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 2 comments on the October 16, 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 combined the 2 comments and provided a response below.

PART D COVERAGE DETERMINATIONS, APPEALS AND GRIEVANCES (CDAG)

Comment 1: A commenter asked how to populate CDAG universes for a payment coverage determination or payment redetermination that also requires a clinical review because it had a utilization management edit or was a non-formulary drug. For a payment coverage determination, the commenter asked whether the related clinical case would be included in Universe Table 1: CD or Universe Table 2: CDER, depending on what type of restriction is on the drug. The commenter noted that if the case was included in Universe Table 1: CD for example, the case would appear as untimely if it exceeded the 72-hour turnaround time. For Universe Table 3: PYMT_D, the case would appear as timely if it met the 14-calendar day timelines standard. Similarly, if a payment redetermination also requires a clinical review, the commenter asked whether the clinical case should be included in Universe Table 4: RD. If the case was included in Universe Table 4: RD, the case would appear as untimely if it exceeded the 7-calendar day timeliness standard but would appeal timely for Universe Table 3: PYMT_D if it met the 14-calendar day timeliness standard.

Response 1: All payment requests should **only** be reported in Universe Table 3: Payment Coverage Determinations and Redeterminations (PYMT_D). As noted in the method of evaluation for audit element 1.5, CMS determines whether the Sponsoring organization provided notification of its determination and made payment (when applicable) no later than 14 calendar days after receipt of the payment coverage determination request. For audit element 1.7, CMS determines whether the Sponsoring organization provided notification of its determination no later than 14 calendar days after receipt of the payment redetermination request, and whether payment was made (when applicable) no later than 30 calendar days after receipt of the request. Commenter(s) may also refer to guidance clarifications for each universe table record layout. Universe Table 1: Standard and Expedited Coverage Determination (CD) Record Layout and Universe Table 2: Standard and Expedited Coverage Determination Exception Requests (CDER) Record Layout, include guidance to **exclude** all requests processed as payment coverage determinations, direct member reimbursement requests, withdraws and exception requests. Universe Table 4: Standard and Expedited Redeterminations (RD) Record Layout includes guidance to **exclude** all requests processed as payment redeterminations and withdrawn cases. The provided exclusions apply to these record layouts regardless of whether clinical review is needed to process the request.

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