Determinations and Redeterminations	Sponsors should report data based on the date the enrollee/enrollee's representative is notified in writing of the coverage determination or redetermination decision. How is 'notified' defined? Is this the day the letter enters the mail stream? What happens if there is returned mail?	N/A
Coverage Determinations and Redeterminations	Section V - Coverage Determination/Redetermination notes that we need to report based on the written notification. If oral was provided first are we are able to report based on oral notification if it came first?	N/A

Coverage Determinations and Redeterminations	In Section V. Coverage Determinations of the 2021 Part D Reporting Requirements, Redeterminations and Reopenings, it states, “Sponsors should report data based on the date the enrollee/enrollee’s representative is notified in writing of coverage determination or redetermination decision”. CMS changed the above paragraph from "date of decision" to the date "notified in writing". In the event that an untimely case is auto-forwarded to the IRE, how should these cases be reported? This change may need some additional clarification in the technical specifications document.	N/A

CMS Response	Revised Requirements/ Documents	Revised Burden Estimates
Revision made.	Yes	No
Language in the Reporting requirements is updated to reflect technical directions for reporting these data.	No	No
Language in the Reporting requirements is updated to reflect technical directions for reporting these data.	No	No

Language in the Reporting requirements is updated to reflect technical directions for reporting these data.	No	No
Language in the Reporting requirements is updated to reflect technical directions for reporting these data.	No	No
Revision made.	Yes	No
Thank you for your comment. We have added a note indicating that elements K and AA are not applicable for the January 1 – December 31, 2021 reporting period. Section 6013 of the SUPPORT Act requires that Part D plan sponsors include ARBs in their MTM programs.	Yes	No

Thank you for your comment. We have added a note indicating that elements K and AA are not applicable for the January 1 – December 31, 2021 reporting period.	Yes	No

Thank you for your comment. We have added a note indicating that elements K and AA are not applicable for the January 1 – December 31, 2021 reporting period.	Yes	No

Thank you for your comment. We have added a note indicating that elements K and AA are not applicable for the January 1 – December 31, 2021 reporting period.	Yes	No

Thank you for your comment. We have added a note indicating that element K is not applicable for the January 1 – December 31, 2021 reporting period. As noted in the May 2020 final rule 85 FR 33796, CMS intends to address all of the remaining proposals from the February 2020 proposed rule 85 FR 9002 in subsequent rulemaking and plans to make any provisions adopted in the subsequent, second final rule, although effective on or before January 1, 2021, applicable no earlier than January 1, 2022.	Yes	No
This comment is out of scope for the Reporting Requirements PRA. Please refer to future rulemaking for details regarding the requirement for Information on Safe Disposal of Prescription Drugs that are Controlled Substances for MTM Enrollees.	No	No

This comment is out of scope for the Reporting Requirements PRA. Please refer to future rulemaking for details regarding the requirement for Information on Safe Disposal of Prescription Drugs that are Controlled Substances for MTM Enrollees.	No	No
Thank you for your comment. We have added a note indicating that element K is not applicable for the January 1 – December 31, 2021 reporting period.	Yes	No

Thank you for your comment. We have added a note indicating that element K is not applicable for the January 1 – December 31, 2021 reporting period. Therefore, please use the current MTM targeting criteria in reference to element F. Please refer to future rulemaking regarding Eligibility for MTMPs and Information on Safe Disposal of Prescription Drugs that are Controlled Substances.	Yes	No
Thank you for your comment. We have added a note indicating that element K is not applicable for the January 1 – December 31, 2021 reporting period. Additional instructions will be released in the CY 2021 Reporting Requirements technical notes.	Yes	No
Please refer to future rulemaking for details regarding the documentation of the distribution of safe disposal information.	No	No

Thank you for your comment. We have added a note indicating that element K is not applicable for the January 1 – December 31, 2021 reporting period.	Yes	No
Thank you for your comment. We have added a note indicating that element AA is not applicable for the January 1 – December 31, 2021 reporting period.	Yes	No

Thank you for your comment. We have added a note indicating that elements K and AA are not applicable for the January 1 – December 31, 2021 reporting period.	Yes	No
Thank you for your comment. We have added a note indicating that element K is not applicable for the January 1 – December 31, 2021 reporting period. Additional instructions will be released in the CY 2021 Reporting Requirements technical notes.	Yes	No

Thank you for your comment. We have added a note indicating that element K is not applicable for the January 1 – December 31, 2021 reporting period. Please refer to future rulemaking for details regarding eligibility for MTM programs.	Yes	No

Thank you for your comment. We have added a note indicating that elements K and AA are not applicable for the January 1 – December 31, 2021 reporting period.	Yes	No

Thank you for your comment. We have added a note indicating that elements K and AA are not applicable for the January 1 – December 31, 2021 reporting period. The technical specifications question cannot be answered at this time pending rulemaking.	Yes	No

Thank you for your comment. We have added a note indicating that elements K and AA are not applicable for the January 1 – December 31, 2021 reporting period.	Yes	No

Please see Medicare Part D Plan Reporting Requirements: Technical specifications for additional technical information. Currently, CMS states that the coverage determination or appeal should be associated with a cumulative opioid hard MME edit or opioid naïve safety 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.	No	No
Please see Medicare Part D Plan Reporting Requirements: Technical specifications for additional technical information. Currently, CMS states that the coverage determination or appeal should be associated with a cumulative opioid hard MME edit or opioid naïve safety 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. Element EE relates to whether an opioid claim was filled subsequent to a POS opioid naïve edit; it does not limit the paid claim to the same opioid that triggered the opioid naïve POS edit.	No	No

If a coverage determination is requested for a drug that involves multiple opioid-related or other plan coverage rules, the plan sponsor must address each issue as part of the coverage determination. For example, if the request involves a drug subject to prior authorization (PA), where the claim also rejected or would reject at the POS because it triggered the care coordination edit, the adjudication of the case must involve both issues. For more information, please refer to the document Frequently Asked Questions (FAQs) about Formulary-Level Opioid Point-of-Sale (POS) Safety Edits dated May 13, 2019. ***See 42 CFR 423.568(e) and section 40.12.2 of the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance.*** Once a coverage determination or redetermination decision has been reached that addresses all relevant plan coverage rules, please report favorable coverage determinations or redeterminations for any applicable opioid safety edit.	No	No

Please see Medicare Part D Plan Reporting Requirements: Technical specifications for additional technical information. Currently, CMS states that rejected claims are counted at the unique plan, beneficiary, prescriber, pharmacy, drug (strength and dosage form), quantity, date of service (DOS) and formulary-level cumulative opioid MME POS edit. For example, if multiple transactions are submitted and rejected by the plan for the same formulary-level cumulative opioid MME POS edit from the same pharmacy for the same beneficiary, prescription (drug, quantity and prescriber) and DOS, this would count as one rejected claim. On the other hand, if a beneficiary attempted to fill the same prescription at 3 different pharmacies, either on the same day or on different days, and the prescription was rejected each time for the same formulary-level cumulative opioid MME POS edit, this would count as 3 rejected claims. Element E would then be out of the total reported in element C, the number of care coordination edit claim rejections overridden by the pharmacist at the pharmacy that also had an opioid claim successfully processed at POS.	No	No

Please see Medicare Part D Plan Reporting Requirements: Technical specifications for additional technical information. Currently, CMS states that claims submitted and/or reversed as a result of a data entry error are not counted (e.g., wrong quantity or day supply entered).	No	No
Modifying the beneficiary's opioid prescription after the pharmacist consults with the prescribing physician may be one method of successfully processing an opioid without initiating the coverage determination process.	No	No

Revisions made.	Yes	No
Yes, the sponsors should report based on the date the enrollee/enrollee's representative is notified in writing of the coverage determination or redetermination. Yes, the day the letter enters the mail stream. Please see Section 10.5.3 of the Parts C & D Grievances, Organization/Coverage Determinations and Appeals Guidance. The mail being returned does not change the date the original decision letter was mailed. The plan should document in their system that the mail was returned and attempt to contact the enrollee/enrollee's representative via phone to get the correct mailing address.	No	No
Plans must report based on the date the enrollee/enrollee's representative was notified in writing of the coverage determination or redetermination.	No	No

If a plan sponsor fails to notify the enrollee/enrollee's representative of its determination in the appropriate timeframe, this failure constitutes an adverse determination, and should be reported as an adverse decision.	No	No