DEPARTMENT OF HEALTH & HUMAN SERVICES
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CENTER FOR MEDICARE

DATE: December 4, 2018

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

FROM: John Scott
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SUBJECT: 2019 Program Audits

The Centers for Medicare & Medicaid Services (CMS) has several announcements in this memo about changes and updates to program audits in 2019.

2019 Program Audit Process 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 2019 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 2019. 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. This comprehensive document eliminates the need for the separate Program Audit Validation Close-Out document previously posted to our website.
- Updates to the validation audit process resulting from the Calendar Year 2019 Final Call Letter; of note:
    - CMS requires the hiring of an independent auditor when there are more than five non-CPE (Compliance Program Effectiveness) conditions that must be tested during the validation audit.
    - The sponsor must copy the independent auditor when submitting the independent validation audit report to CMS.
- Notification that CMS will be sending scheduled program audit engagement letters to sponsors starting in March through July 2019.

Suspension of Data Collection by Program Area

On July 9, 2018, CMS announced its plans to continue using the same audit protocols and record layouts for universes in 2019 that were used in 2017 and 2018 under the existing OMB approved data collection package (CMS 10191 OMB No. 0938-1000[1]) that expires on April 30, 2020. CMS also announced that it will delay implementation of new protocols until audit year 2020 and expects to include the updated audit protocols and record layouts in an upcoming 30-day notice for public comment. Consistent with our goal of reducing burden, CMS is suspending collection of the following data and documentation for the 2019 program audits:

Part D Coverage Determinations, Appeals, and Grievances (CDAG); Part C Organization Determinations, Appeals, and Grievances (ODAG); and Medicare-Medicaid Plan (MMP) Service Authorization Requests, Appeals, and Grievances (SARAG)

In audit year 2019, CMS is suspending collection of its CDAG, ODAG, and SARAG Supplemental Questions at the time of the engagement letter. While information previously collected in these questionnaires is still relevant to the audit, CMS identified that this information is often more relevant when sponsors are producing root cause and impact analyses. CMS encourages sponsors to use the questions as a guide in qualifying and quantifying non-compliance that is identified during its program audit.

In addition, CMS is suspending its collection of Call Logs (i.e., record layouts Tables 16, 14, and 12 in the respective protocols). CMS is still interested in misclassification of coverage requests in these program areas, but will be taking a broader look into misclassification. Specifically, CMS will review a sponsor's oversight of its call routing process during its review of Compliance Program Effectiveness.

Compliance Program Effectiveness (CPE)

We have found that some CPE data and documentation that had been collected in prior audit years is no longer necessary. In particular, information collected in the self-assessment questionnaire is generally reflected in the sponsor's tracer samples, the duration of a First-Tier Entity (FTE) contract at the time of audit is not clearly connected to increased risk of non-compliance, and details regarding the roles of employee and committee members are no longer required for audit purposes. As a result, CMS will suspend the collection of the following information in 2019 but notes that, to the extent that an organization would like to populate and submit these data elements, it is not prohibited from doing so:

- The Self-Assessment Questionnaire;
- Column C: FTE Contract Effective Date within Table 1: First-Tier Entity Auditing & Monitoring (FTEAM) Record Layout; and
- The following Column IDs in Table 2: Employees and Compliance Team (ECT) Record Layout:
  - I: Medicare Compliance Department Employee?
  - J: Compliance Department Job Description

[1] https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Downloads/2017_Medicare_Parts_C_and_D_Program_Audit_Protocols_and_Data_Requests.zip

- K: Compliance Committee Member?
- L: Compliance Committee Member's Role

In addition, the following program area specific elements will be suspended from evaluation in our program audits to eliminate overlap and reduce burden:

- Formulary and Benefit Administration (FA) – Website Review
- Special Needs Plans – Model of Care (SNP-MOC) – Enrollment Verification

Impact of Updated Regulatory and Sub-regulatory Guidance on 2019 Program Audits

Comprehensive Addiction and Recovery Act of 2016

Beginning in audit year 2019, CMS will evaluate sponsors' implementation of the Comprehensive Addiction and Recovery Act (CARA) of 2016 through the program audit process. Specifically, CARA required CMS to establish a framework allowing Part D sponsors to limit at-risk beneficiaries' access to coverage for frequently abused drugs via drug management programs starting in 2019. CMS established the framework in the Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program regulation (83 FR 16440).[2] CMS defined the term "at-risk beneficiary" in §423.100. For 2019, we clarify that beneficiary at-risk determinations are not defined as coverage determinations and, as a result, at-risk determination data will not be collected via program audit universe record layouts in 2019. However, beneficiary at-risk redeterminations will be reported as a part of the total redetermination count within universe submissions responsive to Table 6: Standard Redeterminations (SRD) and Table 8: Expedited Redeterminations (ERD).

Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance

On October 1, 2018, CMS released a draft consolidation of Chapter 13 of the Medicare Managed Care Manual and Chapter 18 of the Prescription Drug Benefit Manual into one comprehensive guidance document. CMS has reviewed industry comments on the proposed guidance and does not anticipate significant changes for the final which we expect will be released in February 2019. Although CMS sees the changes put forth in the updated guidance as a reduction in burden for the industry, CMS will ensure sponsors have an opportunity to implement the updates within their organization before auditing any changes to compliance standards. Upon release of the finalized guidance, CMS will provide detail on how and when any audit compliance standards will be affected.

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.

[2] https://www.federalregister.gov/documents/2018/04/16/2018-07179/medicare-program-contract-year-2019-policy-and-technical-changes-to-the-medicare-advantage-medicare