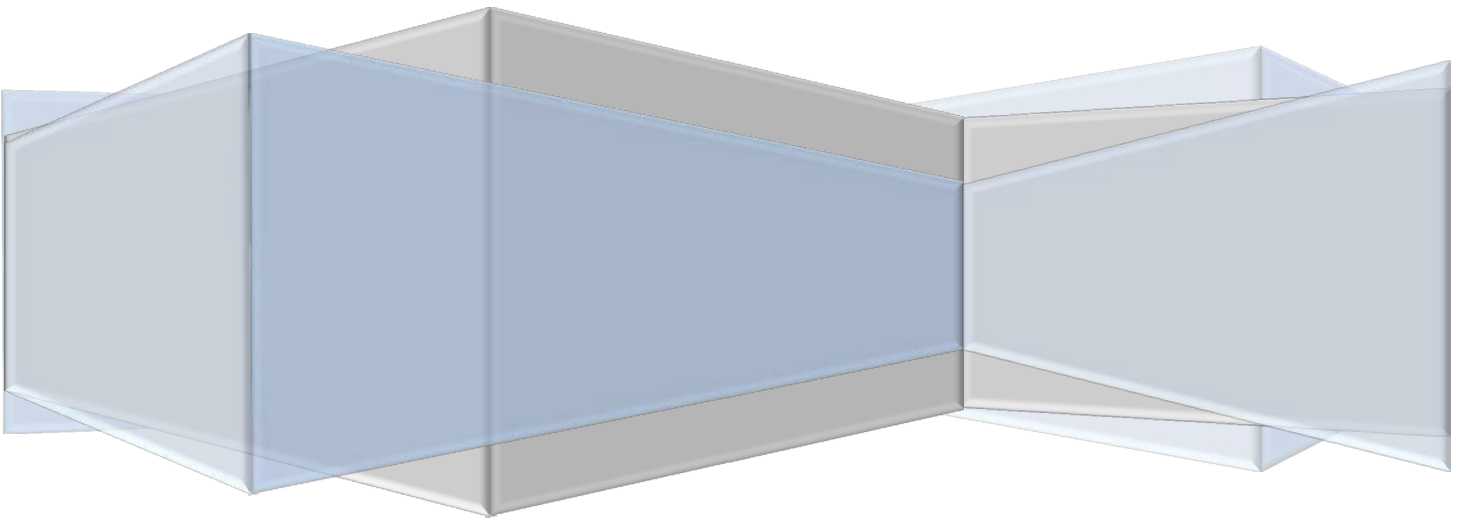




# **Parts C and D Compliance Program Effectiveness (CPE) Program Area AUDIT PROCESS AND DATA REQUEST**



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## Audit Purpose and General Guidelines

1. **Purpose:** To evaluate the sponsor's performance with adopting and implementing an effective compliance program to prevent, detect and correct Medicare Parts C or D program non-compliance and fraud, waste and abuse (FWA) in a timely and well-documented manner. The Centers for Medicare and Medicaid Services (CMS) will perform its audit activities using these instructions (unless otherwise noted).
2. **Review Period:** The review period for the Compliance Program Effectiveness (CPE) audits is 1 year preceding and including the date of the audit engagement letter (prior Month, Day, Year through audit engagement letter Month, Day, and 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. The screenshots must be provided to CMS via a Microsoft® Word or PDF document.
4. **Sponsor Disclosed Issues:** Sponsors will be asked to provide a list of all disclosed issues of non-compliance that are relevant to the program areas being audited and may be detected during the audit. A disclosed issue is one that has been reported to CMS prior to the receipt of the audit start notice (which is also known as the "engagement letter"). Issues identified by CMS through on-going monitoring or other account management/oversight activities during the plan year are not considered disclosed.

Sponsors must provide a description of each disclosed issue as well as the status of correction and remediation using the Pre-Audit Issue Summary template. This template is due within 5 business days after the receipt of the audit start notice. The sponsor's Account Manager will review the summary to validate that "disclosed" issues were known to CMS prior to receipt of the audit start notice.

When CMS determines that a disclosed issue was promptly identified, corrected (or is actively undergoing correction), and the risk to beneficiaries has been mitigated, CMS will not apply the ICAR condition classification to that condition.

**NOTE:** For CPE, CMS wants a list of all disclosed issues relating to a sponsor's compliance program, not issues discovered during compliance activities (such as routine monitoring or auditing). For example: the sponsor disclosed an issue to CMS that during the audit review period the SIU failed to comply with a number of requests for additional information from the MEDIC and enforcement agencies.

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). Invalid Data Submissions (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 the conditions 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.

If the sponsor fails to provide accurate and timely universe submissions twice, CMS will document this as an observation in the sponsor's program audit report. After the third 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. Sponsors will provide universes and supporting documentation that describe the framework and operation of its compliance program and universes to support the implementation of compliance activities conducted within the audit period. If the audit review crosses calendar years, sponsoring organizations must provide the requested documentation (e.g. standards of conduct/code of conduct documents, audit and monitoring work plans, Corporate Compliance/Medicare Compliance/Fraud Waste Abuse (FWA) plan, formal risk assessments, etc.) that covers the entire audit period.

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

- Completed Compliance Officer Questionnaire (Attachment I-A)
- Customized Organizational Structure and Governance PowerPoint Presentation (Attachment I-B)
- Completed First-Tier Downstream and Related Entities (FDR) Operations Questionnaire (Attachment I-C)
- Completed Special Investigation Unit (SIU)/FWA Prevention and Detection Questionnaire (Attachment I-D)
- Standards of Conduct/Code of Conduct document (distributed to employees and FDRs during the audit review period)
- Corporate Compliance/Medicare Compliance/FWA Plan (or similar document in effect during the audit review period)
- Formal Risk Assessments and Compliance Performance Mechanisms that show the extent to which Medicare Parts C and/or D operational areas and FWA risks were identified and compliance goals were monitored during the audit review period
- Audit and Monitoring Work Plans (for internal operations and FDRs, in effect at any time during the audit review period)

**2.2. 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)

**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.
- For each respective universe, the sponsor should include compliance and FWA activities.
- Please refer to Section 40 of the Medicare Parts C and D Compliance Program Guidelines for definitions, flowcharts and guidance on relationships between sponsor and first-tier entities.
- Please refer to Section 50.6 of the Medicare Parts C and D Compliance Program Guidelines for definitions and guidance for routine internal auditing and monitoring requirements and expectations.
- Please refer to Sections 50.6.9 and 50.6.10 for guidance on fraud, waste and abuse monitoring activities and SIU operations.

3. **Submit Universes to CMS:** Sponsors should submit each data universe in the Microsoft Excel (.xlsx) file format with a header row (or Text (.txt) file format without a header row) following the record layouts shown in Appendix A (Tables 1-4). 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 Evaluation

1. **Tracer Sample Selection:** In order to be effective, a sponsor's compliance program must be fully implemented and tailored to the sponsor's unique organization, operations, and circumstances. CMS will use a tracer method to evaluate implementation of applicable compliance elements and determine whether the sponsor's compliance program, as a whole system, functions in a way that is effective to address compliance and FWA issues in a timely and well-documented manner. CMS will select a sample of six (6) cases from the universes and related to the documentation provided to trace the sponsor's response to compliance issues. It is not required that each case in the sample will cover all elements of a compliance program.

For example, a case pulled from the Internal Monitoring (IM) universe may involve a quality monitoring activity performed by a sponsor's quality improvement (QI) department to review and analyze untimely grievances. This activity identified compliance issues that involved additional training and education, communication with involved parties and revisions to processes, and other actions to correct and prevent the issue from recurring in the future. However, after a thorough root cause analysis was completed, the QI department and Compliance Officer determined the issues were isolated with limited beneficiary impact which required engagement by the Compliance Committee but not escalation to senior management or the governing body. While this case touched many of the seven elements of an effective compliance program, due to the detected issues having minimum impact on the Medicare business it was not necessary for the sponsor to implement all of the core requirements and actions identified in Compliance Program Elements I, II, and V.

### **Employee and Compliance Team and First Tier Entity (ECT& FTE) Sample Selection:**

In addition to tracer samples, CMS will select twenty samples from the ECT universe, which will be reviewed for training and accessibility of the Policies & Procedures and Standards of Conduct. Two FTE samples will be selected from the FTEAM universe, which will be reviewed for accessibility of the Policies & Procedures and Standards of Conduct. The sample selections will be uploaded to HPMS the morning of day one of the onsite field work. The review will take place on day three of the onsite field work.

## 2. **Tracer Case Summary and Documentation Reviews:**

- 2.1. **Tracer Case Summary:** For each selected case, sponsors should prepare a written document that provides the specific facts, rationales, and decisions and describe how suspected, detected or reported compliance issues are investigated and resolved by the sponsor in chronological order. The sponsor should ensure each tracer summary, at a minimum, addresses the following points:

- Overview of the issue(s) or activity
- Indicate which compliance and business operations units were involved in detecting and correcting the issue(s)
- Detailed explanation of the issue(s)/ activity (e.g., what the sponsor found, when the sponsor first learned about the issue, and who or which personnel/operational area(s) were involved.)
- Root cause analysis that determined what caused or allowed the compliance issue, problem or deficiency to occur
- Specific actions taken in response to the detected issue(s)/activity
- Processes and procedures affected and revised in response to becoming aware of the issue(s)/activity

- Steps taken to correct the issues/deficiencies at the sponsor or FDR levels, including a timeline indicating the corrective actions fully implemented or, if not implemented, when the sponsor expects the corrective action to be completed.
- Issue escalation (e.g. senior management, compliance oversight committees, governing body, etc.)
- Communication within the sponsor and with its FDRs
- Prevention controls and safeguards implemented in response to the issue(s)/activity

Sponsors must document the facts of each tracer summary using the most effective and efficient method for their business. While the method used frequently by sponsors for tracer summaries are PowerPoint presentations (PPTs), sponsors may use other communication tools such as MS Word, story boards, and/or dashboards. A total of 6 tracer summaries must be submitted to CMS.

**2.2. Supporting Documentation:** During the onsite portion of the audit, CMS will review the summaries and supporting documentation during the tracer reviews with the sponsor to determine if applicable audit elements were effectively met. The sponsor will need access and provide screenshots only for the documents and data that are relevant to a particular case:

- Policies and procedures (Ps&Ps) reviewed and revised in response to detecting and correcting compliance issues.
- 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.
- Evidence of communication to the affected or involved business areas regarding the compliance issues.
- Evidence of the monitoring/auditing activities that occurred as a result of the detected issues.
- Evidence of appropriate accountability and oversight by the sponsor when issues are detected at the FDR level, including response and correction procedures, communication, educational requirements and engagement with compliance department, operational areas and any oversight entities.
- Evidence/explanation of the root cause analysis performed to determine why the issue occurred.
- Description of the beneficiary and/sponsor impact as a result of the detected compliance issues.

**3. Submit Tracer Documentation to CMS:** Sponsors should be prepared to provide only the supporting documentation that is specific for each tracer either by uploading to the Health Plan Management System (HPMS) or providing onsite.



## Audit Elements

### I. Prevention Controls and Activities

This audit element evaluates the sponsor's internal controls to reduce the number of potential non-compliance, FWA and regulatory violations from occurring within all Medicare business operational areas by employees and delegated entities. These compliance controls provide the framework for which the company and its employees operate, convey compliance expectations, prevent repeated issues from recurring and deter minor issues from becoming significant problems with adverse impact to the sponsor's operations and Medicare beneficiaries.

1. **Apply Compliance Standard:** CMS will evaluate cases through the tracer and sample review 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. Also, since some cases may not demonstrate all elements of an effective compliance program, it is acceptable if some of the questions below do not apply. Auditors will note for each question which case demonstrated the sponsor's compliance or non-compliance with the standard.

- 1.1. **Did the sponsor update and distribute their Standards of Conduct and Ps&Ps to their employees/FDRs when appropriate and within required timeframes?**

- 1.2. **Did the sponsor's compliance officer and compliance committee operate in accordance with CMS requirements?**

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

- 1.4. **Did the sponsor have a governing body that exercises reasonable oversight of the Medicare compliance program?**

- 1.5. **Did the sponsor establish and implement effective training and education to ensure its employees, senior administrators and governing body members were aware of the Medicare requirements related to the job function, compliance and FWA?**

- 1.6. **Did the sponsor implement an effective monitoring system to prevent FWA in the delivery of Medicare Parts C and D benefits?**

2. **Sample Case Results:** CMS will test each of the 6 cases through the tracer review. CMS will also conduct interviews and review employee and FTE samples 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:** Cases and conditions may have a one-to-one or a one-to-many relationship. For example, one case may be associated with a single condition or multiple conditions of non-compliance.

## II. Detection Controls and Activities

This audit element evaluates the sponsor's internal controls to monitor and detect potential and suspected compliance issues and activities. These compliance controls identify opportunities for the sponsor to improve the performance of Medicare business operational areas and the compliance program.

1. **Apply Compliance Standard:** CMS will evaluate cases through the tracer and sample review 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. Also, since some cases may not demonstrate all elements of an effective compliance program, it is acceptable if some of the questions below do not apply. Auditors will note for each question which case demonstrated the sponsor's compliance or non-compliance with the standard.
  - 1.1. **Did the sponsor implement a reporting system to receive, record, respond to, and track compliance concerns, questions and reports of suspected or detected non-compliance and FWA that allowed for anonymity and maintains confidentiality (e.g., telephone hotline)?**
  - 1.2. **Did the sponsor implement a risk assessment that identified areas of concern and major compliance risks for its Medicare business operational areas and beneficiaries?**
  - 1.3. **Did the sponsor implement an effective system for monitoring and auditing its internal Medicare Parts C and/or D operations and compliance program effectiveness?**
  - 1.4. **Did the sponsor implement an effective monitoring system to detect and control FWA in the delivery of Medicare Parts C and D benefits?**
  - 1.5. **Did the sponsor properly monitor and audit its FDRs to ensure compliance with all applicable laws, regulations and sub-regulatory interpretive guidance with respect to the Medicare Parts C and/or D delegated functions and responsibilities?**
  - 1.6. **Did the sponsor implement effective communication, monitoring and auditing controls for detected issues involving its FDRs' compliance performance?**
2. **Sample Case Results:** CMS will test each of the 6 cases through the tracer review. CMS will also conduct interviews and review employee and FTE samples 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:** Cases and conditions may have a one-to-one or a one-to-many relationship. For example, one case may be associated with a single condition or multiple conditions of non-compliance.

### III. Correction Controls and Activities

This audit element evaluates the sponsor's escalation processes, timely response and appropriate actions to correct the underlying problems after compliance issues and deficiencies are identified. These compliance controls provide immediate and reasonable response to the detection of misconduct and violations of the Medicare program.

1. **Apply Compliance Standard:** CMS will evaluate cases through the tracer and sample review 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. Also, since some cases may not demonstrate all elements of an effective compliance program, it is acceptable if some of the questions below do not apply. Auditors will note for each question which case demonstrated the sponsor's compliance or non-compliance with the standard.
  - 1.1. **Did the sponsor undertake timely and reasonable corrective action in response to compliance issues, incidents, investigations, complaints or misconduct involving Medicare non-compliance or FWA?**
  - 1.2. **Did the sponsor implement timely corrective actions for detected issues involving its FDRs' compliance performance?**
2. **Sample Case Results:** CMS will test each of the 6 cases through the tracer review. CMS will also conduct interviews and review employee and FTE samples 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:** Cases and conditions may have a one-to-one or a one-to-many relationship. For example, one case 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 Parts C & D Compliance Program Effectiveness (CPE) program area must be submitted as a Microsoft Excel (.xlsx) file with a header row reflecting the field names (or Text (.txt) file without a header row). Do not include the Column ID variable which is shown in the record layout as a reference for a field's column location in an Excel file. 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.

**Note:** There is a maximum of 4000 characters per record row. Therefore, should additional characters be needed for a variable (e.g., description of deficiencies), enter this information on the next record at the appropriate start position.

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

- Include:
  - First-tier entities (FTEs) that have entered into a written agreement with a sponsor to provide administrative or health care services to Medicare enrollees under the Part C and/or D program (e.g., PBM, claims processors, enrollment processes, fulfillment, call centers, credentialing, independent provider groups that manage/oversee a network of physicians).
  - Compliance and FWA audit and monitoring activities of first-tier entities that were conducted by the compliance department, operational areas and SIU to evaluate the compliance performance of first-tier entities.
  - Audit and monitoring activities performed during the audit review period to identify and address potential or suspected non-compliance and FWA at the FDR level in the delivery of Medicare Part C and/or D benefits.
  - Audit and monitoring activities that reviewed reports from FDRs to detect non-compliance and FWA trends and abnormalities
  - Audit and monitoring activities to investigate allegations of non-compliance and fraudulent , wasteful, abusive or questionable behavior performed by FTEs (e.g. employee misconduct, fraudulent provider or pharmacy claims, fraudulent FTE invoices, misuse of Medicare beneficiary information, overpayments, complaints or tips received through hotlines, referrals, members, MEDIC, law enforcement, etc.)
  - Audit and monitoring activities initiated, started, re-opened or completed during the audit review period. This includes auditing and monitoring activities that may have started outside the audit review period, but were completed within the audit review period.
  - Audit and monitoring activities that are performed on a scheduled basis (e.g., weekly, monthly, quarterly, annually, ad-hoc), should be included in the universe each time it was performed.
  - Related entities acting as a first-tier entity to provide administrative or health care services.
  - Other audit or monitoring activities of downstream entities performed by the sponsor during the audit review period.
- Exclude:
  - First-tier entities that do not provide an administrative or health care service function related to the sponsor's Medicare Parts C and/or D contracts.

- Audit and monitoring activities that are performed on a daily basis.
- First-tier entities that were not audited or monitored within the audit review period.
- Downstream or related entities that were not audited/monitored by the sponsor during the audit review period.

Column ID	Field Name	Field Type	Field Length	Description
A	Name of FTE	CHAR Always Required	100	Name of the first-tier entity (FTE) that was audited or monitored.
B	FTE function and responsibilities	CHAR Always Required	400	Brief description of the administrative or health care service function(s) and responsibilities the FTE conducts on behalf of the sponsor.
C	Component	CHAR Always Required	100	Name of the sponsor's component(s), department(s) and/or operational area(s) that work in part or whole with the FTE.
D	Activity Type	CHAR Always Required	10	Enter whether the activity was an "audit" or a "monitoring" activity.
E	Compliance or FWA?	CHAR Always Required	10	Enter whether the activity was a "compliance" or a "FWA" activity. In situations where the activity can be both compliance and FWA related, sponsoring organizations should list "FWA" in the record layout and, during the universe validation process, the sponsoring organization can explain to the audit team which issues are related to both compliance and FWA.
F	Activity Frequency	CHAR Always Required	10	Provide the frequency of the audit or monitoring activity (e.g. weekly, monthly, quarterly, annually, or ad-hoc).
G	Activity Rationale	CHAR Always Required	200	Provide the rationale for conducting the audit or monitoring activity (e.g., monitoring activity was implemented because the function has an immediate impact on members' access to immediate medical care and prescription drugs).
H	Activity Description	CHAR Always Required	400	Provide a description of the audit or monitoring activity (e.g., operational area, training requirements, timeliness, accuracy of organization determinations and notifications, messaging errors, contractual agreements, pharmacy or provider claims, unannounced or onsite audits, spot checks, compliance monitoring, targeted or stratified sampling, audit protocols).

Column ID	Field Name	Field Type	Field Length	Description
I	Activity Start Date	CHAR Always Required	10	<p>Date that the specific audit or monitoring activity was initiated, started or reopened by the sponsor. For example, if the sponsor started monitoring a function of the PBM to ensure it properly implemented its transition policy for new beneficiaries on January 1, 2019, that is the date that would be used for the date the audit or monitoring started.</p> <p>Submit in CCYY/MM/DD format (e.g., 2019/01/01).</p>
J	Activity Completion Date	CHAR Always Required	10	<p>Date that the audit or monitoring activity ended. For example, if the sponsor completed monitoring a function of the PBM to ensure it properly implemented its transition policy for new beneficiaries on January 31, 2019, that is the date that would be used for the date the audit or monitoring completed.</p> <p>Submit in CCYY/MM/DD format (e.g., 2019/01/01). Answer TBD (To Be Determined) if the audit or monitoring activity is currently in progress.</p>
K	Identified Deficiencies	CHAR Always Required	3	<p>Yes (Y), No (N) or To Be Determined (TBD) indicator of whether any issues, deficiencies or findings were discovered during the audit or monitoring activity. Answer TBD if deficiencies have yet to be identified for an ongoing activity.</p>
L	Number of Deficiencies	CHAR Always Required	3	<p>Provide the number of deficiencies, findings or issues identified.</p> <p>Answer TBD if deficiencies have yet to be identified for an ongoing activity.</p>
M	Description of Deficiencies	CHAR Always Required	1000	<p>Provide a summary of deficiencies, findings or issues identified during the audit or monitoring activity. If the audit or monitoring activity was identified in the pre-audit issue summary submitted to CMS, provide the issue number in the description.</p> <p>Answer TBD if deficiencies have yet to be identified for an ongoing activity.</p>

Column ID	Field Name	Field Type	Field Length	Description
N	Corrective Action Required	CHAR Always Required	200	<p>Yes (Y), No (N), or To Be Determined (TBD) indicator of whether corrective action was required for each deficiency/issue identified.</p> <p>Answer “Y” if every previously described deficiency identified during the audit or monitoring activity required a corrective action. Answer “N” if none of the previously described deficiencies required a corrective action. If some but not all of the previously described deficiencies from the audit or monitoring activity required corrective action, specify which deficiencies needed a corrective action and separate by a number as needed (e.g., 1. Part D coverage determinations processed incorrectly – Y, 2. Part D coverage determinations Timeliness – N).</p> <p>Answer TBD if corrective actions have yet to be determined for an ongoing activity.</p>
O	Corrective Action Description	CHAR Always Required	1000	<p>Provide a summary of the corrective action(s) implemented by the sponsor and FTE in response to the noncompliance or potential FWA, including any root cause, timeframes for specific achievements and any ramifications for failing to implement the corrective action satisfactorily.</p> <p>For an audit or monitoring activity that identified multiple issues, separate the corrective actions implemented for each issue by a number as needed (e.g., 1. employee coaching was completed between 2019/02/01 and 2019/02/15 for the errors identified during the 2019/01/01 pharmacy mail order monitoring activity, 2. member remediation was conducted for 50 members that never received their approved medication).</p> <p>Answer TBD if corrective measures have yet to be determine for an ongoing activity. Answer NA if corrective action was not taken or determined necessary by the sponsor for any of the identified issues.</p>

Column ID	Field Name	Field Type	Field Length	Description
P	Activity Results Shared?	CHAR Always Required	500	<p>Provide a summary that describes how the results of the audit or monitoring activity were communicated or shared with sponsor's affected components, compliance department, senior management, and/or the FTE.</p> <p>Answer TBD if results have yet to be determined and shared with others for an ongoing activity.</p>



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

- Include: all **current** employees of the sponsor (permanent, temporary, full-time, part-time) including: senior management, volunteers (e.g., unpaid interns) who have job duties related to the sponsor's Medicare Advantage (Part C) and/or Prescription Drug (Part D) business, and members of the governing body (i.e. Board of Directors) responsible for oversight of the Medicare program who worked/served at any time during the audit review period.
- Exclude: individuals that have left the sponsor, terminated or resigned as of the date of the audit engagement letter.

Column ID	Field Name	Field Type	Field Length	Description
A	Employee ID	CHAR Always Required	15	Internal employee ID assigned by the sponsor. Answer NA if no employee ID was assigned.
B	Employee First Name	CHAR Always Required	50	First name of the employee or governing body member.
C	Employee Last Name	CHAR Always Required	50	Last name of the employee or governing body member.
D	Employee's Title	CHAR Always Required	50	Position or title of the employee or governing body 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	Date of Hire or Appointment	CHAR Always Required	10	Enter the employee's start date with the sponsor or governing body member appointment. Submit in CCYY/MM/DD format (e.g., 1940/01/01).
H	Employee Type	CHAR Always Required	20	Indicate whether the individual is a governing body member, full-time employee, part-time employee, temporary employee, or a volunteer. If an employee fills multiple roles (e.g., full-time employee and governing body member), identify all roles in this field separated by a forward slash (e.g., full-time/BOD).

**Table 3: Internal Auditing (IA) Record Layout**

- **Include:**
  - Compliance and fraud, waste and abuse (FWA) 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 effectively.
  - Audit activities performed during the audit review period to identify and address potential or suspected non-compliance and FWA at the sponsor level in the delivery of Medicare Part C and/or D benefits.
  - Audit activities that reviewed reports from internal operational areas to detect non-compliance and FWA trends and abnormalities.
  - Audit activities to investigate allegations of non-compliance and fraudulent, wasteful, abusive or questionable behavior performed by employees and board members involved in administering or overseeing the sponsor's Medicare Part C and/or D operations (e.g. employee misconduct, internal operations, fraudulent provider or pharmacy claims, fraudulent FTE invoices, misuse of Medicare beneficiary information, overpayments, complaints or tips received through hotlines, referrals, members, MEDIC, law enforcement, etc.)
  - Audit activities initiated, started, re-opened or completed during the audit review period. This includes audit activities that started prior to the audit review period, but were completed within the audit period and activities that were started during the audit review period but not yet completed.
  - Audit activities that are performed on a scheduled basis (e.g., monthly, quarterly, annually, ad-hoc), should be included in the universe each time it was performed.
- **Exclude:**
  - Audit activities for non-Medicare lines of business (e.g., commercial, Medicaid) and audit activities performed for first-tier entities during the audit review period.
  - Audit activities that are performed on a daily basis.

Column ID	Field Name	Field Type	Field Length	Description
A	Component	CHAR Always Required	100	Name of the sponsor's component, department or operational area that was audited.
B	Component Responsibilities	CHAR Always Required	400	Brief description of what responsibilities the component, department or operational area conducts on behalf of the sponsor.
C	Auditor Type	CHAR Always Required	100	Indicate who was responsible for conducting the audit activity (e.g., compliance officer, internal audit department, appeals & grievances staff/manager, external audit firm). For internal staff, provide the name(s) of staff/department involved with conducting the audit activity. For external audit firms, provide the name(s) of the firm/company.

Column ID	Field Name	Field Type	Field Length	Description
D	Compliance or FWA?	CHAR Always Required	10	Enter whether the activity was a “compliance” or a “FWA” activity. In situations where the activity can be both compliance and FWA related, sponsoring organizations should list “FWA” in the record layout and, during the universe validation process, the sponsoring organization can explain to the audit team which issues are related to both compliance and FWA.
E	Audit Frequency	CHAR Always Required	10	Provide the frequency of the audit activity (e.g. weekly, monthly, quarterly, annually, or ad-hoc).
F	Audit Rationale	CHAR Always Required	200	Provide the rationale for conducting the audit activity (e.g., audit activity was implemented because the function has an immediate impact on members’ access to immediate medical care and prescription drugs).
G	Audit Description	CHAR Always Required	400	Provide a description of the audit 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).
H	Audit Start Date	CHAR Always Required	10	Date that the specific audit activity was initiated, started or reopened. For example, if the sponsor started an audit of the appeals process/function within the sponsor on January 1, 2019, that is the date that would be used for the date the audit started.  Submit in CCYY/MM/DD format (e.g., 2019/01/01).
I	Audit Completion Date	CHAR Always Required	10	Date that the specific audit activity ended. For example, if the sponsor ended an audit of the appeals process/function within the sponsor on January 31, 2019, that is the date that would be used for the date the audit ended.  Submit in CCYY/MM/DD format (e.g., 2019/01/01). Answer TBD (To Be Determined) if the audit activity is currently in progress.

Column ID	Field Name	Field Type	Field Length	Description
J	Identified Deficiencies	CHAR Always Required	3	Yes (Y), No (N) or To Be Determined (TBD) indicator of whether any issues, deficiencies or findings were discovered during the audit activity. Answer TBD if deficiencies have yet to be identified for an ongoing activity.
K	Number of Deficiencies	CHAR Always Required	3	Provide the number of deficiencies, findings or issues identified.  Answer TBD if deficiencies have yet to be identified for an ongoing activity.
L	Description of Deficiencies	CHAR Always Required	1000	Provide a summary of all deficiencies, findings or issues identified during the audit activity. If the audit was identified in the pre-audit issue summary submitted to CMS, please include the issue number.  Answer TBD if deficiencies have yet to be identified for an ongoing activity.
M	Corrective Action Required	CHAR	200	Yes (Y), No (N) or To Be Determined (TBD) indicator of whether corrective action is required for each deficiency/issue identified.  Answer “Y” if every previously described deficiency identified during the audit activity required a corrective action. Answer “N” if none of the previously described deficiencies required a corrective action. If some but not all of the previously described deficiencies from the audit activity required corrective action, specify which deficiencies needed a corrective action and separate by a number as needed (e.g., 1. Part D coverage determinations processed incorrectly – Y, 2. Part D coverage determinations Timeliness – N).  Answer TBD if corrective actions have yet to be determined for an ongoing activity.

Column ID	Field Name	Field Type	Field Length	Description
N	Corrective Action Description	CHAR Always Required	1000	<p>Provide a summary of the corrective action(s) implemented by the sponsor in response to the noncompliance or potential FWA, including any root cause analysis, timeframes for specific achievements and any ramifications for failing to implement the corrective action satisfactorily.</p> <p>For an audit activity that identifies multiple issues, separate the corrective actions implemented for each issue by a number as needed (e.g., 1. employee coaching was completed between 2019/02/01 and 2019/02/15 for the errors identified during the 2019/01/01 pharmacy mail order audit activity, 2. member remediation was conducted for 50 members that never received their approved medication).</p> <p>Answer TBD if corrective measures have yet to be determine for an ongoing activity. Answer NA if corrective action was not taken or determined necessary by the sponsor for any of the identified issues.</p>
O	Audit Results Shared?	CHAR Always Required	500	<p>Provide a summary that describes how the results of the audit activity were communicated or shared with sponsor's affected components, compliance department, senior management, and/or the FTE.</p> <p>Answer TBD if results have yet to be determined and shared with others for an ongoing activity.</p>

**Table 4: Internal Monitoring (IM) Record Layouts**

- Include:
  - Compliance and fraud, waste and abuse (FWA) monitoring activities (routine, scheduled and ad-hoc 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 Parts C and/or Part D program requirements and to ensure that corrective actions are undertaken timely and effectively.
  - Monitoring activities performed during the audit review period to identify and address potential or suspected non-compliance and FWA at the sponsor level in the delivery of Medicare Part C and/or D benefits.
  - Monitoring activities that reviewed reports from internal operational areas to detect non-compliance and FWA trends and abnormalities.
  - Monitoring activities to investigate allegations of non-compliance and fraudulent, wasteful, abusive or questionable behavior performed by employees and board members involved in administering or overseeing the sponsor's Medicare Part C and/or D operations (e.g. employee misconduct, internal operations, fraudulent provider or pharmacy claims, fraudulent FTE invoices, misuse of Medicare beneficiary information, overpayments, complaints or tips received through hotlines, referrals, members, MEDIC, law enforcement, etc.)
  - All monitoring activities initiated, started, re-opened or completed during the audit review period. This includes monitoring activities that started prior to the audit review period, but were completed within the audit review period and activities that were started during the audit review period but not yet completed.
  - For monitoring activities that are performed on a scheduled basis (e.g., weekly monthly, quarterly, annually, ad-hoc), it should be included in the universe each time it was performed.
- Exclude:
  - Monitoring activities for non-Medicare lines of business (e.g., commercial, Medicaid).and monitoring activities performed for first-tier entities during the audit review period.
  - Monitoring activities that are performed on a daily basis.

Column ID	Field Name	Field Type	Field Length	Description
A	Component	CHAR Always Required	100	Name of the sponsor's component, department or operational area that was monitored.
B	Component Responsibilities	CHAR Always Required	400	Brief description of what responsibilities the component, department or operational area conducts on behalf of the sponsor.

Column ID	Field Name	Field Type	Field Length	Description
C	Monitor Type	CHAR Always Required	100	Indicate who was responsible for conducting the monitoring activity (e.g., compliance officer, internal audit department, appeals & grievances staff/manager, external audit firm). For internal staff, provide the name(s) of staff/department involved with conducting the monitoring activity. For external firms, provide the name(s) of the firm/company.
D	Compliance or FWA?	CHAR Always Required	10	Enter whether the activity was a “compliance” or a “FWA” activity. In situations where the activity can be both compliance and FWA related, sponsoring organizations should list “FWA” in the record layout and, during the universe validation process, the sponsoring organization can explain to the audit team which issues are related to both compliance and FWA.
E	Monitoring Frequency	CHAR Always Required	10	Provide the frequency of the monitoring activity (e.g. weekly, monthly, quarterly, annually, or ad-hoc).
F	Monitoring Rationale	CHAR Always Required	200	Provide the rationale for conducting the monitoring activity (e.g., monitoring activity was implemented because the function has an immediate impact on members’ access to immediate medical care and prescription drugs).
G	Monitoring Description	CHAR Always Required	400	Provide a description of the monitoring 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).
H	Monitoring Start Date	CHAR Always Required	10	Date that the specific monitoring activity was initiated, started or reopened. For example, if the sponsor started monitoring of the appeals process/function within the sponsor on January 1, 2019 , that is the date that would be used for the date the monitoring started.  Submit in CCYY/MM/DD format (e.g., 2019/01/01).

Column ID	Field Name	Field Type	Field Length	Description
I	Monitoring Completion Date	CHAR Always Required	10	Date that the specific monitoring activity ended. For example, if the sponsor ended monitoring of the appeals process/function within the sponsor on January 31, 2019, that is the date that would be used for the date the monitoring ended. Submit in CCYY/MM/DD format (e.g., 2019/01/01). Answer TBD (To Be Determined) if the monitoring activity is currently in progress.
J	Identified Deficiencies	CHAR Always Required	3	Yes(Y), No (N) or To Be Determined (TBD) indicator of whether any issues, deficiencies or findings were discovered during the monitoring activity. Answer TBD if deficiencies have yet to be identified for an ongoing activity.
K	Number of Deficiencies	CHAR Always Required	3	Provide the number of deficiencies, findings or issues identified.  Answer TBD if deficiencies have yet to be identified for an ongoing activity.
L	Description of Deficiencies	CHAR Always Required	1000	Provide a summary of all deficiencies, findings or issues identified during the monitoring activity. If the monitoring activity is identified in the pre-audit issue summary submitted to CMS, please include the issue number.  Answer TBD if deficiencies have yet to be identified for an ongoing activity.



Column ID	Field Name	Field Type	Field Length	Description
M	Corrective Action Required	CHAR Always Required	200	<p>Yes (Y), No (N) or To Be Determined (TBD) indicator of whether corrective action is required for each deficiency/issue identified. Answer TBD if corrective actions have yet to be determined for an ongoing activity.</p> <p>Answer “Y” if every previously described deficiency identified during the monitoring activity required a corrective action. Answer “N” if none of the previously described deficiencies required a corrective action. If some but not all of the previously described deficiencies from the monitoring activity required corrective action, specify which deficiencies needed a corrective action and separate by a number as needed (e.g., 1. Part D coverage determinations processed incorrectly – Y, 2. Part D coverage determinations Timeliness – N).</p> <p>Answer TBD if corrective actions have yet to be identified for an ongoing activity.</p>

Column ID	Field Name	Field Type	Field Length	Description
N	Corrective Action Description	CHAR Always Required	1000	<p>Provide a summary of the corrective action(s) implemented by the sponsor in response to the noncompliance or potential FWA, including any root cause analysis, timeframes for specific achievements and any ramifications for failing to implement the corrective action satisfactorily.</p> <p>For a monitoring activity that identifies multiple issues, separate the corrective actions implemented for each issue by a number as needed (e.g., 1. employee coaching was completed between 2019/02/01 and 2019/02/15 for the errors identified during the 2019/01/01, pharmacy mail order monitoring activity, 2. member remediation was conducted for 50 members that never received their approved medication).</p> <p>Answer TBD if corrective measures have yet to be determine for an ongoing activity.</p> <p>Answer NA if corrective action was not taken or determined necessary by the sponsor for any of the identified issues.</p>
O	Monitoring Results Shared?	CHAR Always Required	500	<p>Provide a summary that describes how the results of the monitoring activity were communicated or shared with sponsor's affected components, compliance department, senior management and/or the FTE.</p> <p>Answer TBD if results have yet to be determined and shared with others for an ongoing activity.</p>