

Responses to Comments Received
Federal Register Notice on (CMS-10717)
Medicare Part C and Part D Program Audit and Industry-Wide Part C Timeliness Monitoring Project
(TMP) Protocols

CMS received 1 public submission, which included 13 comments on the May 1, 2023, extension of the currently approved Medicare Part C and Part D Program Audit and Industry-Wide Part C Timeliness Monitoring Project (TMP) Protocols information collection. We then combined the 13 comments into 9 unique comments and provided responses in the document below. Comments are categorized first, by those that are general in nature, next, those that pertain to more than one program area and, finally, those that apply to each individual collection tool and program area.

GENERAL COMMENTS

Comment 1: The commenter expressed appreciation for CMS' ongoing commitment to collaboration, transparency, and burden relief to the industry by updating the User Group Resource Document on February 27, 2023. This commenter requested CMS issues a Health Plan Management System (HPMS) memo whenever the User Group Resource Document is updated. This will ensure all stakeholders are aware of and have timely access to this document.

Response 1: We appreciate the commenter's suggestion and will consider industry-wide notification when updates are made to the User Group Resource Document.

CMS Action 1: No changes were made to the protocols in response to this comment. No changes were made to the burden estimate in response to this comment.

MULTIPLE PROGRAM AREAS

Comment 2: The commenter noted that, during 2023 program audits, CMS has posed three new questions to audited sponsors in addition to the questions in the Formulary Administration (FA) Supplemental Questionnaire. Additionally, the commenter noted CMS has consistently asked audited sponsors to expand the Part D Coverage Determinations, Appeals and Grievances (CDAG) Universe Table 7: Comprehensive Addiction and Recovery Act (CARA) At-Risk Determination (AR) Record Layout timeframe due to an absence of cases, along with a narrative explaining why there are no cases during the audited time frame. The commenter recommends CMS add the questions to the FA questionnaire to ensure consistency and industry readiness and, permanently expand the initial audit timeframe for CDAG Universe Table 7: AR to one-year or consider removing it from the collection request entirely.

Response 2: CMS appreciates the suggestion and shares the goal of consistency and industry readiness. We will consider appropriate updates in future revision packages.

CMS Action 2: No changes were made to the protocols in response to this comment. No changes were made to the burden estimate in response to this comment.

PART D FORMULARY AND BENEFIT ADMINISTRATION (FA)

Comment 3: The commenter asked for clarification on how sponsors should populate Universe Table 4: New Enrollee (NE) record layout when they treat all members as “new” for transition fill as of 01/01 for the current plan year. Specifically, should sponsors include all of these members in the NE universe?

Response 3: The NE universe would be populated to only include eligible enrollees for which the sponsor does not utilize prior claims history for purposes of providing transition supplies. We have added clarifying language to the Universe Table 4 instructions to ensure appropriate population of this universe.

CMS Action 3: We updated the NE record layout instructions to read, “Only include eligible enrollees for which the Sponsoring organization does not utilize prior claims history for purposes of providing transition supplies.” No changes were made to the burden estimate in response to this comment.

Comment 4: The commenter recommended CMS clarify the *Enrollment Effective Date* and *Effective Disenrollment Date* fields in the Universe Table 1: Rejected Claims Formulary Administration (RCFA), Universe Table 2: Rejected Claims Transition (RCT), and Universe Table 4: New Enrollee (NE) record layouts. The commenter recommended the dates reflect the enrollee’s current enrollment in MARx for the contract and PBP submitted by the pharmacy. The commenter stated it is difficult to systematically retrieve enrollment date of the enrollee at the time of the claim for enrollees who have been disenrolled and subsequently reenrolled.

Response 4: CMS appreciates the suggestion but declines to make the change at this time. Sponsors must enter the Enrollment Effective Date and Effective Disenrollment date for the enrollee at the PBP level relevant to the contract and plan ID of the enrollee at the time of the claim and as reflected in the sponsor’s enrollment record. We will consider whether an update is appropriate in future revision packages.

CMS Action 4: No changes were made to the protocols in response to this comment. No changes were made to the burden estimate in response to this comment.

PART D COVERAGE DETERMINATIONS, APPEALS AND GRIEVANCES (CDAG)

Comment 5: The commenter noted a sponsor was told to exclude members who were disenrolled/ineligible as of the audit notice date from all universes during a recent CDAG Universe Q&A Call in the 2023 Program Audit season. The commenter noted this exclusion is not stated within the CDAG protocols and recommended CMS formally document this exclusion in the CDAG protocol or the annual program audit update memo if this continues to be a requirement.

Response 5: CMS clarified in the Final MAPD Program Audit Protocol Training that requests from members whose coverage is not yet effective as of the date of the audit engagement letter are excluded from CDAG universes. There is no current exclusion for disenrolled/ineligible members. If requests from these members were processed as coverage determinations, redeterminations or grievances during the universe request period, the cases would be included in the respective CDAG universes.

CMS Action 5: No changes were made to the protocols in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 6: The commenter asked CMS to clarify how sponsors should populate the *Date forwarded to IRE* and *Time forwarded to IRE fields* in Universe Table 1: Standard and Expedited Coverage Determination (CD), Universe Table 2: Standard and Expedited Coverage Determination Exception Requests (CDER), Universe Table 3: Payment Coverage Determinations and Redeterminations (PYMT_D), and Universe Table 4: Standard and Expedited Redeterminations (RD) record layouts. This commenter asked CMS to clarify if these fields should be populated when reconsideration requests are initiated with the IRE or only auto-forwards sent to the IRE.

Response 6: The *Date forwarded to IRE* and *Time forwarded to IRE fields* are not intended to capture when sponsors send information to the IRE at the IRE's request. These fields would be populated with the date and time the sponsor auto-forwarded the case to the IRE. We have updated the *Date forwarded to IRE* and *Time forwarded to IRE* field names and descriptions in CDAG Universe Tables 1-4 to read *Date auto-forwarded to IRE* and *Time auto-forwarded to IRE*.

CMS Action 6: CMS updated the *Date forwarded to IRE* and *Time forwarded to IRE* field names and descriptions in CDAG Universe Tables 1-4 to read *Date auto-forwarded to IRE* and *Time auto-forwarded to IRE* and updated the associated field descriptions to read, "Enter the date the request was auto-forwarded to the IRE" and "Enter the time the request was auto-forwarded to the IRE." No changes were made to the burden estimate in response to this comment.

Comment 7: The commenter asked CMS to remove all references to "time" from the instructions for Universe Table 3: PYMT_D record layout since this record layout contains date elements only.

Response 7: CMS appreciates the suggestion and has removed the following language from the Universe Table 3: PYMT_D record layout instructions, "Enter all fields for a single request in the same time zone. For example, if the Sponsoring organization has systems in EST and CST, all data in a single line item must be in a single time zone."

CMS Action 7: We removed the following language from the Universe Table 3: PYMT_D record layout instructions, "Enter all fields for a single request in the same time zone. For example, if the Sponsoring organization has systems in EST and CST, all data in a single line item must be in a single time zone." No changes were made to the burden estimate in response to this comment.

Comment 8: The commenter requested CMS remove "P for prescribing physician or other prescriber" as a response from field *Who made the request?* in Universe Table 3: PYMT_D record layout. The commenter stated this option does not comport with section 40.6 of the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance.

Response 8: CMS appreciates the suggestion however declines to make this change. 42 CFR §423.566 (c)(3) allows for the prescribing physician or other prescriber to request a coverage determination on behalf of the enrollee.

CMS Action 8: No changes were made to the protocols in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 9: The commenter asked CMS to remove the following instruction from Universe Table 6: GRV_D record layout, "Grievances with multiple issues must be entered as a single line item, unless the Sponsoring organization issued separate notifications." The commenter stated their internal process

includes separating grievances that fall under different categories which causes a grievance with multiple complaints to populate as two separate line items within the universe. The commenter mentioned it is labor and resource intensive to combine the grievances for program audit purposes. Additionally, based on how the commenter processes grievances, they believe CMS is reviewing more than 20 grievance samples which is inconsistent with protocols.

Response 9: CMS allows grievances with multiple issues to be listed as multiple line items within the GRV_D universe if a sponsor is treating the issues individually and is issuing separate notifications. For purposes of the MAPD program audits sponsors may combine grievances into a single line item for cases in which the sponsor processes multiple grievances as one and issues a single notification. If this does not address the commenter's concern, please contact our audit mailbox at [Part C Part D Audit@cms.hhs.gov](mailto:Part_C_Part_D_Audit@cms.hhs.gov).

CMS Action 9: No changes were made to the protocols in response to this comment. No changes were made to the burden estimate in response to this comment.