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**DATE:** December 16, 2022

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

**FROM:** John A. Scott  
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**SUBJECT:** 2022 Program Audit Updates

The Centers for Medicare & Medicaid Services (CMS) has several announcements in this memo about changes and updates to program audits in 2022.

### **2022 Program Audit Protocols**

CMS announced on May 26, 2021, that the Final Audit Protocols for the Medicare Part C and Part D Program Audits and Industry-Wide Part C Timeliness Monitoring Project (CMS-10717) were approved by the Office of Management and Budget (OMB 0938-1395 expires 05/31/2024) and would be used for Medicare Parts C and D program audits starting in 2022. CMS has also finalized the 2022 program audit protocols for Medicare-Medicaid Plans (MMPs). Collectively, these protocols and supporting data collection instruments are available for download at <https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/ProgramAudits>.

New program audit objectives for 2022 include:

- Part C Organization Determinations, Appeals and Grievances (ODAG) review of the unified Medicare and Medicaid grievance and appeals procedures for Medicare Advantage dual eligible special needs plans (D-SNP) Applicable Integrated Plans (AIPs) as defined in 42 CFR § 422.561;
- Part C Organization Determinations, Appeals and Grievances (ODAG) new adjudication timeframe requirements for organization determinations and plan reconsiderations related to requests for Part B drugs; and
- Part D Coverage Determinations, Appeals and Grievances (CDAG) Administration of Drug Management Program (DMP) audit element.

CMS's program audits will focus on the criteria listed in the protocols, but we may review factors not specifically addressed in the protocol when we discover other related requirements are not being met. In addition, the protocols are not a substitute for a review of the applicable

statutes or regulations. The data collection specifications and tools described in the program audit protocols, including the record layout instructions are used for auditing and monitoring activities and by themselves should not be used to interpret policy.

With the approval of the Final Audit Protocols for the Medicare Part C and Part D Program Audits and Industry-Wide Part C Timeliness Monitoring Project (CMS-10717), CMS also implemented use of the CMS Independent Validation Audit Work Plan template. This template is required for independent validation audits of sponsors that underwent program audits in 2021 and beyond.

In August 2021, CMS also hosted a three-part training series to provide technical assistance on the final audit protocols it will use to conduct the Medicare Part C and Part D Program Audits (CMS-10717). The presentation materials as well as the recordings and transcripts from the three training sessions are available on the CTEO Event Archives page at [https://www.cms.gov/Outreach-and-Education/Training/CTEO/Event\\_Archives](https://www.cms.gov/Outreach-and-Education/Training/CTEO/Event_Archives). CMS expects to post a resource document for stakeholders containing questions received following the trainings and CMS's responses 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>.

## **2022 Program Audit Process Overview Updates**

Annually, CMS releases the Program Audit Process Overview document to provide stakeholders with information about what to expect during a program audit. CMS has updated the 2022 version of this document and posted it 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 recommends that sponsors read this document to understand how program audits will be conducted in 2022. Specifically, this document includes:

- Information pertaining to every phase of the program audit, starting with receipt of an audit engagement letter through audit validation and close out.
- An update regarding the Compliance Program Effectiveness (CPE) reviews. CMS will notify sponsors in the audit engagement letter whether the CPE portion of the audit will be conducted onsite at the sponsor's location.
- Information regarding Health Plan Management System (HPMS) program audit universe submissions. Recent HPMS updates require program audit universe submission files to be zipped prior to upload in HPMS. Sponsors must save universe files as a ZIP File type (.zip) prior to uploading them to HPMS for submission.
- Updated program audit classification definitions. Sponsoring organizations will receive a condition when CMS identifies noncompliance. Causes of noncompliance may relate to non-existent or vague policies and procedures, issues with systems, internal controls, training, operations or staffing. For each condition, CMS reviews the impact of the identified noncompliance and classifies each condition accordingly. Each condition will have one of the following classifications applied:

- Immediate Corrective Action Required (ICAR) – Audit findings that inappropriately delay, restrict or limit an enrollee’s access to required medications and/or services are classified as ICARs. Generally, these are significant findings that require immediate action to mitigate impact on enrollees. The ICAR counts as two points in the audit scoring methodology.
- Corrective Action Required (CAR) – Audit findings that do not have an immediate impact on the enrollee’s ability to request or receive medications and/or services but are still significant are classified as CARs. The CAR counts as one point in the audit scoring methodology.
- Observation Requiring Corrective Action (ORCA) – Audit findings that are limited in scope, or otherwise mitigated, are classified as observations requiring corrective action. Generally, these findings are less significant but require attention to ensure any enrollee impact is resolved and/or to prevent further noncompliance. Observations requiring corrective action do not count as points in the audit scoring methodology.
- Observation – Audit findings that are insignificant are classified as observations. Generally, these findings represent an anomaly and do not require corrective action. Observations do not count as points in the audit scoring methodology.

CMS will be sending scheduled program audit engagement letters to sponsors starting in February through July 2022.

For additional questions related to these announcements or the program audit process, please contact the program audit mailbox at [part\\_c\\_part\\_d\\_audit@cms.hhs.gov](mailto:part_c_part_d_audit@cms.hhs.gov).