DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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CENTER FOR MEDICARE

DATE: December 19, 2023

TO: All Current and Prospective Medicare Advantage, Prescription Drug Plan, Section 1876 Cost, and Medicare-Medicaid Plan Organizations

FROM: John A. Scott
Director, Medicare Parts C and D Oversight and Enforcement Group

SUBJECT: 2024 Program Audit Updates

The Centers for Medicare and Medicaid Services (CMS) has several announcements in this memorandum related to its 2024 program audits.

2024 Program Audits

On April 12, 2023, CMS issued a final rule (CMS-4201-F) that included new requirements regarding coverage criteria and the use of utilization management (UM) requirements in the Medicare Advantage (MA) program. In this rule, CMS clarified coverage criteria for basic benefits and the use of prior authorization, added continuity of care requirements, and required an annual review of UM tools. The regulations, which are applicable to coverage beginning January 1, 2024, will help ensure that people with MA have timely access to medically necessary care and receive access to the same medically necessary care they would receive in Traditional Medicare.

As we first announced on October 24, 2023, in the HPMS memo titled, "2024 Oversight Activities," CMS will conduct both routine and focused audits of organizations in 2024 to assess compliance with the coverage and UM requirements finalized in CMS-4201-F. For MA organizations (MAOs) who have routine program audits scheduled for 2024, these audits will follow our standard process similar to prior years, covering all applicable program areas, but will target the new UM requirements during the Part C Organization Determinations, Appeals, and Grievances (ODAG) review, as well as the Compliance Program Effectiveness (CPE) review. In addition, CMS is also adding new focused audits for plans who don't have routine scheduled audits, which are limited to ODAG and CPE, and are designed specifically to target compliance with the coverage and UM policies in CMS-4201-F. Through this combination of routine and focused audits in 2024, CMS expects to evaluate the UM-related performance of plans serving approximately 88% of people with MA. This expansion of our audit activity will help make sure that MA beneficiaries get the care they need without excessive burden or delays and have access to the benefits and services to which they are entitled.

During both the routine and focused program audits, CMS will utilize physician reviewers to review denied requests to assess whether MAOs are meeting new clinical coverage requirements, such as following coverage and benefit conditions included in Traditional Medicare laws, and when permissible, applying internal coverage criteria only when coverage criteria are not fully established in statute, regulation, National Coverage Decisions, and Local Coverage Decisions. CMS program audits will also ensure that internal coverage criteria are publicly available, MAOs are only using physicians (or other appropriate health care professionals) with appropriate expertise in the field of medicine for the service at issue when issuing adverse medical necessity decisions, and MAOs have established UM committees in accordance with regulatory requirements, including who the members of the committee are and the responsibilities they are required to complete.

2024 Program Audit Protocols

On October 16, 2023, CMS announced an opportunity for sponsoring organizations and other stakeholders to comment on the proposed extension of its Final Audit Protocols for the Medicare Part C and Part D Program Audits and Industry-Wide Part C Timeliness Monitoring Project (CMS-10717). This comment period closed on November 15, 2023. Upon OMB approval, CMS will make the aforementioned protocols available on the program audit website located at: https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/ProgramAudits.html. CMS will use the OMB-approved version of CMS-10717 to conduct its 2024 program audits and will begin sending scheduled program audit engagement letters to sponsoring organizations starting in January through July 2024[1].

Additional Information on the 2024 Program Audits

In addition, 2024 program audits will:

- Apply the 2022 MMP Audit Protocols and Data Requests to any audit that includes a Medicare-Medicaid Plan.
- Suspend collection of three universes, including:
    - *Table 3: Prescription Drug Event (PDE)* found in the Part D Formulary and Benefit Administration (FA) program audit protocol and data request. In response to stakeholder feedback, CMS tested the use of PDE data already collected under 42 CFR §§ 423.319(b) and 423.404(f) and determined it could also be used for program audit purposes.
    - *Table 7: Comprehensive Addiction and Recovery Act (CARA) At-Risk Determination (AR)* found in the Part D Coverage Determinations, Appeals and Grievances (CDAG) program audit protocol and data request, due to the low volume of data received. Sponsors will continue to submit appeals of at-risk determinations in CDAG Universe Table 4: Standard and Expedited Redeterminations (RD) and at-risk determinations fully or partially overturned by the IRE, ALJ, or MAC in CDAG Universe Table 5: Part D Effectuations of Overturned Decisions by IRE, ALJ or MAC (EFF_D).

[1] CMS will begin sending engagement letters for focused audits in January. Engagement letters for routine program audits will be sent beginning in late February, similar to prior years.

    - *Table 6: Dual Special Needs Plan – Applicable Integrated Plan Reductions, Suspensions, and Terminations (AIP)* found in the ODAG program audit protocol and data request. CMS will continue to monitor updates to regulations applicable to special needs plans (SNP) and will use this information to make decisions on future protocol revisions.
- Require sponsoring organizations to hire an independent auditor when there are more than 5 conditions unrelated to the CPE review that must be tested during the validation audit.
    - Once a sponsoring organization meets or exceeds the threshold and an independent audit is required, all findings (including CPE conditions) identified during the program audit must be validated by the independent auditor[2].
    - Likewise, if the sponsoring organization's audit results are below the threshold, CMS would conduct the validation of all findings.

Program Audit Resources

In preparation for 2024 program audits, CMS would like to take the opportunity to remind sponsoring organizations that the following resources are available on the Program Audits website at: https://www.cms.gov/medicare/audits-compliance/part-c-d/program-audits. These resources include:

- User Group Resource Document
- FA Validation Work Plan Training for Medicare Advantage and Prescription Drug Plans
- Program Audit Process Overview Document

Questions related to the program audit process can be sent to the program audit mailbox at part_c_part_d_audit@cms.hhs.gov.

[2] FA conditions classified as an *Observation Requiring Corrective Action (ORCA)* are included in the number of conditions that would require an independent auditor; however, FA ORCAs will be addressed by the CMS Account Manager when an independent auditor is required.