60-Day Comment
Response Document

Detailed Summary of
Comments

Section	Comment
Coverage Determinations and Redeterminations	CMS is proposing to change the reporting date of data from “based on the date the coverage determination or redetermination decision is made” to “based on the date the enrollee/enrollee’s representative is notified in writing of the coverage determination or redetermination decision. Per the guidance in the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance document, section 40.14, a plan is not required to send a written confirmation of a withdrawal. Since a plan may not send a written confirmation for all cases, it is unclear as to which date should be used for reporting withdrawals if the party was not “notified in writing” as stated in the proposed guidance.

	For all elements that include "favorable coverage determination or appeal", is this only related to coverage determination or Redetermination that yields a favorable decision in terms of the opioid nave day supply safety edit? If a claim rejected for a Utilization Management edit AND the opioid nave edit, but the coverage determination or Redetermination was requested and submitted only for the Utilization Management edit, would a favorable decision for the Utilization Management edit (but no decision on the opioid nave edit, as it was not requested) be included in this reporting?
DUR	

MTM	Since element F "Met the specified targetir or N (no)" is documenting all members wh

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)).”

		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, or Drug management program at-risk beneficiary)."
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."
MTM		

Commenter's Recommendation	CMS Response
UHC strongly recommends that CMS keep the current reporting date based on “decision date” for all coverage determination and redetermination cases. In addition, using the “decision date” would align with CMS’s reporting criteria for audit universes.	Thank you for your recomendation, but the plans must report based on the date the enrollee/enrollee's representative was nofitied in writing of the coverage determination or redeterination. Please note that the timelines category no longer exists, but it important the plans issue the written decision with the required timeframe. Also, there is no regulatory citation regarding written notification for withdrawn requests; therefore, the plan may report based on the date they withdrew the request. This information should be clearly documented in the plan's system of record.

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.

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.

N/A

N/A	Thank you for your comment. In the February 18, 2020 proposed rule (85 FR 9002), CMS proposed to implement section 6064 of the SUPPORT Act. Under our proposed revisions to § 423.153(d), at-risk beneficiaries would be targeted for enrollment in a sponsor's MTM program. The existing criteria that Part D sponsors currently use to target beneficiaries for MTM program enrollment would remain unchanged, so that two groups of enrollees would now be targeted for enrollment: the first group would include enrollees who meet the existing criteria (multiple chronic diseases, multiple Part D drugs and Part D drug costs); and the second group would include enrollees who are determined to be at-risk beneficiaries under § 423.100. Therefore, if finalized, Element F "Met the specified targeting criteria per CMS - Part D requirements. (Y (yes) or N (no)" would include beneficiaries who meet the existing criteria (multiple chronic diseases, multiple Part D drugs and Part D drug costs); and include MTM enrollees who are determined to be at-risk beneficiaries under §?423.100. Beneficiaries who met either or both groups would be marked as Yes.

OutcomesMTM requests 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)?	Thank you for your comment. In the February 18, 2020 proposed rule (85 FR 9002), CMS proposed to implement section 6064 of the SUPPORT Act. Under our proposed revisions to § 423.153(d), at-risk beneficiaries would be targeted for enrollment in a sponsor's MTM program. The existing criteria that Part D sponsors currently use to target beneficiaries for MTM program enrollment would remain unchanged, so that two groups of enrollees would now be targeted for enrollment: the first group would include enrollees who meet the existing criteria (multiple chronic diseases, multiple Part D drugs and Part D drug costs); and the second group would include enrollees who are determined to be at-risk beneficiaries under § 423.100. Therefore, if finalized, Element F "Met the specified targeting criteria per CMS - Part D requirements. (Y (yes) or N (no)" would include beneficiaries who meet the existing criteria (multiple chronic diseases, multiple Part D drugs and Part D drug costs); and include MTM enrollees who are determined to be at-risk beneficiaries under §?423.100. Beneficiaries who met either or both groups would be marked as Yes.

OutcomesMTM 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.	CMS revised element K to include Multiple chronic diseases/multiple Part D drugs/cost threshold, Drug management program at-risk beneficiary, or Both. Additionally, please see the response above. If Element F = Yes, specify in Element K which group of targeting criteria per CMS - Part D requirements in § 423.153(d)(2) the beneficiary met (Multiple chronic diseases/multiple Part D drugs/cost threshold, Drug management program at-risk beneficiary, or Both) and in Element J report the date the beneficiary met the specified targeting criteria per CMS – Part D requirements. If the beneficiary met both targeting criteria groups, report the date for the criteria the beneficiary met first if different.
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.	Thank you for your comment. In the February 18, 2020 proposed rule (85 FR 9002), CMS proposed to implement section 6103 of the SUPPORT Act. CMS proposed to revise §?423.153(d)(1)(vii) to include a requirement that all MTM enrollees receive at least annually, as part of the CMR, a TMR, or another follow up service, information about safe disposal of prescription drugs that are controlled substances, take back programs, in-home disposal, and cost-effective means of safe disposal of such drugs. If finalized through the rulemaking process, more guidance will be forthcoming related to the data requirements and technical specifications.

Revised Requirements/Documents	Revised Burden Estimates
No	No

No	No

No	No

No	No

Yes No

No No