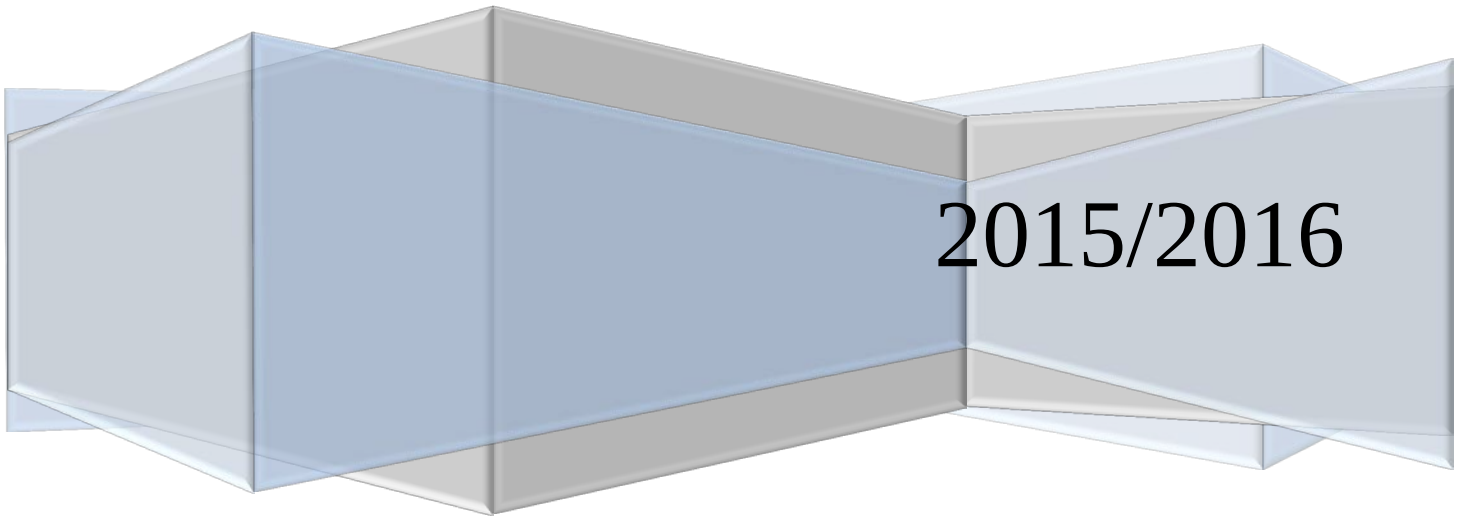
Part C and D Compliance Program Effectiveness (CPE) Program Area

AUDIT PROCESS AND DATA REQUEST



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Audit Purpose and General Guidelines

1. **Purpose**: To evaluate performance in the seven areas outlined below related to a sponsor's Medicare compliance program effectiveness (CPE). The Centers for Medicare & Medicaid Services (CMS) will perform its audit activities using these instructions (unless otherwise noted).

   The seven audit areas are:
   - Written Policies, Procedures and Standards of Conduct
   - Compliance Officer, Compliance Committee, and Governing Body
   - Effective Training and Education
   - Effective Lines of Communication
   - Effective System for Routine Monitoring and Auditing
   - Systems and Procedures for Promptly Responding to Compliance Issues
   - Sponsor Oversight and Accountability of First-Tier, Downstream, and Related Entities (FDRs)

2. **Review Period**: The review period for the Compliance Program Effectiveness audits is 1 year preceding the date of the audit engagement letter (prior Month, Day, Year through audit engagement letter Month, Day, Year).

3. **Responding to Documentation Requests**: The sponsor is expected to present its supporting documentation during the audit and take screen shots or otherwise upload the supporting documentation, as requested, to the secure site using the designated naming convention and within the timeframe specified by the CMS Audit Team.

4. **Sponsor Disclosed and Self-Identified Issues**: Sponsors will be asked to provide a list of all previously disclosed and self-identified issues of non-compliance, from January 1, 2015 through the date of the audit start notice, which CMS may find in your data universes. **For 2016:** the period will be from January 1, 2016 through the date of the audit start notice. A disclosed issue is one that has been reported to CMS prior to the date of the audit start notice (which is also known as the "engagement letter"). A self-identified issue is one that has been discovered by the sponsor for which no prior notification has been provided to CMS. If CMS identifies an issue through on-going monitoring or other account management/oversight activities during the plan year and reported that issue to the sponsor, the sponsor should list that issue as self-identified. Please do not include all issues identified by your organization, just those that are relevant to the areas being audited. Please identify if the issue is corrected, uncorrected and the date when correction occurred.

   Within 5 business days after receipt of the engagement letter, sponsors must provide a description of each issue as well as the remediation status using the Pre-Audit Issue Summary template (Attachment VIII). The sponsor's Account Manager will review the summary for accuracy and completeness. Account Managers (AMs) will be expected to validate that issues identified as "disclosed" were known to CMS prior to the date of the audit start notice. The AMs will also validate the "disclosed" issue status of "corrected" and may also be asked to validate that issues have not been omitted from the "disclosed" summary.

   CMS will consider an issue corrected if there is evidence of appropriate and adequate remediation in the sponsor's systems and for its beneficiaries either prior to or during the "audit review

period", but before receipt of the audit start notice. The "audit review period" refers to the period covered by the related universe request.

Issues that are reported as uncorrected will automatically be cited as conditions in the CMS audit report. Issues reported as corrected after the date of the audit start notice will be treated as uncorrected issues.

Issues that are reported as corrected prior to the audit universe review period will be assumed to be corrected. However, if the issue is identified during the course of the audit, CMS will cite the applicable conditions in the audit report. CMS will not otherwise validate correction of issues identified as corrected.

Issues that are reported as corrected during the universe review period will either be validated for correction during the audit or during the validation of correction of audit findings, based on the type of issue identified. Auditors will validate correction if it can be accomplished simply (e.g., running a test claim through the sponsor's system to ensure edits were properly reprogrammed or confirming a change was made in the system to a letter template, ensuring required language was included). When correction is validated the issue will be noted as an observation in the organization's audit report. If validation of correction is not feasible during the audit (e.g., would be time consuming or insufficient data exists) then the organization will be cited the applicable conditions related to the disclosed/self-identified issue in their audit report and CMS will validate correction during audit validation.

5. **Calculation of Score:** CMS will determine if each condition cited is an Observation (0 points), Corrective Action Required (CAR) (1 point) or an Immediate Corrective Action Required (ICAR) (2 points). **For 2016:** CMS will add a new type of condition, called Invalid Data Submission (IDS). IDS conditions will be cited when a sponsor is not able to produce an accurate universe within 3 attempts. IDS conditions will be worth one point.

   CMS will then add the score for that audit element to the scores for the remainder of the audit elements in a given protocol and then divide that number (i.e., total score), by the number of audit elements tested to determine the sponsor's overall CPE audit score. Some elements and program areas may not apply to certain sponsors and therefore will not be considered when calculating program area and overall audit scores. Observations will be recorded in the draft and final reports, but will not be scored and therefore will not be included in the program area and audit scores.

6. **Informing Sponsor of Results:** CMS will provide daily updates regarding conditions discovered that day (unless the tracer has been pended for further review). CMS will provide a preliminary summary of its findings at the exit conference. The CMS Audit team will do its best to be as transparent and timely as possible in its communication of audit findings. Sponsors will also receive a draft audit report which they may formally comment on and then a final report will be issued after consideration of a sponsor's comments on the draft.

Universe Preparation & Submission

1. **Responding to Universe Requests**: The sponsor is expected to provide accurate and timely universe submissions within 15 business days of the engagement letter date. CMS may request a revised universe if data issues are identified. The resubmission request may occur before and/or after the entrance conference depending on when the issue was identified. Sponsors will have a maximum of 3 attempts to provide complete and accurate universes, whether these attempts all occur prior to the entrance conference or they include submissions prior to and after the entrance conference. However, 3 attempts may not always be feasible depending on when the data issues are identified and the potential for impact to the audit schedule. When multiple attempts are made, CMS will only use the last universe submitted.

   For 2016: If multiple attempts are made and the sponsor fails to provide accurate and timely universe submissions after the first 2 attempts, CMS will document this as an observation in the sponsor's program audit report. After the 3rd failed attempt or when the sponsor determines after fewer attempts that they are unable to provide an accurate universe within the timeframe specified during the audit, the sponsor will be cited an Invalid Data Submission (IDS) condition relative to each element that cannot be tested, grouped by the type of case.

2. **Pull Universes and Submit Documentation:** The universes and documentation collected for this program area test the sponsor's performance in compliance program effectiveness. The sponsor will provide universes that describe the framework and operation of its compliance program and universes to support the implementation of compliance and FWA-related activities conducted within the audit period.

   Documentation: Sponsors should submit the following documentation in either a Microsoft Word (.docx), Microsoft Excel (.xlsx) or Portable Document File (PDF):

   - Organizational Structure and Governance PowerPoint Presentation
   - Completed CPE Self-Assessment Questionnaire
   - Standards of Conduct/Code of Conduct (distributed to employees and FDRs during the audit period)
   - Corporate Compliance/Medicare Compliance/Fraud, Waste and Abuse Plan (or similar document in effect during the audit period)
   - Formal Risk Analysis or Assessments (by which all Medicare Part C and/or D operational areas were taken into account and major compliance issues and potential FWA risks were identified during the audit period)
   - Audit and Monitoring Work Plans (for internal operations and FDRs, in effect at any time during the audit period)

   Data Universes: Universes should be compiled using the appropriate record layouts as described in Appendix A. These record layouts include:

   - First-Tier Entity Auditing and Monitoring (FTEAM)
   - Employee and Compliance Team (ECT)
   - Internal Auditing (IA)
   - Internal Monitoring (IM)
   - Fraud, Waste and Abuse Monitoring (FWAM)

NOTE: For each respective universe, the sponsor should include all items that match the description for that universe for all contracts and PBPs in its organization as identified in the audit engagement letter.

3. **Submit Universes to CMS:** Sponsors should submit each data universe in the Microsoft Excel (.xlsx) or Comma Separated Values (.csv) file format with a header row following the record layouts shown in Appendix A, Tables 1-5. The sponsor should submit its universes in whole and not separately for each contract and PBP. The sponsor should submit all documentation with its universes.

Sample Selection

1. **Sample Selection:** CMS will use a tracer approach to evaluate whether the sponsor's compliance program, as a whole system, functions in a way that is effective to address incidents of non-compliance and FWA. CMS will select 6 tracer samples (compliance activities or events) to review during the onsite portion of the audit. All six tracer samples will be pulled from the sponsor's universe submissions, however, CMS auditors have the discretion to substitute or select additional tracers from internal and external resources. Resources could include the CMS Account Manager, concerns or complaints from providers and enrollees plan members, compliance enforcement activity (e.g., Notices of Non-Compliance and Warning Letters) and regulatory and sub-regulatory guidance memos issued via HPMS (e.g., Common Conditions, Improvement Strategies and Best Practices based on 2014 Program Audit Reviews). CMS will consider several factors when making tracer sample selections including the scope of the sponsor's Medicare Part C and/or D program, business functions, adequate resources, staffing resources, compliance history, current compliance risks, and aggravating or mitigating circumstances that have had an impact on the sponsor's operations, etc.

   Tracer Discussion Guides and Supporting Case File Documentation Requested
   Each tracer will be used to evaluate all applicable compliance program requirements. Tracer reviews will be conducted in a real-time walkthrough with all parties involved with addressing and correcting the compliance issue(s).

   Sponsors will be expected to develop a PowerPoint Presentation (Tracer PPT) for each tracer to document the full story of the compliance and/or FWA issue. A completed Tracer PPT must include, at a minimum, statements or rationales **and** supporting documentation (e.g., screen prints, website screenshots, attestations, links to intranet or websites, policies, meeting minutes, emails, reports, action plans, results, etc.) that will trace the issue through the compliance program and explain how the sponsor identified, communicated, responded and corrected the issue with all internal and external parties involved.

   Sponsors will have three (3) options for providing supporting documentation for the six (6) tracer samples:

   (1) Incorporate the documentation into the Tracer PPTs
   (2) Submit documentation electronically via the Secure File Transfer Protocol (SFTP)
   (3) Have immediate access to the documentation during the onsite audit

Audit Elements

I. Written Policies, Procedures and Standards of Conduct

1. **Review Tracer Case Documentation:** During the onsite portion of the audit CMS will review all tracer sample case documentation to determine if the compliance program elements were effectively met. The sponsor will need access to the following documents and data and may be requested to produce screenshots of any of the following:

    - List of current Medicare compliance program policies and procedures.
    - The policy and procedure covering the process that was in effect before the issue was identified, if any.
    - Any revisions to the policy and procedure in response to the identified issue.
    - If a policy and procedure did not exist prior to the time the issue occurred, an explanation of how your organization operated.
    - If a policy and procedure was not reviewed and revised in response to the identified issue, an explanation outlining the rationale for sponsor's determination that revisions were not necessary.
    - Any revisions to the compliance policies and procedures as a result of the tracer.
    - For the employees/ FDRs involved in the selected tracer sample.
        (a) For each identified employee/volunteer/ FDR, please provide documentation (e.g., sign-in sheets, employee attestations, electronic certifications of completion, etc.) that confirms: Standards of Conduct/Code of Conduct distributed to employee/volunteer/FDR, along with the date of distribution.

2. **Apply Compliance Standard**: At a minimum, CMS will evaluate cases against the following criteria. CMS may review factors not specifically addressed in these questions if it is determined that there are other related CPE requirements not being met.

    2.1. Does the sponsor's Standards of Conduct and Ps&Ps contain the information mandated under the regulation?

    2.2. Does the sponsor update/ distribute their Standards of Conduct and Ps & Ps to their employees/ FDRs within 90 days of hire, when there are updates and annually thereafter?

3. **Tracer Sample Case Results:** CMS will test each of the 6 tracers. CMS will also conduct interviews while onsite to provide insight and additional information on the sponsor's compliance program. If CMS requirements are not met, conditions (findings) are cited. If CMS requirements are met, no conditions (findings) are cited. **NOTE**: Tracers and conditions may have a one-to-one or a one-to-many relationship. For example, one tracer may be associated with a single condition or multiple conditions of non-compliance.

II. Compliance Officer, Compliance Committee, Governing Body

1. **Review Tracer Case Documentation:** During the onsite portion of the audit, CMS will review all tracer sample case documentation to determine if the compliance program elements were effectively met. The sponsor will need access to the following documents and data and may be requested to produce screenshots of any of the following:

   - Any Compliance Committee meeting minutes documenting the issue was discussed during one or more meetings following the identification of the issue.
   - All documentation that details the content of the meeting, including specific reports, charts, or other documents that the Compliance Committee meeting minutes refer to or that were otherwise reviewed or discussed during each meeting.
   - Provide data that details the dates of the meetings, what was discussed, materials that were shared at the meeting regarding compliance (e.g., PowerPoint presentations, emails, handouts, reports, memoranda, etc.)
   - Board of Directors meeting minutes documenting the issue was a topic of discussion at one or more Board of Directors meetings following the identification of the issue.
   - All documentation that details the content of the meeting, including specific reports, charts, presentation materials or other documents that the Board of Directors meeting minutes refer to or that were otherwise reviewed or discussed during each meeting.
   - Provide data that details the dates of the meetings, what was discussed, materials that were shared at the meeting regarding compliance (e.g., PowerPoint Presentations, emails, handouts, reports, memoranda, etc.)
   - Any evidence that the issue was shared with the CEO.
   - Any directives the CEO or Board of Directors provided to the compliance office related to the identified issue.

2. **Apply Compliance Standard:** At a minimum, CMS will evaluate cases against the following criteria. CMS may review factors not specifically addressed in these questions if it is determined that there are other related CPE requirements not being met.

   2.1. Did the sponsor demonstrate appropriate reporting of Medicare compliance issues to the governing body and senior management/executives?

   2.2. Does the sponsor have a compliance officer and compliance committee in accordance with regulations?

   2.3. Does the sponsor have a governing body that exercises reasonable oversight of the Medicare compliance program?

3. **Tracer Sample Case Results:** CMS will test each of the 6 tracers. CMS will also conduct interviews while onsite to provide insight and additional information on the sponsor's compliance program. If CMS requirements are not met, conditions (findings) are cited. If CMS requirements are met, no conditions (findings) are cited. **NOTE**: Tracers and conditions may have a one-to-one or a one-to-many relationship. For example, one tracer may be associated with a single condition or multiple conditions of non-compliance.

III. Effective Training and Education

1. **Review Tracer Case Documentation:** During the onsite portion of the audit CMS will review all tracer sample case documentation to determine if the compliance program elements were effectively met. The sponsor will need access to the following documents and data and may be requested to produce screenshots of any of the following:

    - For employees, senior management and governing body members identified, provide evidence that mandatory Medicare compliance training was given.
    - For employees, senior management and governing body members identified, provide any evidence that operational training related to the issue identified was given (if determined necessary).
    - For employees, senior management and governing body members identified provide evidence that FWA training was provided.
    - Please include the date, topic, audience, and method of education for trainings.
    - Provide a description of how the sponsor feels the training and education were effective in reducing compliance and FWA risks.

2. **Apply Compliance Standard:** At a minimum, CMS will evaluate cases against the following criteria. CMS may review factors not specifically addressed in these questions if it is determined that there are other related CPE requirements not being met.

    2.1 Did the sponsor establish, maintain and implement effective compliance and FWA training and education?

3. **Tracer Sample Case Results:** CMS will test each of the 6 tracers. CMS will also conduct interviews while onsite to provide insight and additional information on the sponsor's compliance program. If CMS requirements are not met, conditions (findings) are cited. If CMS requirements are met, no conditions (findings) are cited. **NOTE**: Tracers and conditions may have a one-to-one or a one-to-many relationship. For example, one tracer may be associated with a single condition or multiple conditions of non-compliance.

IV. Effective Lines of Communication

1. **Review Tracer Case Documentation:** During the onsite portion of the audit CMS will review all tracer sample case documentation to determine if the compliance program elements were effectively met. The sponsor will need access to the following documents and data and may be requested to produce screenshots of any of the following:

    - Evidence of communication(s) to the affected or involved business area(s) regarding the issue.
    - Call logs, emails, memos, etc. showing communication(s) were made.
    - An explanation of how communication usually occurs when an issue is discovered.
    - Evidence of the mechanisms used to communicate information and regulatory changes from the compliance officer to others (e.g., employees, senior leadership, FDRs).
    - Evidence of mechanism(s) used by employees, FDRs and enrollees to report issues (e.g., hotline number or website).

2. **Apply Compliance Standard:** At a minimum, CMS will evaluate cases against the following criteria. CMS may review factors not specifically addressed in these questions if it is determined that there are other related CPE requirements not being met.

    2.1. Did the sponsor establish and implement effective communication regarding compliance and FWA issues or concerns between its compliance officer, employees, members of the governing body and FDRs?

3. **Tracer Sample Case Results:** CMS will test each of the 6 tracers. CMS will also conduct interviews while onsite to provide insight and additional information on the sponsor's compliance program. If CMS requirements are not met, conditions (findings) are cited. If CMS requirements are met, no conditions (findings) are cited. **NOTE**: Tracers and conditions may have a one-to-one or a one-to-many relationship. For example, one tracer may be associated with a single condition or multiple conditions of non-compliance.

V. Effective System for Routine Monitoring and Auditing

1. **Review Tracer Case Documentation:** During the onsite portion of the audit CMS will review all tracer sample case documentation to determine if the compliance program elements were effectively met. The sponsor will need access to the following documents and data and may be requested to produce screenshots of any of the following:

    - An explanation/ evidence of sponsor's Medicare Part C and/or D risk assessment indicating how issues are identified.
    - Copies of monitoring reports showing the outcomes of monitoring conducted on the identified issue.
    - If monitoring occurred over a period of time, copies of trending reports showing the trend of the issue (i.e., the issue is being or has been remediated over time or the issue is still occurring).
    - Copies of audit reports showing the results of any audits conducted for the identified issue.
    - Evidence/ explanation of any follow up done as a result of the monitoring/ auditing of the identified issue.
    - For employees, evidence that the employees were checked monthly against the OIG/GSA exclusion lists.
    - For FDRs, evidence that the FDRs (and their employees) were checked monthly against the OIG/GSA exclusion lists.

2. **Apply Compliance Standard:** At a minimum, CMS will evaluate cases against the following criteria. CMS may review factors not specifically addressed in these questions if it is determined that there are other related CPE requirements not being met.

    2.1. Did the sponsor establish and maintain an effective risk assessment for identifying compliance and FWA risks?

    2.2. Did the sponsor establish and maintain and effective system for monitoring and auditing its Medicare Parts C and D operations and compliance program effectiveness?

    2.3. Did the sponsor review OIG/GSA exclusion lists for employees and FDRs, as required?

    2.4. Did the sponsor establish and maintain an effective monitoring system to prevent, detect and control FWA in the delivery of Medicare Parts C and D benefits?

3. **Tracer Sample Case Results:** CMS will test each of the 6 tracers. CMS will also conduct interviews while onsite to provide insight and additional information on the sponsor's compliance program. If CMS requirements are not met, a condition (finding) are cited. If CMS requirements are met, no conditions (findings) are cited. **NOTE**: Tracers and conditions may have a one-to-one or a one-to-many relationship. For example, one tracer may be associated with a single condition or multiple conditions of non-compliance.

VI. Procedures and Systems for Promptly Responding to Compliance Issues

1. **Review Tracer Case Documentation:** During the onsite portion of the audit CMS will review all tracer sample case documentation to determine if the compliance program elements were effectively met. The sponsor will need access to the following documents and data and may be requested to produce screenshots of any of the following:

    - Explanation/ evidence of a root cause analysis performed to determine why the identified issue occurred.
    - Copies/ explanation of detailed corrective actions that were taken regarding the identified issue.
    - A timeline indicating the corrective actions have been fully implemented or, if not fully implemented, when the sponsor expects the corrective action to be completed.
    - If corrective actions were not taken, please provide an explanation of rationale for not implementing corrective action.

2. **Apply Compliance Standard**: At a minimum, CMS will evaluate cases against the following criteria. CMS may review factors not specifically addressed in these questions if it is determined that there are other related CPE requirements not being met.

    2.1 Did the sponsor undertake timely and reasonable corrective action in response to compliance incidents, issues, investigations, complaints or misconduct involving potential Medicare program noncompliance or potential FWA?

3. **Tracer Sample Case Results:** CMS will test each of the 6 tracers. CMS will also conduct interviews while onsite to provide insight and additional information on the sponsor's compliance program. If CMS requirements are not met, conditions (findings) are cited. If CMS requirements are met, no conditions (findings) are cited. **NOTE**: Tracers and conditions may have a one-to-one or a one-to-many relationship. For example, one tracer may be associated with a single condition or multiple conditions of non-compliance.

VII. Sponsor Accountability and Oversight of FDRs

1. **Review Tracer Case Documentation:** During the onsite portion of the audit CMS will review all tracer sample case documentation to determine that the compliance program elements were effectively met. The sponsor will need access to the following documents and data and may be requested to produce screenshots of any of the following:

    - Explanation or rationale that details how the sponsor correctly identifies those entities with which they contract that quality as FDRs, and are required to comply with CMS requirements for FDRs.
    - Any written policies and procedures relating to oversight of the sponsor's FDRs, including business areas or departments that manage the performance of FDRs.
    - Operational policies and procedures (if any)
    - Evidence that compliance P&Ps and Code of Conduct were distributed to the sponsor's FDRs
    - Evidence of communication to compliance committee, Board of Directors, and/or CEO of any compliance issues involving the FDR.
    - Evidence ensuring the sponsor's FDRs (including the FDR's employees) have satisfied the general compliance and FWA training requirement by completing the CMS training modules on the Medicare Learning Network (MLN) (i.e., MLN-generated certificate of completion, attestation, training logs, spreadsheets, etc.).
    - Evidence of effective communication regarding compliance issues concerning FDRs.
    - Evidence of the strategy to monitor and audit the sponsor's FDRs during the audit period
    - If it was impractical and/or cost prohibitive to monitor or audit all first-tier entities for all compliance program requirements during the audit period, provide the risk assessment(s) performed to identify the highest risk first-tier entities audited/monitored during the audit period.
    - Any risk assessments used to identify the monitoring or auditing activities.
    - All documents, work plans, results, and reports relating to the monitoring or auditing activities and services performed by the sponsor's FDRs.
    - Evidence that the sponsor's FDR was checked against the OIG/ Exclusion lists (i.e., screen print of the results of the check, documentation that clearly shows the name of the entity/individual checked, the date the check was performed, and the results of the check)
    - Explanation/ evidence of a root cause analysis performed to determine why the identified issue occurred.
    - Copies/ explanation of detailed corrective actions that were taken regarding the identified issue.
    - A timeline indicating the corrective actions have been fully implemented or, if not fully implemented, when you expect the corrective action to be completed.
    - If corrective actions were not taken, please provide an explanation of rationale for not implementing corrective action.

2. **Apply Compliance Standard:** At a minimum, CMS will evaluate cases against the following criteria. CMS may review factors not specifically addressed in these questions if it is determined that there are other related CPE requirements not being met.

2.1. Did the sponsor properly oversee its FDRs to ensure compliance with all applicable laws, rules and regulations with respect to Medicare Parts C and D delegated responsibilities?

2.2. Did the sponsor distribute the necessary compliance policies and code of conduct to its FDRs?

2.3. Did the sponsor ensure general compliance and FWA trainings were completed by its FDRs?

2.4. Did the sponsor demonstrate effective communication with its FDRs?

2.5. Did the sponsor demonstrate effective routine auditing and monitoring of its FDRs?

2.6. Did the sponsor demonstrate timely and effective corrective action for identified issues or incidents of noncompliance/FWA?

3. **Tracer Sample Case Results:** CMS will test each of the 6 tracers. CMS will also conduct interviews while onsite to provide insight and additional information on the sponsor's compliance program. If CMS requirements are not met, conditions (findings) are cited. If CMS requirements are met, no conditions (findings) are cited. **NOTE**: Tracers and conditions may have a one-to-one or a one-to-many relationship. For example, one tracer may be associated with a single condition or multiple conditions of non-compliance.

Appendix

Appendix A—Compliance Program Effectiveness (CPE) Record Layouts

The universes for the Part C & D Compliance Program Effectiveness (CPE) program area must be submitted as a Microsoft Excel (.xlsx) or Comma Separated Values (.csv) files with a header row. Do not include additional information outside of what is dictated in the record layout. Submissions that do not strictly adhere to the record layout will be rejected.

Please use a comma (,) to separate multiple values within one field if there is more than on piece of information for a specific field.

Note: There is a maximum of 4,000 characters per record row. Therefore, should additional characters be needed for a variable, enter this information on the next record at the appropriate start position.

Table 1: First Tier Entity Auditing and Monitoring (FTEAM) Record Layout

- Include: all audit and monitoring activities performed by the sponsor to ensure that its first-tier entities are in compliance with Medicare Part C and/or D program requirements.
    - Audit and monitoring activities initiated, started or re-opened or completed during the audit period. This includes auditing and monitoring activities that started outside the audit period, but were completed within the audit period.
    - For monitoring activities that are performed on a scheduled basis (monthly, quarterly, annually), it should be included in the universe each time it was performed. If a monitoring activity is conducted *daily*, only include it once in the universe, but identify all deficiencies, corrective actions, etc. for all monitoring performed throughout the audit period.
    - If a related entity is acting as a first-tier entity to provide administrative or health care services, include in the universe.
    - If a sponsor chose to monitor or audit a downstream entity directly instead of first-tier entity, include in the universe.
- Exclude: First-tier entities that that do not provide an administrative or health care service function related to the sponsor's Medicare Parts C and/or D contracts.

Column ID	Field Name	Field Type	Field Length	Description
A	Name of FTE	CHAR Always Required	50	Name of the first tier entity (FTE) that was audited or monitored.
B	Description of FTE function and responsibilities	CHAR Always Required	500	Brief description of the administrative or health care service function(s) and responsibilities the FTE conducts on behalf of the sponsor.

Column ID	Field Name	Field Type	Field Length	Description
C	Effective Date of Contract	CHAR Always Required	10	How long has the sponsor contracted with the FTE to perform Part C or Part D functions? Submit in CCYY/MM/DD format (e.g., 2015/01/01).
D	Name of Component	CHAR Always Required	50	Name of the sponsor component, department or operational area affected or works in part or whole with the FTE.
E	Date Activity Started	CHAR Always Required	10	Provide the date that the audit or monitoring activity was initiated, started or reopened. Submit in CCYY/MM/DD format (e.g., 2015/01/01).
F	Date Activity Completed	CHAR Always Required	10	Provide the date that the audit or monitoring ended. Submit in CCYY/MM/DD format (e.g., 2015/01/01). Enter TBD if the audit or monitoring event is currently in progress.
G	Type of Activity	CHAR Always Required	10	Enter whether the activity was an “audit” or a “monitoring “activity
H	Activity Description	CHAR Always Required	500	Provide a description of the audit or monitoring activity (e.g., an 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, etc.)
I	Frequency of Activity	CHAR Always Required	20	Provide the frequency of the audit or monitoring activity (i.e., weekly, monthly, quarterly, annually, ad-hoc, etc.)
J	Were compliance risks identified?	CHAR Always Required	2	Yes (Y) /No (N) indicator of whether the audit or monitoring activity performed was based on being identified through a risk analysis or assessment.

Column ID	Field Name	Field Type	Field Length	Description
K	Were any issues or deficiencies discovered?	CHAR Always Required	3	Yes(Y)/No (N) indicator of whether any issues, deficiencies of findings were discovered during the audit and monitoring activity. Answer TBD if the audit or monitoring event is currently in progress and deficiencies have yet to be identified.
L	Number of Deficiencies	CHAR Always Required	3	Provide the number of deficiencies, findings or issues identified. Answer NA if no deficiencies were identified or discovered.
M	Description of Deficiencies	CHAR Always Required	1000	Provide a description of all deficiencies, findings or issues identified during the audit or monitoring activity. If the audit or monitoring activity is identified in the pre-audit issue summary submitted to CMS, provide the issue number. If audit or monitoring event is currently *in progress* and deficiencies have yet to be identified, explain why this activity is still in progress with an estimated date in which the activity will be closed and/or deficiencies will be identified Answer NA if no deficiencies were discovered.
N	Was corrective action taken?	CHAR Always Required	3	Yes (Y) /No (N) indicator of whether corrective action has been taken. Answer TBD if the monitoring event is currently in progress and corrective action has yet to be determined.

Column ID	Field Name	Field Type	Field Length	Description
O	Corrective Action Description	CHAR Always Required	1000	Provide a description of the corrective action(s) implemented by the Sponsor and FTE in response to the noncompliance or potential FWA, including any root cause analysis for what caused the deficiencies/problems, timeframes for specific achievements and any ramifications for failing to implement the corrective action satisfactorily. Answer NA if no corrective action was taken or determined not necessary by the sponsor.
P	Were audit/monitoring results shared with others?	CHAR Always Required	750	Describe how the results of the monitoring or audit activity/corrective action were communicated or shared with sponsor's affected components, compliance department, senior management, and the FTE.

Table 2: Employees and Compliance Team (ECT) Record Layout

- Include: all **current** employees of the organization (permanent, temporary, full-time, part-time, including senior management), volunteers (e.g., unpaid interns) who have job duties (full-time or part-time) related to the sponsor's Medicare Advantage (Part C) and/or Prescription Drug (Part D) business. This universe includes members of your Board of Directors who worked/served at any time during the audit period.
- Exclude: individuals that have left the organization, terminated, resigned or do not work on the Medicare Parts C and/or D line of business.

Column ID	Field Name	Field Type	Field Length	Description
A	Employee ID	CHAR Always Required	15	Enter the internal employee ID if there is one. Or NA if this field is not applicable.
B	Employee First Name	CHAR Always Required	50	First name of the employee.
C	Employee Last Name	CHAR Always Required	50	Last name of the employee.
D	Employee's Title	CHAR Always Required	50	Position or Title of the employee, volunteer or board member.
E	Employee's Organizational Component	CHAR Always Required	50	Component or department in which the employee works (e.g., appeals, marketing, customer service)
F	Physical Location	CHAR Always Required	100	Geographical or office location of the employee (e.g., Baltimore, MD.-Central Headquarters)
G	Direct Phone Number	CHAR Always Required	15	Contact phone number for employee's office or desk. Submit in 10-digit number format (e.g., 410-555-5555)
H	Date of Hire	CHAR Always Required	10	Date the employee started working for the sponsor. Submit in CCYY/MM/DD format (e.g., 1940/01/01).
I	Type of Employee	CHAR Always Required	20	Indicate whether the employee is full time, part time, temporary, or a volunteer.

Column ID	Field Name	Field Type	Field Length	Description
J	Does the employee work in/for the Medicare Compliance Department?	CHAR Always Required	1	Yes(Y)/No (N) indicator of whether the employee fully or partially works to support the operations of the Medicare Compliance Department or Compliance Officer. Note: Indicate Yes (Y) for any full-time compliance staff, as well as any staff from an operational area that serve as a primary compliance liaison between the Compliance Department and its operational area.
K	Description of job functions for Compliance Department	CHAR Always Required	1500	Describe the job duties of the compliance officer and any compliance staff (e.g., internal audit, training, privacy, SIU). Please also provide the length of time they have held that position.
L	Employee a member of the compliance committee?	CHAR Always Required	1	Yes(Y)/No (N) indicator of whether the employee is a part of the Compliance Committee that addresses Medicare compliance issues.
M	Compliance Committee member's role	CHAR Always Required	1500	Provide a description of the role and/or expertise each member brings to the compliance committee (e.g., Manager of appeals & grievances responsible for addressing Part C appeals and grievance issues and concerns that severely impact enrollees and developing corrective action plans for the affected internal departments and FDR.) Answer NA if employee is not a member of the compliance committee.

Table 3: Internal Auditing (IA) Record Layout

- Include: All audit activities *(formal review of compliance with a particular set of standards as base measures)* performed by the sponsor to ensure that its internal business and/or operational areas are in compliance with Medicare Parts C and D program requirements and to ensure that corrective actions are undertaken, timely and effective.
    - All audit activities initiated, started or re-opened or completed during the audit period. This includes audit and monitoring activities that started prior to the audit period, but were completed within the audit period and activities that were started during the audit period but not yet completed.
    - Audit activities that are performed on a scheduled basis (monthly, quarterly, annually), should be included in the universe each time it was performed. If an auditing activity is conducted *daily*, only include it once in the universe, but identify all deficiencies, corrective actions, etc. for all auditing performed throughout the audit period.
- Exclude: Audit activities for non-Medicare lines of business (e.g., commercial, Medicaid)

Column ID	Field Name	Field Type	Field Length	Description
A	Name of Component	CHAR Always Required	50	Name of the sponsor component, department or operational area audited.
B	Description of Responsibilities	CHAR Always Required	500	Brief description of what responsibilities the component, department or operational area conducts on behalf of the sponsor.
C	Date Audit Started	CHAR Always Required	10	Provide the date that the audit or monitoring activity was initiated, started or reopened. Submit in CCYY/MM/DD format (e.g., 2015/01/01).
D	Date Audit Completed	CHAR Always Required	10	Provide the date that the audit ended. Submit in CCYY/MM/DD format (e.g., 2015/01/01). Enter TBD if the audit is currently in progress.
E	Frequency of Audit	CHAR Always Required	50	Frequency of the audit activity (e.g., daily, weekly, monthly, quarterly, annually, ad-hoc, incident/event-based).

Column ID	Field Name	Field Type	Field Length	Description
F	Internal or External Auditors	CHAR Always Required	100	Who conducted the audit activity? (e.g., compliance officer, internal audit department, appeals & grievances staff/manager, external audit firm) For internal staff, provide the names of staff/department involved with conducting the audit activity. For external audit firm, provide the name of the firm/company.
G	Audit Description	CHAR Always Required	500	Description of the audit (e.g., an 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, etc.)
H	Were compliance risks identified?	CHAR Always Required	1	Yes (Y) /No (N) indicator of whether the audit activity performed was based on being identified through a risk analysis or assessment.
I	Were any issues or deficiencies discovered?	CHAR Always Required	3	Yes(Y)/No (N) indicator of whether any issues, deficiencies of findings were discovered during the audit activity. Answer TBD if the audit is currently in progress and deficiencies have yet to be identified.
J	Number of Deficiencies	CHAR Always Required	3	Provide the number of deficiencies, findings or issues identified. Answer NA if no deficiencies were identified or discovered.

Column ID	Field Name	Field Type	Field Length	Description
K	Description of Deficiencies	CHAR Always Required	1000	Provide a full description of all deficiencies, findings or issues identified during the audit activity. If the audit is identified in the pre-audit issue summary submitted to CMS, please include the issue number. If audit event is currently *in progress* and deficiencies have yet to be identified, explain why this activity is still in progress with an estimated date in which the activity will be closed and/or deficiencies will be identified Answer NA if no deficiencies were discovered.
L	Was corrective action taken?	CHAR	3	Yes (Y) /No (N) indicator of whether corrective action has been taken. Answer TBD if the audit event is currently in progress and corrective action has yet to be determined.
M	Corrective Action Description	CHAR Always Required	1000	Provide a description of the corrective action(s) implemented by the sponsor in response to the noncompliance or potential FWA, including any root cause analysis for what caused the deficiencies/problems, timeframes for specific achievements and any ramifications for failing to implement the corrective action satisfactorily. Answer NA if no corrective action was taken or determined not necessary by sponsor.
N	Were audit results shared with others?	CHAR Always Required	750	Describe how the results of the audit/corrective actions were communicated or shared with the sponsor's affected components, business areas, compliance department, and senior management.

Table 4: Internal Monitoring (IM) Record Layouts

- Include: all monitoring activities *(routine, scheduled and incident/event-based reviews as part of normal operations)* performed by the sponsor to test and confirm internal business and/or operational areas are in compliance with Medicare Part C and/or Part D program requirements and to ensure that corrective actions are undertaken, timely and effective.
    - All monitoring activities initiated, started or re-opened or completed during the audit period. This includes monitoring activities that started prior to the audit period, but were completed within the audit period and activities that were started during the audit period but not yet completed.
    - For monitoring activities that are performed on a scheduled basis (monthly, quarterly, annually, daily), it should be included in the universe each time it was performed. If a monitoring activity is conducted *daily*, only include it once in the universe, but identify all deficiencies, corrective actions, etc. for all monitoring performed throughout the year.
- Exclude: Monitoring activities for non-Medicare lines of business (e.g., commercial, Medicaid)

Column ID	Field Name	Field Type	Field Length	Description
A	Name of Component	CHAR Always Required	50	Name of the sponsor component, department or operational area that was monitored.
B	Description of Responsibilities	CHAR Always Required	500	Brief description of what responsibilities the component, department or operational area conducts on behalf of the sponsor.
C	Date Monitoring Started	CHAR Always Required	10	Provide the date that the audit or monitoring activity was initiated, started or reopened. Submit in CCYY/MM/DD format (e.g., 2015/01/01).
D	Date Monitoring Completed	CHAR Always Required	10	Provide the date that the audit or monitoring activity ended. Submit in CCYY/MM/DD format (e.g., 2015/01/01).
E	Frequency of Monitoring	CHAR Always Required	20	Frequency of the monitoring activity (e.g., weekly, monthly, quarterly, annually, ad-hoc, incident/event-based)
F	Internal or External Auditors	CHAR Always Required	100	Who conducted the monitoring activity? (e.g., compliance officer, internal audit department, appeals & grievances staff/manager)

Column ID	Field Name	Field Type	Field Length	Description
G	Description of Monitoring	CHAR Always Required	500	Description of what was monitored. What did the monitoring activity focus on? e.g., an operational area, training requirements, timeliness, accuracy of organization determinations and notifications, messaging errors, contractual agreements, hotline calls, spot checks, compliance monitoring, targeted or stratified sampling, audit protocols, etc.)
H	Were compliance risks identified?	CHAR Always Required	1	Yes (Y) /No(N) indicator of whether the monitoring activity performed was based on being identified through a risk analysis or assessment
I	Were any issues or deficiencies discovered?	CHAR Always Required	3	Were any issues or deficiencies discovered during the monitoring activity? Yes (Y), No (N), or TBD. Answer TBD if the monitoring event is currently in progress and deficiencies have yet to be identified.
J	Number of Deficiencies	CHAR Always Required	3	Provide the actual number of deficiencies, findings or issues identified.
K	Description of Deficiencies	CHAR Always Required	1000	Provide a full description of all deficiencies, findings or issues identified during the monitoring activity. If the monitoring event is identified in the pre-audit issue summary submitted to CMS, please include the issue number. If monitoring event is currently *in progress* and deficiencies have yet to be identified, explain why this activity is still in progress with an estimated date in which the activity will be closed and/or deficiencies will be identified Answer NA if no deficiencies were discovered.

Column ID	Field Name	Field Type	Field Length	Description
L	Was corrective action taken?	CHAR Always Required	3	Yes (Y) /No (N) indicator of whether corrective action has been taken. Answer TBD if the monitoring event is currently in progress and corrective action has yet to be determined.
M	Corrective Action Description	CHAR Always Required	1000	Provide a description of the corrective action(s) implemented by the Sponsor in response to noncompliance and potential FWA discovered during the audit, including any root cause analysis for what caused the deficiencies/problems, timeframes for specific achievements and any ramifications for failing to implement the corrective action satisfactorily. Answer NA of this field is not applicable.
N	Were monitoring results shared with others?	CHAR Always Required	750	Describe how the results of the monitoring activity were communicated or shared with sponsor's affected components, compliance department, senior management, and the FTE.

Table 5: Fraud Waste and Abuse Monitoring (FWAM)

- Include: all monitoring activities and investigations performed during the audit period to identify and address potential or suspected fraud, waste and abuse (FWA) at both the sponsor and FDR levels in the delivery of Medicare Part C and/or D benefits. All potential incidents of FWA identified by an sources (e.g., auditing, monitoring, self-evaluation, hotline calls, law enforcement)
    - Monitoring: Include specific monitoring activities performed to prevent or detect FWA through the review of reports from operational areas and FDRs and use of data analysis (e.g., predictive analytics, data mining, outlier analysis) to detect trends and abnormalities both internally and externally (e.g., comparison of claim information against other data, prescribing and dispensing practices of providers, fraudulent activities of plan members, aberrant pharmacy billing, medical claims, PLATO, Medicare waste by identifying overpayments, etc.)
    - Investigations: Include all informal or formal activities to investigate allegations of fraudulent or questionable behavior performed by employees or FDRs involved in the sponsor's Medicare Part C and/or D operations. Please include employee misconduct, fraudulent provider or pharmacy claims, fraudulent vendor (FDR) invoices, misuse of Medicare beneficiary information, overpayments, complaints or tips received through hotlines, referrals, internal operational areas, FDRs/contractors, overpayments, fraud alerts from CMS, providers, members, MEDIC, law enforcement, etc.
- Exclude: non-Medicare Parts C and/or D FWA monitoring, investigations or actions (e.g., commercial, Medicaid)

Column ID	Field Name	Field Type	Field Length	Description
A	Name of Component, FDR or Enrollee	CHAR Always Required	50	Name of the sponsor component, department, FDR or enrollee that was monitored or investigated for potential or suspected FWA.
B	Was this FWA effort related to Medicare?	CHAR Always Required	3	Yes(Y)/No (N) indicator of whether the FWA event related to Medicare? Answer TBD if the monitoring event is currently in progress and the FWA status is yet to be determined.

Column ID	Field Name	Field Type	Field Length	Description
C	Type of FWA Activity	CHAR Always Required	20	Indicate if the activity is related to "Monitoring" or an "Investigation" NOTE: *Monitoring* is the use of data analysis/claims information/CMS fraud alerts to identify internal/external unusual patterns, practices, providers. *Investigation* refers to case development for detected or reported cases of noncompliance, illegal, fraudulent, or wasteful activity.
D	Date FWA Activity Started	CHAR Always Required	10	Provide the date that the monitoring or investigation activity was initiated, started or reopened. Submit in CCYY/MM/DD format (e.g., 2015/01/01).
E	Date FWA Activity Completed	CHAR Always Required	10	Provide the date that the monitoring or investigation ended. Submit in CCYY/MM/DD format (e.g., 2015/01/01).
F	Frequency of FWA Activity	CHAR Always Required	20	Frequency of the monitoring or investigation (e.g., weekly, monthly, quarterly, annually, ad-hoc, incident/event-based)
G	Internal or External Auditors	CHAR Always Required	100	Who conducted the monitoring or investigation (e.g., operational area, compliance department, legal, SIU, FDR).
H	Description of FWA Activity	CHAR Always Required	1000	Description of what was monitored or investigated (operational area, pharmacy claims, provider claims, employee, enrollee or FDR misconduct).
I	Were FWA Risks Identified?	CHAR Always Required	1	Yes(Y) or No (N) indicator of whether the monitoring effort or investigation was initiated based on being identified through a risk analysis or assessment.

Column ID	Field Name	Field Type	Field Length	Description
J	Communication & Reporting Mechanism	CHAR Always Required	1	Yes(Y) or No (N) indicator of whether the monitoring effort or investigation performed based on an inquiry submitted to the sponsor's compliance/FWA reporting system? (e.g., telephone hotlines, mail drops, email, website).
K	Were any issues or deficiencies discovered?	CHAR Always Required	3	Yes(Y) or No (N) indicator of whether any issues, findings or deficiencies were discovered during the monitoring effort or investigation? Answer TBD if the monitoring event is currently in progress and deficiencies have yet to be identified.
L	Number of Deficiencies	CHAR Always Required	3	Provide the number of deficiencies, findings or issues identified. Answer NA if no deficiencies were identified or discovered.
M	Description of Deficiencies	CHAR Always Required	1000	Provide a description of all deficiencies, findings or issues identified during the monitoring activity or investigation. If the monitoring event is identified in the pre-audit issue summary submitted to CMS, please provide the issue number. If monitoring event or investigation is currently *in progress* and deficiencies have yet to be identified, explain why this activity is still in progress with an estimated date in which the activity will be closed and/or deficiencies will be identified. Answer NA if no deficiencies were discovered.

Column ID	Field Name	Field Type	Field Length	Description
N	Was corrective action taken?	CHAR Always Required	3	Yes (Y) /No (N) indicator of whether corrective action has been taken. Answer TBD if the monitoring event is currently in progress and corrective action has yet to be determined.
O	Corrective Action Description	CHAR Always Required	1000	Provide a description of the corrective action(s) implemented by the sponsor in response to potential or suspected FWA discovered during the monitoring or investigation, including any root cause analysis for what caused the deficiencies/problems, timeframes for specific achievements and any ramifications for failing to implement the corrective action satisfactorily. Answer NA of this field is not applicable.
P	Were monitoring results shared with others?	CHAR Always Required	750	Describe how the results of the monitoring activity or investigation were communicated or shared with sponsor's affected components, compliance department, senior management, and the FTE.