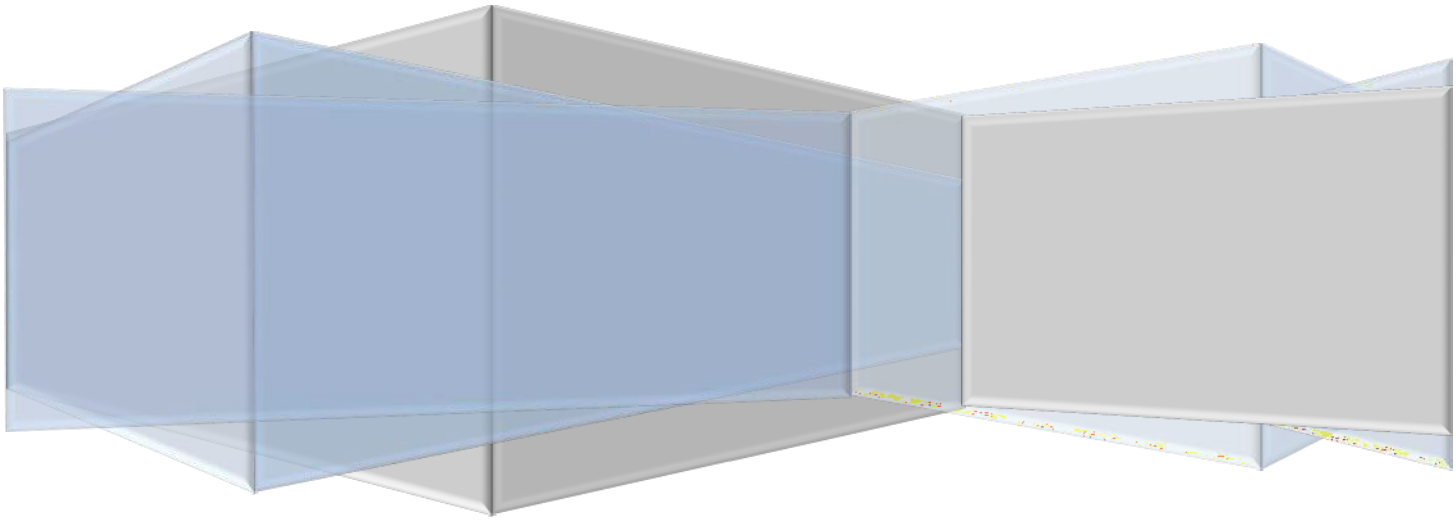
Medicare Part C and Part D Compliance Program Effectiveness (CPE)

PROGRAM AUDIT PROTOCOL AND DATA REQUEST



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Program Audit Protocol

Purpose

To evaluate performance in the areas outlined in this Program Audit Protocol and Data Request related to Compliance Program Effectiveness (CPE). The Centers for Medicare and Medicaid Services (CMS) performs its program audit activities in accordance with the CPE Program Audit Data Request and applying the compliance standards outlined in this Program Audit Protocol and the Program Audit Process Overview document. At a minimum, CMS will evaluate cases against the criteria listed below.

Audit Elements Tested

1. Prevention Controls and Activities
2. Detection Controls and Activities
3. Correction Controls and Activities

Audit Element	Compliance Standard	Data Request	Method of Evaluation	Criteria Effective 01/01/2021
Not Applicable	Integrity Testing	Supplemental Documentation: • Compliance Officer Questionnaire • Customized Organizational Structure and Governance PowerPoint Presentation • First Tier, Downstream, and Related Entities (FDR) Operations Oversight Questionnaire • Standards of Conduct/Code of Conduct document (in effect at any time during the audit review period) • Risk Assessments and Compliance Performance Mechanisms that show the extent to which Medicare Parts C and/or D operational areas, FDRs, and FWA risks were identified, and compliance goals were monitored at any time during the audit review period. • Audit and Monitoring Work Plans (for both internal operations and FDRs) in effect at any time during the audit review period Universe Table 1: Compliance Oversight Activities (COA)	Conduct completeness and accuracy check of supplemental documentation via desk review. Verify: • Questionnaires are complete (i.e., all questions answered) • Other documents represent all those in effect during the scope of universe request. Conduct completeness and accuracy check of Universe Table 1 via desk review. Verify universe is in accordance with the record layout: • Specifications (e.g., inclusion and exclusion language, scope of universe request) • Descriptions (e.g., all fields completed in correct format) Review all supplemental documentation submitted with Universe Table 1. The integrity of the universe and supplemental documents will be questioned if the submissions are incomplete, were not prepared in accordance with Program Audit Data Request instructions, or a variance is discovered in oversight activities.	42 CFR § 422.504(e) 42 CFR § 423.505(e) 42 CFR § 422.504(f) 42 CFR § 423.505(f)

Audit Element	Compliance Standard	Data Request	Method of Evaluation	Criteria Effective 01/01/2021
Prevention, Detection, or Correction	1.1	Supplemental Documentation: • Compliance Officer Questionnaire • Standards of Conduct/Code of Conduct document (in effect at any time during the audit review period) • Customized Organizational Structure and Governance PowerPoint Presentation Universe Table 1: Compliance Oversight Activities (COA) Supporting Documentation: • Written compliance policies and procedures	Conduct review of supplemental and supporting documentation via interviews with compliance officer and individuals responsible for SIU/FWA and FDR oversight, as applicable. Assess whether Sponsoring organization's written compliance policies, procedures, and standards of conduct: Articulate the Sponsoring organization's commitment to comply with all applicable Federal and State standards; Describe compliance expectations as embodied in the standards of conduct; Implement the operation of the compliance program; Provide guidance to employees and others on dealing with potential compliance issues; Identify how to communicate compliance issues to appropriate compliance personnel. Describe how potential compliance issues are investigated and resolved by the Sponsoring organization; and Include a policy of non-intimidation and non-retaliation for good faith participation in the compliance program, including but not limited to reporting potential issues, investigating issues, conducting self-evaluations, audits and remedial actions, and reporting to appropriate officials. Select targeted samples of 20 audit participants and 2 First Tier Entities (FTEs) from attendance logs and impacted individuals and entities from tracers, supporting documentation and/or supplemental documentation. Sample selections will be provided to the Sponsoring organization on the first day of the onsite audit. Evaluate the 20 samples and 2 FTEs via live presentation by Sponsoring organization or review of evidence (e.g., accessibility of compliance policies and procedures and Standards of Conduct via the intranet, FTE attestation).	42 CFR § 422.503(b)(4)(vi)(A) 42 CFR § 423.504(b)(4)(vi)(A)

Audit Element	Compliance Standard	Data Request	Method of Evaluation	Criteria Effective 01/01/2021
Prevention, Detection, or Correction	1.2	Universe Table 1: Compliance Oversight Activities (COA) Tracer case summaries Supplemental Documentation: • Compliance Officer Questionnaire • Customized Organizational Structure and Governance PowerPoint Presentation Supporting Documentation: • Evidence that compliance issues were communicated to the appropriate compliance personnel, senior management, and oversight entities. • Meeting minutes/agendas, letters/correspondence, etc. to support statements within the tracer case summaries	Select 6 tracer case samples by targeting those that represent compliance risk to Sponsoring organization's operations and enrollees with the likelihood of touching multiple elements of a compliance program, including intelligence obtained from documentation received with the universe. When available, choose: Pharmacy benefit management; Appeals and grievances, including oversight of call routing process; FTE performing a delegated function; Quality improvement program, if applicable; Network management; Enrollment and disenrollment, agent/broker misrepresentation, quality of care, including issues reported through compliance mechanisms; Customer/member services; or Compliance actions (e.g., Notices of Noncompliance, Warning Letters) relative to the audit review period. Other information available to CMS (and, therefore, not requested from Sponsoring organizations) may be used for tracer case sample selection, such as: Compliance actions; Enforcement actions; or Memorandums issued via the Health Plan Management System. Tracer case sample selections will be provided to the Sponsoring organization two weeks prior to the Entrance Conference. Evaluate the 6 tracer case summaries via live presentation by Sponsoring organization, including interviews with compliance officer and individuals responsible for SIU/FWA and FDR oversight, as applicable. Assess whether: Sponsoring organization designated an employee of the organization, parent organization, or corporate affiliate as the compliance officer; Compliance officer and compliance committee demonstrated appropriate accountability and reporting of Medicare compliance issues to appropriate senior management and governing body; and Governing body exercised oversight of the Medicare compliance program. Note: Discussion may include compliance oversight perspective on preliminary issues discovered during the earlier portion of the Audit Field Work phase.	42 CFR § 422.503(b)(4)(vi)(B) 42 CFR § 423.504(b)(4)(vi)(B)

Audit Element	Compliance Standard	Data Request	Method of Evaluation	Criteria Effective 01/01/2021
Prevention, Detection, or Correction	1.3	Supplemental Documentation: • Compliance Officer Questionnaire • Customized Organizational Structure and Governance PowerPoint Presentation Supporting Documentation: • Employee and governing body members training records	Conduct review of supplemental and supporting documentation via interviews with compliance officer and individuals responsible for SIU/FWA and FDR oversight, as applicable. Assess whether compliance training was provided annually to the compliance officer and organization employees, the Sponsoring organization's chief executive and other senior administrators, managers, and governing body members. Use the same 20 samples of audit participants from attendance logs and impacted individuals from tracers, supporting documentation and/or supplemental documentation. Sample selections will be provided to the Sponsoring organization on the first day of the onsite audit. Evaluate the 20 samples via live presentation by Sponsoring organization or review of evidence (e.g., training attendance log, training certificate, employee attestation of receipt of compliance policies and procedures and Standards of Conduct).	42 CFR § 422.503(b)(4)(vi)(C) 42 CFR § 423.504(b)(4)(vi)(C)

Audit Element	Compliance Standard	Data Request	Method of Evaluation	Criteria Effective 01/01/2021
Prevention, Detection, or Correction	1.4	Tracer case summaries Supplemental Documentation: • Compliance Officer Questionnaire • Customized Organizational Structure and Governance PowerPoint Presentation • First Tier, Downstream, and Related Entities (FDR) Operations Oversight Questionnaire Supporting Documentation: • Evidence of communication to the affected or involved business areas regarding compliance issues. • Evidence of oversight activities that occurred as a result of the detected issue(s) • Description of the enrollee and/or Sponsoring organization impact as a result of the detected compliance issues • Meeting minutes/agendas, letters/correspondence, etc. to support statements within the tracer case summaries	Evaluate the 6 tracer case summaries via live presentation by Sponsoring organization, including interviews with compliance officer and individuals responsible for SIU/FWA and FDR oversight, as applicable. Assess whether Sponsoring organization: • Established effective lines of communication between the compliance officer, members of the compliance committee, employees, managers and governing body, and FDRs; and • Implemented a reporting system that is accessible to all and allowed a method for anonymous and confidential good faith reporting of potential compliance issues as they are identified.	42 CFR § 422.503(b)(4)(vi)(D) 42 CFR § 423.504(b)(4)(vi)(D)

Audit Element	Compliance Standard	Data Request	Method of Evaluation	Criteria Effective 01/01/2021
Prevention, Detection, or Correction	1.5	Supplemental Documentation: • Compliance Officer Questionnaire • Standards of Conduct/Code of Conduct document (in effect at any time during the audit review period)	Conduct review of supplemental documentation via interviews with compliance officer and individuals responsible for SIU/FWA and FDR oversight, as applicable. Assess whether Sponsoring organization has well-publicized disciplinary standards through implementation of procedures which encourage good faith participation in the compliance program by all affected individuals. These standards must include policies that: • Articulate expectations for reporting compliance issues and assist in their resolution. • Identify noncompliance or unethical behavior; and • Provide for timely, consistent, and effective enforcement of the standards when noncompliance or unethical behavior is determined.	42 CFR § 422.503(b)(4)(vi)(E) 42 CFR § 423.504(b)(4)(vi)(E)

Audit Element	Compliance Standard	Data Request	Method of Evaluation	Criteria Effective 01/01/2021
Prevention, Detection, or Correction	1.6	Tracer case summaries Supplemental Documentation: • Compliance Officer Questionnaire • First Tier, Downstream, and Related Entities (FDR) Operations Oversight Questionnaire • Risk Assessments and Compliance Performance Mechanisms that show the extent to which Medicare Parts C and/or D operational areas, FDRs, and FWA risks were identified, and compliance goals were monitored at any time during the audit review period • Audit and Monitoring Work Plans (for both internal operations and FDRs) in effect at any time during the audit review period Supporting Documentation: • Evidence of oversight activities that occurred as a result of the detected issue(s) • Description of the enrollee and/or Sponsoring organization impact as a result of the detected compliance issues • Meeting minutes/agendas, letters/correspondence, etc. to support statements within the tracer case summaries	Evaluate the 6 tracer case summaries via live presentation by Sponsoring organization, including interviews with compliance officer and individuals responsible for SIU/FWA and FDR oversight, as applicable. Assess whether Sponsoring organization established and implemented an effective system for routine monitoring and identification of compliance risks including internal monitoring and audits of its internal operations and FTEs to evaluate compliance with CMS requirements and the overall effectiveness of the compliance program.	42 CFR § 422.503(b)(4)(vi)(F) 42 CFR § 423.504(b)(4)(vi)(F)

Audit Element	Compliance Standard	Data Request	Method of Evaluation	Criteria Effective 01/01/2021
Prevention, Detection, or Correction	1.7	Tracer case summaries Supplemental Documentation: • Compliance Officer Questionnaire • First Tier, Downstream, and Related Entities (FDR) Operations Oversight Questionnaire Supporting Documentation: • Policies and procedures reviewed and revised in response to detecting and correcting compliance issues. • Training provided in response to identifying and correcting compliance issues. • Evidence of oversight activities that occurred as a result of the detected issue(s) • Evidence of accountability and oversight by the Sponsoring organization when issues are detected at the FDR level, including response and correction procedures, communication, educational requirements and engagement with the compliance department, operational areas and oversight entities. • Description of the enrollee and/or Sponsoring organization impact as a result of the detected compliance issues • Meeting minutes/agendas, letters/correspondence, etc. to support statements within the tracer case summaries	Evaluate the 6 tracer case summaries via live presentation by Sponsoring organization, including interviews with compliance officer and individuals responsible for SIU/FWA and FDR oversight, as applicable. Assess whether Sponsoring organization promptly responded to compliance issues, investigated potential compliance problems identified, or corrected such compliance problems promptly and thoroughly to reduce potential for recurrence and ensure ongoing compliance with CMS requirements.	42 CFR § 422.503(b)(4)(vi)(G) 42 CFR § 423.504(b)(4)(vi)(G)

Program Audit Data Request

Audit Engagement and Universe Submission Phase

Universe Submissions

Sponsoring organizations must submit the universe, comprehensive of all contracts and Plan Benefit Packages (PBP) identified in the audit engagement letter, in either Microsoft Excel (.xlsx) file format with a header row or Text (.txt) file format without a header row. Descriptions and clarifications of what must be included in each submission and data field are outlined in the universe record layout below. Characters are required in all requested fields, unless otherwise specified, and data must be limited to the request specified in the record layout. Sponsoring organizations must provide accurate and timely universe submissions within 15 business days of the audit engagement letter date. Submissions that do not strictly adhere to the record layout specifications will be rejected.

Universe Requests

1. Universe Table 1: Compliance Oversight Activities (COA) Record Layout

Universe Record Layout	Scope of Universe Request*
Table 1	Submit a list of all compliance oversight activities that occurred during the 26-week period preceding and including the date of the audit engagement letter.

***** CMS reserves the right to expand the review period to ensure sufficient universe size.

Please use the guidance below for the following record layout:

Universe Table 1: Compliance Oversight Activities (COA) Record Layout

- Include all auditing, monitoring, and investigation activities (including compliance and fraud, waste and abuse (FWA) activities) that were initiated, performed, or closed, related to the Sponsoring organization's Medicare Advantage (Part C) and/or Prescription Drug (Part D) business during the universe request period. Include the activity if the Activity Start Date (Column ID G) or Activity Completion Date (Column ID H) falls within the universe request period, or if the activity is still in progress but the start and completion dates fall outside the universe period.
- Daily activities should be rolled up into an aggregate time period of one month and included in the universe each time the aggregate time period into which they were rolled occurred.
- Use consistent naming conventions throughout the submitted universe. For instance, when the name of the Sponsoring organization's component (e.g., department, operational area, business unit) is requested, a consistent response (e.g., Agent Broker vs. Agent/ Broker vs. AB vs. A/B) must be used.
- Ensure that all fields are populated; do not leave any fields blank (e.g., if there are no deficiencies enter "0" for Number of Deficiencies in Column ID I, and Column ID J (Description of Deficiencies) would be "NA".

Column ID	Field Name	Field Type	Field Length	Description
A	Component	CHAR Always Required	100	Enter the name of the Sponsoring organization's department, operational area, or First Tier Entity that is the focus. of the oversight activity.
B	Activity Type	CHAR Always Required	30	Enter the activity type as: • Auditing • Monitoring • Investigations
C	Compliance or FWA?	CHAR Always Required	10	Enter whether the activity was: • Compliance • FWA • Both
D	Activity Frequency	CHAR Always Required	30	Enter the frequency of the oversight activity. Valid values include but are not limited to: • Daily • Weekly • Bi-monthly • Monthly • Quarterly • Semi-annually • Annually • Ad-hoc
E	Activity Rationale	CHAR Always Required	200	Enter the rationale for conducting the activity (e.g., routine audit stemming from risk assessment and/or work plan, referral from FTE, or hotline complaint, operational failure/metric outlier/etc., or audit activity was implemented because the function has an immediate impact on enrollees' access to immediate medical care and prescription drugs).

Column ID	Field Name	Field Type	Field Length	Description
F	Activity Description	CHAR Always Required	400	Provide a description of the activity (e.g., operational area, training requirements, timeliness, accuracy of organization determinations and notifications, messaging errors, contractual agreements, unannounced or onsite audits, spot checks, compliance monitoring, targeted or stratified sampling, audit protocols).
G	Activity Start Date	CHAR Always Required	10	Enter the date that the specific activity was initiated. For example, if the Sponsoring organization started an audit of the appeals process/ function within the Sponsoring organization on January 1, 2020, that is the date that would be used for the date the activity started. Submit in CCYY/MM/DD format (e.g., 2020/01/01).
H	Activity Completion Date	CHAR Always Required	10	Enter the date that the specific activity was completed. For example, if the Sponsoring organization completed an audit of the appeals process/function within the Sponsoring organization on January 31, 2020, that is the date that would be used for the date the activity ended. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter TBD (To Be Determined) if the activity is currently in progress.

Column ID	Field Name	Field Type	Field Length	Description
I	Number of Deficiencies	CHAR Always Required	3	Enter the number of deficiencies, findings, or issues identified. Enter TBD if deficiencies have yet to be identified for an ongoing activity.
J	Description of Deficiencies	CHAR Always Required	1000	Provide a summary of all deficiencies, findings or issues identified during the oversight activity. If the oversight activity is identified in the pre-audit issue summary submitted to CMS, please include the issue number. Enter TBD if deficiencies have yet to be identified for an ongoing activity.
K	Corrective Action Required	CHAR Always Required	3	Enter: • Y (for Yes) if any deficiencies were identified during the activity and they required a corrective action. • N (for No) if none of the deficiencies identified during the activity required a corrective action. • TBD if corrective actions have yet to be determined for an ongoing activity.
L	Activity Results Shared?	CHAR Always Required	50	Enter whether activity results were shared: • N (for No) if the results were not shared, or • Y (for Yes) if the results were shared. Also enter the name of the person or Group with whom activity results were shared.

Supplemental Documentation Submissions

Sponsoring organizations must submit the requested documentation identified below in either a Microsoft Word (.docx), Microsoft Excel (.xlsx.), Microsoft PowerPoint (.pptx), or Adobe Portable Document File (.pdf). Sponsoring organizations must submit this documentation within 15 business days of the audit engagement letter date, unless otherwise specified.

Supplemental Documentation Requests

1. Compliance Officer Questionnaire
2. Customized Organizational Structure and Governance PowerPoint Presentation
3. First Tier, Downstream, and Related Entities (FDR) Operations Oversight Questionnaire
4. Standards of Conduct/Code of Conduct document (in effect at any time during the audit review period)
5. Risk Assessments and Compliance Performance Mechanisms that show the extent to which Medicare Parts C and/or D operational areas, FDRs, and FWA risks were identified, and compliance goals were monitored at any time during the audit review period. Compliance performance mechanisms could include (but are not limited to) monthly compliance dashboards that track the goals and statuses of the identified risk/issue, self-assessments, surveys, or any other tools or mechanisms (outside the risk assessment) that are used to identify potential compliance risks.
6. Audit and Monitoring Work Plans (for both internal operations and FDRs) in effect at any time during the audit review period

Tracer Case Summary Submissions

In response to each tracer case summary requested, Sponsoring organizations must prepare and submit a written document in either a Microsoft Word (.docx), Microsoft Excel (.xlsx.), Microsoft PowerPoint (.pptx), or Adobe Portable Document File (.pdf) of a story board and/or dashboard prior to the Entrance Conference. The summary document must provide the specific facts, rationales, and decisions around how suspected, detected, or reported compliance issues are investigated and resolved by the Sponsoring organization. The following information must be included in each summary document in chronological order:

a. An overview of the issue(s) or activity
b. Which compliance and business operations units were involved in detecting and correcting the issue(s)
c. A detailed explanation of the issue(s)/activity (e.g., what the Sponsoring organization found, when the Sponsoring organization first learned about the issue, and who or which personnel/operational area(s) were involved.)
d. A root cause analysis that determined what caused or allowed the compliance issue, problem, or deficiency to occur.
e. The specific actions taken in response to the detected issue(s)/activity.
f. The processes and procedures that were affected by the issue(s)/activity and that were revised in response to becoming aware of the issue(s)/activity.
g. The steps taken to correct the issue(s)/deficiencies at the Sponsoring organization and/or FDR levels, including a timeline indicating the corrective actions implemented or, if not implemented, when the Sponsoring organization expects the corrective action to be completed.
h. How the issue was escalated (e.g., senior management, compliance oversight committees, governing body, etc.)
i. All relevant communications within the Sponsoring organization and with its FDRs regarding the issue.
j. Each prevention control and safeguard implemented in response to the issue(s)/activity.

Tracer Case Summary Requests

CMS will request a total of 6 tracer case summaries.

Audit Field Work Phase

Supporting Documentation Submissions

During audit field work, CMS will review 6 tracer case summaries in addition to 20 employee samples of audit participants and 2 FTEs selected from attendance logs, tracers, supplemental documentation and/or supporting documentation to determine whether the Sponsoring organization is compliant with its Part C and/or Part D contract requirements. To facilitate this review, the Sponsoring organization must have access to, and the ability to save and upload screenshots of supporting documentation and data relevant for a particular case, including, but not limited to:

- Written compliance policies and procedures
- Evidence that compliance issues were communicated to the appropriate compliance personnel, senior management, and oversight entities.
- Training provided in response to identifying and correcting compliance issues.

- Employee and governing body members training records
- Evidence of communication to the affected or involved business areas regarding compliance issues.
- Evidence of oversight activities that occurred as a result of the detected issue(s)
- Evidence of accountability and oversight by the Sponsoring organization when issues are detected at the FDR level, including response and correction procedures, communication, educational requirements and engagement with the compliance department, operational areas and oversight entities.
- Description of the enrollee and/or Sponsoring organization impact as a result of the detected compliance issues
- Meeting minutes/agendas, letters/correspondence, etc. to support statements within the Tracer Case Summaries

If not previously provided, the Sponsoring organizations are expected to submit supporting documentation within 2 business days of the request.

Root Cause Analysis Submissions
Sponsoring organizations may be required to provide a root cause analysis using the Root Cause Template provided by CMS. Sponsoring organizations have 2 business days from the date of request to respond.

Verification of Information Collected: CMS may conduct integrity tests to validate the accuracy of all universes, impact analyses, and other related documentation submitted in furtherance of the audit. If data integrity issues are noted, Sponsoring organizations may be required to resubmit their data.