60-Day Comment Response Document

Overview of Comments

CMS received various comments from Part D sponsors, PBMs and other associations. We received 16 comments regarding the following reporting sections: Enrollment/Disenrollment, Improving Drug Utilization Review Controls, Medication Therapy Management, Grievances and Coverage Determinations and Redeterminations. There were several comments regarding Medication Therapy Management.

Detailed Summary of Comments

Section	Comment	Commenter's Recommendation
Enrollment/Disenrollment	Element K: In previous years this was only for stand-alone plans. Is this changing to include MA and MAPD enrollments?	N/A

Improving Drug Utilization Review Controls	Data Element Q - Of the total reported in element N, the number of unique beneficiaries with at least one rejected opioid claim due to the hard opioid MMED POS edit that also had an opioid claim successfully processed (paid) for an opioid drug subject to the hard opioid MED edit such as, but not limited to, through a favorable coverage determination or process.	Can CMS clarify if data from this element would include denied coverage determinations with a subsequent approval under an appeal e.g. redetermination, ALJ, Maximux etc.?
MTM	The CY2019 reporting tech specs have a new field for Date CMR written summary in CMS standardized format was provided or sent. The mail date for the CMR written summary in CMS standardized format can occur after the patient opts out or after the end of the calendar year.	Please provide additional guidance or confirm that there will not be submission rejections if the Date CMR written summary in CMS standardized format occurs after opt out date or after the end of the calendar year.

MTM	United asks that CMS not finalize the following proposed element related to Medication Therapy Management (MTM): Element H: Beneficiary in a long term care facility at the time of the first CMR offer? (Y (yes), N (no), or U (unknown))" because plans may not always be able to determine if the beneficiary is in a LTC facility at the time of the first CMR offer, particularly if the offer is sent via a letter to the beneficiary.	United recommends that CMS align the wording of the long-term care facility data element H with the wording of the cognitive impairment data element and add "or delivery of CMR" to the end. This would allow plans more flexibility in how they report this information and minimize any burden in doing so.

MTM	Element H: Asking for Beneficiary in a Long Term Care Facility at the time of the first CMR offer? Y (yes), N (no), or U (unknown). Currently there is not a standard or accurate way for plans to determine whether or not a beneficiary is in a nursing home at the time of a CMR offer. In light of this fact, we're concerned with what expectations CMS would have when it comes to accuracy of this reported data element. Because the data would be of variable quality across plans, we're also unsure of how this data would be useful for CMS or what purpose it would serve. Finally, as a plan, we're required to reach out and engage targeted beneficiaries in our MTM program regardless of whether or not they reside in a nursing home. We're unsure how adding this data element, even if it were able to be reported accurately, would be valuable for program evaluation.	N/A

MTM	Element H: “Beneficiary in a long term care facility at the time of the first CMR offer? (Y (yes), N (no), or U (unknown)).”	We request additional information as to what would define a long term care facility from data sources, prescription claims indicators, long term institutional files, or other data sources.
MTM	Element O: “If offered a CMR [comprehensive medication review] recipient of (initial) offer.”	We request additional information as to whether a caregiver’s name, relationship to the member, or both are required.

MTM	Element R: “Date CMR written summary in CMS standardized format was provided or sent. (If more than 1 CMR was performed, report the date the initial CMR written summary was provided or sent.)”	We request additional information as to whether CMS or HPMS will reject the data if the CMR is completed in late December (e.g. December 28, 2019), but we do not have a mail date until January (e.g. January 2, 2020) useful comments: Total Number of Grievances Number of Expedited Grievances Other Grievances Coverage Determinations and Exceptions: 1 KS Redeterminations: 2 AG Coverage Determinations and Redeterminations: Reopenings: 4: Date of original disposition Coverage Determinations and Redeterminations: Reopenings: 7: Date case was reopened"

Grievances	Sponsor Should: Report data based on the date the grievance decision was made.	Please clarify the requirement to "report by the date the grievance decision was made" versus reporting "by the date the complainant was notified of the grievance outcome?" It appears the "date the decision was made" terminology being carried over from other reporting sections under Part D like CD's and Redetermination's. This really doesn't work for grievances, because resolution should be based on when the member is notified of the outome of their grievance.
Grievances	Sponsor should not: Limit grievance reporting to include only CTM data.	Please clairfy if CTM data should be counted in grievance data? CMS already has this volume and timeliness information in-house so past guidance has indicated that plans should not include CTM data when reporting grievance metrics annually because it would be duplicated and counted twice.

Coverage Determinations/Redeterminations	Withdrawn/Dismissed CDs	We request that CMS clarify whether element A1 includes or excludes Withdrawn and Dismissed Coverage Determinations; and whether elements D1 through R1 include or exclude Withdrawn and Dismissed Coverage Determinations. We would also recommend that CMS publish data validation calculations as part of the Medicare Part D Reporting Requirements.

Coverage Determinations/Redeterminations	CMS is proposing to clarify and revise the “Coverage Determinations and Redeterminations” section of the reporting requirements, including by moving the reporting of “withdrawn” and “dismissed” coverage determinations and redeterminations out of the specific disposition categories (i.e., utilization management exceptions, formulary exceptions, etc.) and into the summary total categories (i.e., total number of withdrawn coverage determinations and redeterminations, total number of dismissed coverage determinations and redeterminations, etc.).	We agree with CMS’ expectation that these changes will clarify reporting under this section of the Part D reporting requirements, and support the proposed modifications accordingly.

General	The opioid crisis is one of the few things modern politicians agree on. Why would CMS not take this opportunity to drag the Part D data processing speed into the current decade?	There is no technical or cost reason why Part D plans should not be able to provide CMS with data from fully financially adjudicated clinical events on a nightly basis. Doing so would not inherently be more complex than any other fully automated process. Exporting the data every night, is an fully automated task. No one should be using a type-writer. Because some Part D plans might protest, we recommend that CMS choose weekly or monthly reporting requirements. Moreover, we suggest that CMS become fare more consistent in ejecting Part D plans that are slow to perform accurate data reporting.
General	Reporting Frequency	Access to Medicare Part D data on a weekly or monthly basis would significantly increase the insights
General	Reporting Frequency-Please provide the necessary regulatory clarification required to keep the data from Part D from being dammed up for months at a time.	N/A

General	Pharmacy Acceess Reporting Section: For the CY 2019 Reporting Requirements, CMS is proposing to remove the “Retail, Home Infusion, and Long Term Care Pharmacy Access” reporting section because the “data collection is no longer necessary for monitoring purposes.” We believe the proposed removal is consistent with the Administration’s broader goal to reduce administrative burden and increase efficiency under the Medicare program.	We recommend that the agency move forward with finalizing this change as proposed.

CMS Response	Revised Requirements/Documents	Revised Burden Estimates
MA-PD enrollment/disenrollment activity is to be reported under the Medicare Part D Plan Reporting Requirements. MA-only (i.e., no Part D) enrollment/disenrollment activity is to be reported under the Medicare Part C Plan Reporting Requirements. Yes, element K has been revised to be reported for both MA and PDP contracts.	No	No

Yes, this would include approved appeals as well.	No	No
There is currently no such submission rejection for "Date CMR written summary in CMS standardized format was provided or sent".	No	No

Element H has been updated with this suggested wording. Thank you for the recommendation.	Yes	No

Element H has been updated to include "or delivery of CMR" in order to stay consistent with the wording in element G and to allow sponsors to collect LTC information at the time of the CMR.	Yes	No

Element H has been updated to include "or delivery of CMR" in order to stay consistent with the wording in element G and to allow sponsors to collect LTC information at the time of the CMR. CMS is not prescriptive of which data sources may be used to define a long term care facility, but all sources listed by the commenter are appropriate.	Yes	No
Element O has been updated to define recipient as "Beneficiary, Beneficiary's prescriber; Caregiver; or Other authorized individual" to stay consistent with wording in element U.	Yes	No

There is currently no such submission rejection for "Date CMR written summary in CMS standardized format was provided or sent".	No	No

Plans should report based on when the member/apporinted representative is notified of the decision.	No	No
Plans should not use CTM reports to report grievances. Some beneficiaries may file a complaint in CTM, as well as a grievance with the plan. Plans should report the grievances filed by beneficiaries with the plan.	No	No

Withdrawn and Dismissed CDs are not included in element A - they have their own total.	No	No

Thank you for your comment.	No	No

Thank you for your comment. The data submitted as part of this data collection are used for retrospective monitoring and oversight of the Part D program. Therefore, we collect the Improving Drug Utilization Review Controls (opioid edit) data on an annual basis. These data reflect the impact of the edits such as the number of rejected claims and overrides. This is separate from the requirements for Part D sponsors to submit prescription drug event (PDE) data to CMS on a more frequent basis.	No	No
Thank you for your comment. We will consider your recommendation in the near future.	No	No
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Thank you for your comment.	No	No