Current Section in CMS-10191	Original Language	Clarification or Change	Revised Language
Attachments I, II, III, IV, V, and VI (CPE, FA, CDAG, ODAG, SNP-MOC, and MTM) Audit Process and Data Request Audit Purpose and General Guidelines Disclosed and Self-Identified Issues	**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.	Modified the Disclosed and Self-Identified issues section in every protocol. We are no longer asking for self-identified issues- only issues that have been previously reported (disclosed) to CMS. Those issues will be reported on the Pre-Audit Issue Summary and will be due 5 days from the date of the audit start notice. The Pre-Audit Issue Summary will no longer be called Attachment VIII. All references to Attachment VIII has been removed. Included new language relating to downgrading conditions based on issues that were disclosed, promptly identified, and corrected.	**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 impact the submitted universes. 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.

Current Section in CMS-10191	Original Language	Clarification or Change	Revised Language
	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. **NOTE:** For timeliness tests, CMS will make allowances for corrected issues provided that after the reported correction date, at least 6 consecutive weeks of data remain in the audit review period. If at least 6 weeks are not available, the usual timeliness tests will be conducted on the entire universe and conditions will be cited based on the results. CMS will ensure correction of those timeliness conditions during audit validation.		

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Attachments I, II, III, IV, V, and VI (CPE, FA, CDAG, ODAG, SNP-MOC, and MTM) Audit Process and Data Request	2017	Removed year specific reference	None
Attachment I CPE Audit Process and Data request Universe Preparation & Submission Documentation	Completed CPE Self-Assessment Questionnaire	Added language to specify the corresponding attachment of the protocol.	Completed CPE Self-Assessment Questionnaire (Attachment I-A)
Attachment I CPE Audit Process and Data request Universe Preparation & Submission Documentation	Completed Compliance Officer Questionnaire	Added language to specify the corresponding attachment of the protocol.	Completed Compliance Officer Questionnaire (Attachment I-B)
Attachment I CPE Audit Process and Data request Universe Preparation & Submission Documentation	Organizational Structure and Governance PowerPoint Presentation	Added language to specify the corresponding attachment of the protocol.	Customized Organizational Structure and Governance PowerPoint Presentation (Attachment I-C)
Attachment I CPE Audit Process and Data request Universe Preparation & Submission Documentation	Completed First-Tier Downstream and Related Entities (FDR) Operations Questionnaire	Added language to specify the corresponding attachment of the protocol.	Completed First-Tier Downstream and Related Entities (FDR) Operations Questionnaire (Attachment I-D)

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Attachment I CPE Audit Process and Data request Universe Preparation & Submission Documentation	Completed Special Investigation Unit (SIU)/FWA Prevention and Detection Questionnaire	Added language to specify the corresponding attachment of the protocol.	Completed Special Investigation Unit (SIU)/FWA Prevention and Detection Questionnaire (Attachment I-E)
Attachment I CPE Audit Process and Data request Universe Preparation & Submission Documentation	Standards of Conduct/Code of Conduct document (distributed to employees and FDRs during the audit period)	Changed "audit period" to "audit review period" to reflect consistency with the protocol.	Standards of Conduct/Code of Conduct document (distributed to employees and FDRs during the audit review period)
Attachment I CPE Audit Process and Data request Universe Preparation & Submission Documentation	Corporate Compliance/Medicare Compliance/Fraud, Waste and Abuse Plan (orsimilar document in effect during the audit period)	Changed "audit period" to "audit review period" to reflect consistency with the protocol.	Corporate Compliance/Medicare Compliance/Fraud, Waste and Abuse Plan (orsimilar document in effect during the audit review period)
Attachment I CPE Audit Process and Data request Universe Preparation & Submission Documentation	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 period	Changed "audit period" to "audit review period" to reflect consistency with the protocol.	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

Current Section in CMS-10191	Original Language	Clarification or Change	Revised Language
Attachment I CPE Audit Process and Data request Universe Preparation & Submission Documentation	Audit and Monitoring Work Plans (for internal operations and FDRs, in effect at anytime during the audit period)	Changed “audit period” to “audit review period” to reflect consistency with the protocol.	Audit and Monitoring Work Plans (for internal operations and FDRs, in effect at anytime during the audit review period)
Attachment I CPE Audit Process and Data request Universe Preparation & Submission Data Universes	None	Added clarification regarding sponsors to include both compliance and FWA activities in the data universes.	For each respective universe, the sponsor should include compliance and FWA activities.
Attachment I CPE Audit Process and Data request Universe Preparation & Submission Data Universes	None	Added clarification regarding policy guidance for fraud, waste and abuse monitoring and SIU operations.	Please refer to Sections 50.6.9 and 50.6.10 for guidance on fraud, waste and abuse monitoring activities and SIU operations.

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Attachment I CPE Audit Process and Data request Tracer Evaluation 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 • Detailed explanation of the issue(s) (e.g., what the sponsor found, when the sponsor first learned about the issue, the root cause, 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) • Processes and procedures affected and revised in response to becoming aware of the issue(s) • 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. • Communication within the sponsor and with its FDRs • Prevention controls and safeguards implemented in response to the issue(s) Sponsors may document the facts of each tracer summary using the most effective and efficient method for their business including but not limited to MS Word, MS Excel, and MS PowerPoint, story boards, and/or dashboards.	Modified language to reflect additional details that should be included in the tracer case summaries and specified the number of summaries that must be submitted to CMS.	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

Current Section in CMS-10191	Original Language	Clarification or Change	Revised Language
			• Prevention controls and safeguards implemented in response to the issue(s)/activity Sponsors must document the facts of each tracer case 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 case summaries must be submitted to CMS.
Attachment I CPE Audit Process and Data request Tracer Evaluation Supporting Documentation	During the onsite portion of the audit, CMS will review documentation in support of tracer summaries 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.	Modified language to reflect the types of documentation that will be reviewed during the tracer reviews.	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.
Attachment I CPE Audit Process and Data request Tracer Evaluation 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 onsite.	Changed “onsite” to “providing onsite”.	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 onsite.

Current Section in CMS-10191	Original Language	Clarification or Change	Revised Language
Attachment I CPE Audit Process and Data request Table 1 - Introductory Text	**Bullet 1**: Include: First-tier entities (FTEs) that are truly delegated a function on behalf of the sponsor (e.g., PBM, claims processors, enrollment processes, fulfillment, call centers, credentialing, independent provider groups that manage/oversee a network of physicians). Audit and monitoring activities of first-tier entities that were conducted by the compliance department and operational areas to evaluate the compliance performance of first-tier entities. 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., daily, monthly, quarterly, annually), should be included in the universe each time it was performed. If an 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 review period. 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.	Modified instructions to reflect the inclusion of FWA and compliance monitoring and auditing activities in the FTEAM universe. Removed references to daily activities and added clarification regarding sponsors who have been in operation for less than one year	**Bullet 1**: 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.

Current Section in CMS-10191	Original Language	Clarification or Change	Revised Language
Attachment I CPE Audit Process and Data request Table 1 - Introductory Text	**Bullet 2**: 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. First-tier entities that were not audited or monitored within the audit review period. Downstream entities that were not audited/monitored by the sponsor during the audit review period.	Modified instructions to clarify that daily audit and monitoring activities and related entities not audited or monitored should be excluded from the universe.	**Bullet 2**: 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
Attachment I CPE Audit Process and Data request Table 1 - Column F	**Field Name**: Activity Frequency	Added a new field to indicate whether the monitoring or audit activity is compliance or FWA related. Shifted all letters down one beginning with Column F.	**Field Name**: Compliance or FWA?
Attachment I CPE Audit Process and Data request Table 1 - Column G	**Field Name**: Activity Rationale	Column F in the previous version is now Column G.	**Field Name**: Activity Frequency
Attachment I CPE Audit Process and Data request Table 1 - Column H	**Field Name**: Activity Description	Column G in the previous version is now Column H.	**Field Name**: Activity Rationale
Attachment I CPE Audit Process and Data request Table 1 - Column I	**Field Name**: Activity Start Date	Column H in the previous version is now Column I.	**Field Name**: Activity Description

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Attachment I CPE Audit Process and Data request Table 1 - Column J	**Column I Field Name**: Activity Start Date **Description**: 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, 2017, that is the date that would be used for the date the audit or monitoring started. For an audit or monitoring activity conducted on a daily basis, only include the most recent start date.	Column I in the previous version is now Column J. Removed all references to daily monitoring/audit activities from the Activity Start Date description.	**Column J Field Name**: Activity Start Date **Description**: 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, 2017, that is the date that would be used for the date the audit or monitoring started.
Attachment I CPE Audit Process and Data request Table 1 - Column K	**Column J Field Name**: Activity Completion Date **Description**: 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, 2017, that is the date that would be used for the date the audit or monitoring completed. For an audit or monitoring activity conducted on a daily basis, only include the completion date for the previously indicated most recent start date.	Column J in the previous version is now Column K. Removed all references to daily monitoring/audit activities from the Activity Completion Date description.	**Column K Field Name**: Activity Completion Date **Description**: 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, 2017, that is the date that would be used for the date the audit or monitoring completed.
Attachment I CPE Audit Process and Data request Table 1 - Column L	**Field Name**: Number of Deficiencies	Column K in the previous versions is now Column L.	**Field Name**: Identified Deficiencies
Attachment I CPE Audit Process and Data request Table 1 - Column M	**Column L Field Name**: Number of Deficiencies **Description**: Provide the number of deficiencies, findings or issues identified. For an audit or monitoring activity conducted on a daily basis, include the total number of deficiencies identified in all of the daily or monitoring activities during the audit review period.	Column L in the previous version is now Column M. Modified language to instruct sponsors to provide a summary in the field and remove root cause and all references to daily monitoring/audit activities from the Number of Deficiencies description.	**Column M Field Name**: Number of Deficiencies **Description**: Provide the number of deficiencies, findings or issues identified.

Current Section in CMS-10191	Original Language	Clarification or Change	Revised Language
Attachment I CPE Audit Process and Data request Table 1 - Column N	**Column M Field Name**: Description of Deficiencies **Description**: Provide a description of all deficiencies, findings or issues identified during the audit or monitoring activity, including the root cause. If the audit or monitoring activity was identified in the pre-audit issue summary submitted to CMS, provide the issue number in the description. For an audit or monitoring activity conducted on a daily basis, include all deficiencies identified in all audit or monitoring activities during the audit review period. Separate by a number as needed (e.g., 1. 2017/01/01 monitoring of sponsor's pharmacy network mail order identified incorrect dosage for 200 members, 2. 2017/01/02 monitoring of sponsor's pharmacy network mail order identified no issues). Answer TBD if deficiencies have yet to be identified for an ongoing activity.	Column M in the previous version is now Column N.	**Column N Field Name**: Description of Deficiencies **Description**: 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. Answer TBD if deficiencies have yet to be identified for an ongoing activity
Attachment I CPE Audit Process and Data request Table 1 - Column O	**Field Name**: Corrective Action Description	Column N in the previous version is now Column O.	**Field Name**: Corrective Action Required
Attachment I CPE Audit Process and Data request Table 1 - Column P	**Column O Field Name**: Corrective Action Description: **Description**: Provide a full 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, timeframes for specific achievements and any ramifications for failing to implement the corrective action satisfactorily.	Column O in the previous version is now Column P. Modified Corrective Action Description language to instruct sponsors to provide a summary instead of full description.	**Column P Field Name**: Corrective Action Description **Description**: 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.

Current Section in CMS-10191	Original Language	Clarification or Change	Revised Language
Attachment I CPE Audit Process and Data request Table 1 - Column Q	**Column P Field Name**: Activity Results Shared? **Description**: Describe 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. For an audit or monitoring activity that identified multiple issues, separate how the results of each issue were communicated with internal and external stakeholders by a number as needed (e.g., 1. the compliance department sent the pharmacy services department a formal report of the billing errors and member impact identified during the pharmacy mail order monitoring and is responsible for the ongoing tracking and trending of the pharmacy's performance with the mail order benefit, 2. the members impacted by the pharmacy errors were communicated to the Medicare Pharmacy Officer and Pharmacy Services staff for immediate remediation). Answer TBD if results have yet to be determined and shared with others for an ongoing activity.	Column P in the previous version is now Column Q. Modified Activity Results Shared description language to instruct sponsors to provide a summary instead of full description.	**Column Q Field Name**: Activity Results Shared? **Description**: 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. Answer TBD if results have yet to be determined and shared with others for an ongoing activity.
Attachment I CPE Audit Process and Data request Table 2 - Column B	**Field Name**: Employee First Name **Description**: First name of the employee.	Added governing body member to field description.	**Field Name**: Employee First Name **Description**: First name of the employee or governing body member.
Attachment I CPE Audit Process and Data request Table 2 - Column C	**Field Name**: Employee Last Name **Description**: Last name of the employee.	Added governing body member to field description.	**Field Name**: Employee Last Name **Description**: Last name of the employee or governing body member.
Attachment I CPE Audit Process and Data request Table 2 - Column D	**Field Name**: Employee's Title **Description**: Position or title of the employee.	Added governing body member to field description.	**Field Name**: Employee's Title **Description**: Position or title of the employee or governing body member.

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Attachment I CPE Audit Process and Data request Table 2 - Column G	**Field Name**: Direct Phone Number	Removed Direct Phone Number field from the universe. Column H in the previous version is now Column G.	**Field Name**: Date of Hire or Appointment
Attachment I CPE Audit Process and Data request Table 2 - Column H	**Column I Field Name**: Employee Type **Description**: Indicate whether the employee is full-time, part-time, temporary, or a volunteer.	Column I in the previous version is now Column H. Added governing body member to field description.	**Column H Field Name**: Employee Type **Description**: Indicate whether the individual is a governing body member, full-time employee, part-time employee, temporary employee, or a volunteer.
Attachment I CPE Audit Process and Data request Table 2 - Column I	**Column J Field Name**: Medicare Compliance Department Employee? **Description**: Yes(Y)/No (N) indicator of whether the employee works for the Medicare Compliance Department. 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 in any capacity.	Column J in the previous version is now Column I. Removed the "Note" from the field description	**Column I Field Name**: Medicare Compliance Department Employee? **Description**: Yes(Y)/No (N) indicator of whether the employee works for the Medicare Compliance Department.
Attachment I CPE Audit Process and Data request Table 2 - Column J	**Column K Field Name**: Compliance Department Job Description	Column K in the previous version is now Column J.	**Column J Field Name**: Compliance Department Job Description
Attachment I CPE Audit Process and Data request Table 2 - Column K	**Column L Field Name**: Compliance Committee Member? **Description**: Yes(Y) or No (N) indicator of whether the employee is a member of the compliance committee that addresses Medicare compliance issues.	Column L in the previous version is now Column K. Provided examples of the types of compliance committees and added governing body member to field description.	**Column K Field Name**: Compliance Committee Member? **Description:** Yes(Y) or No (N) indicator of whether the employee or governing body member participates on a compliance committee that addresses Medicare compliance issues (e.g. corporate compliance committee, compliance and audit committee of the board, committee that focuses on the compliance of FDRs.
Attachment I CPE Audit Process and Data request Table 2 - Column L	**Column M Field Name**: Compliance Committee Member's Role **Description**: Provide a description of the role and/or expertise each employee brings as a member of 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 FDRs.)	Column M in the previous version is now Column L. Modified language to instruct sponsors to provide a summary instead of full description.	**Column L Field Name**: Compliance Committee Member's Role **Description**: Provide a summary of the role and/or expertise each employee brings as a member of 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 FDRs

Current Section in CMS-10191	Original Language	Clarification or Change	Revised Language
Attachment I CPE Audit Process and Data request Table 3 - Instructions	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 effectively. All 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., daily, monthly, quarterly, annually), should be included in the universe each time it was performed. If an audit 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 review period.	Modified instructions to reflect the inclusion of FWA and compliance auditing activities in the IA universe. Removed references to daily audit activities from the universe.	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.
Attachment I CPE Audit Process and Data request Table 3 - Instructions	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.	Added language clarifying that daily audit activities to the excluded from the universe.	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.

Current Section in CMS-10191	Original Language	Clarification or Change	Revised Language
Attachment I CPE Audit Process and Data request Table 3 - Column D	**Column D Field Name**: Audit Frequency	Added a new field beginning at Column D to indicate whether the audit activity is compliance or FWA related. All columns shifted down one as a result.	**Column D Field Name**: Compliance or FWA? **Description**: Enter whether the activity was a "compliance" or a "FWA" activity.
Attachment I CPE Audit Process and Data request Table 3 - Column E	**Column D Field Name**: Audit Frequency **Description**: Provide the frequency of the audit activity (i.e., daily, weekly, monthly, quarterly, annually, or ad-hoc).	Column D in the previous version is now Column E. Removed "daily" from the field description.	**Column E Field Name**: Audit Frequency **Description**: Provide the frequency of the audit activity (i.e., weekly, monthly, quarterly, annually, or ad-hoc).
Attachment I CPE Audit Process and Data request Table 3 - Column F	**Column E Field Name**: Audit Rationale	Column E in the previous version is now Column F.	**Column F Field Name**: Audit Rationale
Attachment I CPE Audit Process and Data request Table 3 - Column G	**Column F Field Name**: Audit Description	Column F in the previous version is now Column G.	**Column G Field Name**: Audit Description
Attachment I CPE Audit Process and Data request Table 3 - Column H	**Column G Field Name**: Audit Start Date **Description**: 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, 2017, that is the date that would be used for the date the audit started. For an audit activity conducted on a daily basis, only include the most recent start date.	Column G in the previous version is now Column H. Removed all references to daily activities.	**Column H Field Name**: Audit Start Date **Description**: 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, 2017, that is the date that would be used for the date the audit started.

Current Section in CMS-10191	Original Language	Clarification or Change	Revised Language
Attachment I CPE Audit Process and Data request Table 3 - Column I	**Column H Field Name**: Audit Completion Date **Description**: 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, 2017, that is the date that would be used for the date the audit ended. For an audit activity conducted on a daily basis, only include the completion date for the previously indicated most recent start date.	Column H in the previous version is now Column I. Removed all references to daily activities from the description.	**Column I Field Name**: Audit Completion Date **Description**: 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, 2017, that is the date that would be used for the date the audit ended.
Attachment I CPE Audit Process and Data request Table 3 - Column J	**Column I Field Name**: Identified Deficiencies	Column I in the previous version is now Column J.	**Column J Field Name**: Identified Deficiencies
Attachment I CPE Audit Process and Data request Table 3 - Column K	**Column J Field Name**: Number of Deficiencies **Description**: Provide the number of deficiencies, findings or issues identified. For an audit activity conducted on a daily basis, include the total number of deficiencies identified in all of the daily audit activities during the audit review period.	Column J in the previous version is now Column K. Removed all references to daily activities from the description.	**Column K Field Name**: Number of Deficiencies **Description**: Provide the number of deficiencies, findings or issues identified.
Attachment I CPE Audit Process and Data request Table 3 - Column L	**Column K Field Name**: Description of Deficiencies **Description**: Provide a full description 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.	Column K in the previous version is now Column L. Modified language to instruct sponsors to provide a summary instead of full description.	**Column L Field Name**: Description of Deficiencies **Description**: 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.
Attachment I CPE Audit Process and Data request Table 3 - Column M	**Column L Field Name**: Corrective Action Required	Column L in the previous version is now Column M.	**Column M Field Name**: Corrective Action Required

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Attachment I CPE Audit Process and Data request Table 3 - Column N	**Column M Field Name**: Corrective Action Description **Description**: 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, timeframes for specific achievements and any ramifications for failing to implement the corrective action satisfactorily.	Column N in the previous version is now Column N. Modified language to instruct sponsors to provide a summary instead of full description.	**Column N Field Name**: Corrective Action Description **Description**: 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.
Attachment I CPE Audit Process and Data request Table 3 - Column O	**Column N Field Name**: Audit Results Shared? **Description**: Describe how the results of the audit activity were communicated or shared with sponsor's affected components, compliance department, senior management, and/or the FTE. For an audit activity that identified multiple issues, separate how the results of each issue were communicated with internal and external stakeholders by a number as needed (e.g., 1. the compliance department sent the pharmacy services department a formal report of the billing errors and member impact identified during the pharmacy mail order monitoring and is responsible for the ongoing tracking and trending of the pharmacy's performance with the mail order benefit, 2. the members impacted by the pharmacy errors were communicated to the Medicare Pharmacy Officer and Pharmacy Services staff for immediate remediation).	Column N in the previous protocol is now Column O. Modified language to instruct sponsors to provide a summary instead of full description and removed language identifying multiple issues.	**Column O Field Name**: Audit Results Shared? **Description**: 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.
Attachment I CPE Audit Process and Data request Table 4 - Introductory Text	**Bullet 1**: 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 Parts C and/or Part D program requirements and to ensure that corrective actions are undertaken timely and effectively. 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.	Modified instructions to reflect the inclusion of FWA and compliance auditing activities in the IA universe. Removed references to daily audit activities from the universe.	**Bullet 1**: 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.

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	For monitoring activities that are performed on a scheduled basis (e.g., daily, 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 year.		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.
Attachment I CPE Audit Process and Data request Table 4 - Introductory Text	**Bullet 2**: 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.	Added language clarifying that daily audit activities to the excluded from the universe.	**Bullet 2**: 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.
Attachment I CPE Audit Process and Data request Table 4 - Column D	**Column D Field Name**: Monitoring Frequency	Added a field to indicate whether the audit activity is compliance or FWA related. Shifted all columns down beginning with Column D.	**Column D Field Name**: Compliance or FWA? **Description**: Enter whether the activity was a "compliance" or a "FWA
Attachment I CPE Audit Process and Data request Table 4 - Column E	**Column D Field Name**: Monitoring Frequency **Description**: Provide the frequency of the monitoring activity (i.e., daily, weekly, monthly, quarterly, annually, or ad-hoc).	Column D in the previous version is now Column E. Removed "daily" from the field description.	**Column E Field Name**: Monitoring Frequency **Description**: Provide the frequency of the monitoring activity (e.g. weekly, monthly, quarterly, annually, or ad-hoc).

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Attachment I CPE Audit Process and Data request Table 4 - Column F	**Column E Field Name**: Monitoring Rationale	Column E in the previous version is now Column F.	**Column F Field Name**: Monitoring Rationale
Attachment I CPE Audit Process and Data request Table 4 - Column G	**Column F Field Name**: Monitoring Description	Column F in the previous version is now Column G.	**Column G Field Name**: Monitoring Description
Attachment I CPE Audit Process and Data request Table 4 - Column H	**Column G Field Name**: Monitoring Start Date **Description**: 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, 2017, that is the date that would be used for the date the monitoring started. For a monitoring activity conducted on a daily basis, only include the most recent start date.	Column G in the previous version is now Column H. Removed daily activities from the field description.	**Column H Field Name**: Monitoring Start Date **Description**: 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, 2017, that is the date that would be used for the date the monitoring started.
Attachment I CPE Audit Process and Data request Table 4 - Column I	**Column H Field Name**: Monitoring Completion Date **Description**: 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, 2017, that is the date that would be used for the date the monitoring ended. For a monitoring activity conducted on a daily basis, only include the completion date for the previously indicated most recent start date.	Removed daily activities from the field description.	**Column I Field Name**: Monitoring Completion Date **Description:** 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, 2017, that is the date that would be used for the date the monitoring ended.
Attachment I CPE Audit Process and Data request Table 4 - Column J	**Column I Field Name**: Identified Deficiencies	Column I in the previous version is now Column J.	**Column J Field Name**: Identified Deficiencies

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Attachment I CPE Audit Process and Data request Table 4 - Column K	**Column J Field Name**: Number of Deficiencies **Description**: Provide the number of deficiencies, findings or issues identified. For a monitoring activity conducted on a daily basis, include the total number of deficiencies identified in all of the daily monitoring activities during the audit review period.	Column J in the previous protocol is now Column K. Removed daily activities from the field description.	**Column K Field Name**: Number of Deficiencies **Description**: 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.
Attachment I CPE Audit Process and Data request Table 4 - Column L	**Column K Field Name**: Description of Deficiencies	Column K in the previous version is now Column L.	**Column L Field Name**: Description of Deficiencies
Attachment I CPE Audit Process and Data request Table 4 - Column M	**Column L Field Name**: Corrective Action Required	Column L in the previous version is now Column M.	**Column M Field Name**: Corrective Action Required
Attachment I CPE Audit Process and Data request Table 4 - Column N	**Column M Field Name**: Corrective Action Description **Description:** 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.	Column M in the previous version is now Column N. Modified description language to instruct sponsors to provide a summary instead of full description.	**Column N Field Name**: Corrective Action Description **Description**: Provide a summary of the corrective action(s) implemented by the sponsor 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.
Attachment I CPE Audit Process and Data request Table 4 - Column ID O	**Column ID N Field Name:** Monitoring Results Shared? **Description:** Describe how the results of the monitoring activity were communicated or shared with sponsor's affected components, compliance department, senior management, and/or the FTE. For a monitoring activity that identified multiple issues, separate how the results of each issue were communicated with internal and external stakeholders by a number as needed (e.g., 1. the compliance department sent the pharmacy services department a formal report of the billing errors and member impact identified during the pharmacy mail order monitoring and is responsible for the ongoing tracking and trending of the pharmacy's performance with the mail order benefit, 2. the members impacted by the pharmacy errors were communicated to the Medicare Pharmacy Officer and Pharmacy Services staff for immediate remediation).	Column ID N in the previous version is now Column ID O. Modified description language to instruct sponsors to provide a summary instead of full description and removed language identifying multiple issues.	**Column ID O Field Name:** Monitoring Results Shared? **Description:** 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.

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Attachment I-A Medicare Advantage and Prescription Drug Compliance Program Effectiveness SAQ Instructions	Note: Sponsoring Organizations should not interpret every question as a mandatory CMS requirement, but rather as a guide in evaluating the effectiveness of their Compliance Program. While Element V of the Medicare Part C and D Compliance Program Guidelines – *Well Publicized Disciplinary Standards* –is a required and critical component of a compliance program, it has been omitted from this version of the SA-Q. This version of the SA-Q is a tool to be used with the 2017 Compliance Program Effectiveness Audit Protocol. However, sponsoring organizations must ensure structures and procedures are in place to successfully implement all required elements of a compliance program. This document will help your organization evaluate the effectiveness of your Medicare Compliance Program.	Modified language to clarify the instructions for completing the SAQ.	This version of the SA-Q tool is to be used with the 2017 Compliance Program Effectiveness Audit Protocol. Sponsoring Organizations should not interpret every question as a mandatory CMS requirement, but rather as a guide to establish and maintain the core requirements of a compliance program to prevent, detect and correct Medicare program non-compliance and fraud, waste and abuse. This questionnaire is identical to the Medicare Part C and D Compliance Program Guidelines and can be used as a monitoring tool to assist sponsors with evaluating their compliance program for CMS requirements. While Element V of the Medicare Part C and D Compliance Program Guidelines – *Well Publicized Disciplinary Standards* –is a required and critical component of a compliance program, it has been omitted from this version of the SA-Q. However, sponsoring organizations must ensure structures and procedures are in place to successfully implement all required elements of a compliance program Please note the use of this tool by itself does not constitute a formal audit of the compliance program. For example, the formal audit of the compliance program effectiveness should be meet the definition of "audit" noted in the Compliance Program Guidelines and performed by staff not affiliated in any way with the Compliance department. Directions for completing the self-assessment questionnaire: Please respond to each question according to the status of your compliance program during the audit review period. If the answer is "YES" to any question below, check the "YES" box and provide a BRIEF description of what documents support that response in the "Documentation" column. The documentation description should also provide a cross reference (when applicable) to where this documentation can be located. For example, if your response is "YES" to the third question below

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Attachment I-A Medicare Advantage and Prescription Drug Compliance Program Effectiveness SAQ Instructions (cont'd)			*("Do your written Ps & Ps and/or Standards of Conduct articulate the organization's commitment to comply with all applicable Federal and State standards including but not limited to statutes, regulations and sub regulatory guidance"),* please indicate the section/page of the Standards of Conduct or policies and procedures where these compliance provisions are found. If the answer is "NO" to a question, check the "NO" box and document the rationale for the response in the "Documentation" column. For the limited situations when a question does not apply to your organization, enter "N/A" in the "YES/NO" box and document the rationale for the response in the "Documentation" column. If multiple individuals are responsible for the compliance program (e.g. Corporate Compliance Officer, Medicare Compliance Officer, SVP of Audit and Compliance) and have different responses to the questions, please consolidate responses and incorporate into one document. Please specifically note the following when completing the questionnaire:
Attachment I-A Medicare Advantage and Prescription Drug Compliance Program Effectiveness SAQ	Question #7 Does your compliance officer have express authority (oral or written, preferably written) to make in-person reports to your CEO and Board of Directors in the compliance officer's sole discretion?	Changed "board of directors: to "governing body".	Question #7 Does your compliance officer have express authority (oral or written, preferably written) to make in-person reports to your CEO and governing body in the compliance officer's sole discretion?
Attachment I-A Medicare Advantage and Prescription Drug Compliance Program Effectiveness SAQ	Question #10 Does your Board of Directors periodically receive compliance reports on Medicare program noncompliance and Medicare fraud, waste and abuse ("FWA") which include issues identified, investigated, and resolved?	Changed "board of directors" to "governing body".	Does your governing body periodically receive compliance reports on Medicare program noncompliance and Medicare fraud, waste and abuse ("FWA") which include issues identified, investigated, and resolved?

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Attachment I-A Medicare Advantage and Prescription Drug Compliance Program Effectiveness SAQ	Question #11 If your compliance officer does not report in-person to your Board of Directors, are his/her reports routed through the compliance infrastructure?	Changed “board of directors” to “governing body”.	Question #11 If your compliance officer does not report in person to your governing body, as his/her reports routed through the compliance infrastructure?
Attachment I-A Medicare Advantage and Prescription Drug Compliance Program Effectiveness SAQ	Question #15 Does your compliance officer and compliance committee provide the Board of Directors with regularly scheduled updates on the status and activities of the compliance program, including compliance program outcomes, the results of internal and external audits and about all government compliance enforcement activity?	Changed “board of directors” to “governing body”.	Question #15 Does your compliance officer and compliance committee provide the governing body with regularly scheduled updates on the status and activities of the compliance program, including compliance program outcomes, the results of internal and external audits and about all government compliance enforcement activity?
Attachment I-A Medicare Advantage and Prescription Drug Compliance Program Effectiveness SAQ	Question #16 Do you establish, implement and provide effective training and education, addressing compliance and FWA for your employees, including temporary employees, volunteers and Board of Directors?	Changed “board of directors” to “governing body”.	Question #16 Do you establish, implement and provide effective training and education, addressing compliance and FWA for your employees, including temporary employees, volunteers and governing body?
Attachment I-A Medicare Advantage and Prescription Drug Compliance Program Effectiveness SAQ	Question #22 Do you have an effective method(s) to communicate information from your compliance officer to others, within a reasonable time frame, including changes in laws, regulations and sub- regulatory guidance as well as changes to your Standards of Conduct and Ps & Ps?	Added “HPMS memos” to the question.	Question #22 Do you have an effective method(s) to communicate information from your compliance officer to others, within a reasonable time frame, including changes in laws, regulations and sub- regulatory guidance, HPMS memos, as well as changes to your Standards of Conduct and Ps & Ps?
Attachment I-A Medicare Advantage and Prescription Drug Compliance Program Effectiveness SAQ	Question #23 Do your Standards of Conduct and/or Ps & Ps require your employees and members of the Board of Directors to report compliance concerns and potential FWA?	Changed “board of directors” to “governing body”.	Question #23 Do your Standards of Conduct and/or Ps & Ps require your employees and members of the governing body to report compliance concerns and potential FWA?
Attachment I-A Medicare Advantage and Prescription Drug Compliance Program Effectiveness SAQ	Question #24 Do you have a system to receive, record, respond to and track compliance questions or concerns and reports of potential FWA from your employees, members of your Board of Directors, FDRs and their employees and enrollees?	Changed “board of directors” to “governing body”.	Question #24 Do you have a system to receive, record, respond to and track compliance questions or concerns and reports of potential FWA from your employees, members of your governing body, FDRs and their employees and enrollees?

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Attachment I-A Medicare Advantage and Prescription Drug Compliance Program Effectiveness SAQ	Question #28 Are your reporting mechanisms user- friendly, easy to access and navigate and available 24 hours a day for employees, members of your Board of Directors and FDRs?	Changed "board of directors" to "governing body".	Question #28 Are your reporting mechanisms user-friendly, easy to access and navigate and available 24 hours a day for employees, members of your governing body and FDRs?
Attachment I-A Medicare Advantage and Prescription Drug Compliance Program Effectiveness SAQ	Question #35 Does your compliance officer or his/her designees provide updates on the results of monitoring and auditing activities to your compliance committee, CEO, senior leadership and Board of Directors?	Changed "board of directors" to "governing body".	Question #35 Does your compliance officer or his/her designees provide updates on the results of monitoring and auditing activities to your compliance committee, CEO, senior leadership and governing body?
Attachment I-A Medicare Advantage and Prescription Drug Compliance Program Effectiveness SAQ	Question #44 Do you audit the effectiveness of your compliance program at least annually (once a year)? NOTE: The CMS program audit of a sponsor's compliance program effectiveness does NOT satisfy this audit requirement. Sponsor must conduct its own audit of the effectiveness of	Modified language to clarify the requirement for an annual compliance program effectiveness requirement.	Question #44 Do you conduct a formal audit to evaluate the effectiveness of your compliance program at least annually (once a year)? NOTE: The formal audit should produce an audit report with results and identified root cause(s) and a corrective action plan should be a part of the evaluation. The CMS program audit of a sponsor's compliance program effectiveness does NOT satisfy this audit requirement. Sponsor must conduct its own audit of the effectiveness of its compliance program at least annually.
Attachment I-A Medicare Advantage and Prescription Drug Compliance Program Effectiveness SAQ	Question #47 Do you review the OIG and GSA exclusion lists for your employees (including temporary employees), volunteers, consultants and the members of your board of directors prior to hiring/contracting/appointment and monthly thereafter?	Changed "board of directors" to "governing body".	Question #47 Do you review the OIG and GSA exclusion lists for your employees (including temporary employees), volunteers, consultants and the members of your governing body prior to hiring/contracting/appointment and monthly thereafter?
Attachment I-B Medicare Advantage and Prescription Drug Compliance Program Effectiveness CO-Q	This questionnaire will assist CMS with understanding how the Medicare Compliance Officer is vested in the day-to-day operations of the Medicare compliance program and the processes for working with key business operations and reporting to senior management and oversight bodies on the activities and status of the Medicare program. We recognize that your time is valuable and appreciate your availability to provide responses to our questions regarding the compliance program.	Added clarifying language to reflect the purpose of the questionnaire and how to record responses for multiple individuals.	This questionnaire will assist CMS with understanding the sponsoring organization's mechanisms for overseeing the performance and effectiveness of the compliance program from the compliance officer's perspective. The responses to these questions may be discussed during the onsite portion of the CPE audit. We recognize that your time is valuable and appreciate your availability to provide responses to our questions regarding the compliance program. If multiple individuals are responsible for the operations and oversight of the compliance program (e.g. Corporate Compliance Officer, Medicare Compliance Officer, SVP of Audit and Compliance) and have different responses to the questions, please consolidate responses and incorporate into one document.

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Attachment I-B Medicare Advantage and Prescription Drug Compliance Program Effectiveness CO-Q	Question #1 How long have you been employed at [MA/PD] Sponsor?	Modified the question.	Question #1 How long have you been employed with the sponsor and served as the Compliance Officer of the Medicare line of business?
Attachment I-B Medicare Advantage and Prescription Drug Compliance Program Effectiveness CO-Q	Question #3 Please describe your background and how it relates to your role as Compliance Officer.	Modified the question.	Question #2 Briefly describe your background and how it relates to your role as an effective Compliance Officer for the sponsor.
Attachment I-B Medicare Advantage and Prescription Drug Compliance Program Effectiveness CO-Q	Question #4 Who do you report to?	This question was removed from the document.	None
Attachment I-B Medicare Advantage and Prescription Drug Compliance Program Effectiveness CO-Q	Question #6 Please describe your responsibility for the regulatory compliance of the Medicare program.	This question was removed from the document.	None
Attachment I-B Medicare Advantage and Prescription Drug Compliance Program Effectiveness CO-Q	None	Added this question to the questionnaire.	Question #3 Provide a general view of your responsibilities as the Compliance Officer.
Attachment I-B Medicare Advantage and Prescription Drug Compliance Program Effectiveness CO-Q	Question #7 Briefly describe the design and infrastructure of the compliance program, including whether the program has centralized or decentralized organizational structures. Centralized organizational structures rely on the individual to make decisions and provide direction for the company. Decentralized organizational structures often have several individuals making decisions and rely on a team environment at different levels in the business.	This question was removed from the document	None
Attachment I-B Medicare Advantage and Prescription Drug Compliance Program Effectiveness CO-Q	Question #8 If centralized, please answer 8a & 8b: Is the compliance staff dedicated to your C/D lines of business or do they also have responsibilities relative to the marketplace, Medicaid and/or commercial products? Is the compliance staff assigned to specific operational departments? If so, based on what criteria?	This question was removed from the document.	None

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Attachment I-B Medicare Advantage and Prescription Drug Compliance Program Effectiveness CO-Q	Question #9 If decentralized, please answer 9a – 9d: a. How many compliance staff sit within operations? What area? b. Does your compliance staff have responsibilities other than compliance? c. How often does your compliance staff report issues and provide updates to you? What sorts of information about the operation of the compliance program do you regularly receive from your compliance staff?	This question was removed from the document.	None
Attachment I-B Medicare Advantage and Prescription Drug Compliance Program Effectiveness CO-Q	Question #10 What tools and processes do you have in place that keep you up-to-date on tasks and assignments that have been delegated to both operational and compliance staff?	Modified the question.	Question #5 What are some of the tools used to keep the compliance department up-to-date on tasks and assignments that have been delegated to both operational and FDRs?
Attachment I-B Medicare Advantage and Prescription Drug Compliance Program Effectiveness CO-Q	Question #11 Do you have sufficient support and resources to successfully perform your responsibilities as compliance officer over the Medicare Parts C and/or D program? Please explain.	This question was removed from the document.	None
Attachment I-B Medicare Advantage and Prescription Drug Compliance Program Effectiveness CO-Q	Question #12 Do you face any challenges as a compliance officer of the Medicare Parts C and/or D program? Are there any barriers that you face in overcoming these challenges?	This question was removed from the document.	None
Attachment I-B Medicare Advantage and Prescription Drug Compliance Program Effectiveness CO-Q	Question #13 What resources do you use on a regular basis to keep yourself current on CMS compliance, audit, and enforcement information?	Modified the document.	Question #6 What resources do you use on a regular basis to keep the organization current on CMS compliance, audit, and enforcement information and activities?
Attachment I-B Medicare Advantage and Prescription Drug Compliance Program Effectiveness CO-Q	Question #14 Tell us about the structure and operation of the compliance committee.	This question was removed from the document.	None

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Attachment I-B Medicare Advantage and Prescription Drug Compliance Program Effectiveness CO-Q	Question #15 Do you have specific criteria for determining what issues are and which are not reported to the compliance committee?	This question was removed from the document.	None
Attachment I-B Medicare Advantage and Prescription Drug Compliance Program Effectiveness CO-Q	Question #16 What are your expectations, as the Compliance Officer, about what the Compliance Committee should do once issues are reported to it?	This question was removed from the document.	None
Attachment I-B Medicare Advantage and Prescription Drug Compliance Program Effectiveness CO-Q	Question #17 Who reports compliance issue to the governing body?	This question was removed from the document.	None
Attachment I-B Medicare Advantage and Prescription Drug Compliance Program Effectiveness CO-Q	Question #18 Are all compliance issues reported to the governing body?	This question was removed from the document.	None
Attachment I-B Medicare Advantage and Prescription Drug Compliance Program Effectiveness CO-Q	Question #19 If all compliance issues are not reported to the governing body, please explain how you determine which issues are and which are not reported to them.	This question was removed from the document.	None
Attachment I-B Medicare Advantage and Prescription Drug Compliance Program Effectiveness CO-Q	Question #20 Who reports compliance issues to the governing body?	This question was removed from the document.	None
Attachment I-B Medicare Advantage and Prescription Drug Compliance Program Effectiveness CO-Q	Question #21 In what format are issues reported?	This question was removed from the document.	None

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Attachment I-B Medicare Advantage and Prescription Drug Compliance Program Effectiveness CO-Q	Question #22 Is the governing body subsequently made aware of corrective actions and the results of actions?	This question was removed from the document.	None
Attachment I-B Medicare Advantage and Prescription Drug Compliance Program Effectiveness CO-Q	Question #23 How do you ensure any new employees (including temporary workers and volunteers) and governing body members receive general compliance training and fraud, waste and abuse (FWA) training upon hire or appointment?	This question was removed from the document.	None
Attachment I-B Medicare Advantage and Prescription Drug Compliance Program Effectiveness CO-Q	Question #24 How often do you provide general compliance training and FWA training to your employees and governing body members?	This question was removed from the document.	None
Attachment I-B Medicare Advantage and Prescription Drug Compliance Program Effectiveness CO-Q	None	Added a new question to the document.	Question #7 Provide an example of a compliance issue you had to deal with during the audit review period that involved a Medicare operational area and/or a first-tier, downstream or related entity (FDR) and impacted a significant number of your enrollees from receiving their health or drug benefits time in accordance with CMS requirements. Describe what happened and how you handled
Attachment I-B Medicare Advantage and Prescription Drug Compliance Program Effectiveness CO-Q	None	Added a new question to the questionnaire.	Question #8 Provide an example of a time when communicating compliance issues to the compliance committee, senior management or governing body regarding was challenging. Briefly discuss how you handled it.
Attachment I-B Medicare Advantage and Prescription Drug Compliance Program Effectiveness CO-Q	None	Added a new question to the document.	Question #9 Describe a recent experience you had with a miscommunication with an employee(s) when dealing with suspected, detected or reported incidents of noncompliance or fraud, waste and abuse (FWA)? How did you or the compliance department solve the problem

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Attachment I-B Medicare Advantage and Prescription Drug Compliance Program Effectiveness CO-Q	None	Added a new question to the document.	Question #10 During the audit review period, have you ever had to make a decision when no or limited internal or CMS policy was available to provide guidance on how to handle the issue? Describe what happened and how you handled it.
Attachment I-B Medicare Advantage and Prescription Drug Compliance Program Effectiveness CO-Q	None	Added a new question to the document.	Question #11 What has been your experience in dealing with poor compliance performance of Medicare operations within your organization? Provide an example
Attachment I-B Medicare Advantage and Prescription Drug Compliance Program Effectiveness CO-Q	None	Added a new question to the document.	Question #12 In your position as Compliance Officer, what types of decisions do you make at your level without consulting with senior management ultimately responsible for the Medicare Advantage and/or Part D contract with CMS? What are some of indicators that tell you to escalate the decision or issue to senior management?
Attachment I-B Medicare Advantage and Prescription Drug Compliance Program Effectiveness CO-Q	None	Added a new question to the document.	Question #13 CMS understands that every compliance issue is not presented to senior management or the governing body. Explain the criteria used by the compliance department for escalating issues to the CEO and senior management that present high-impact risks to the organization. Include how/when the parties are advised of operational and regulatory compliance activities (e.g. critical discussions with the CMS Account Manager, Notices of Non-Compliance, Civil Money Penalties, Marketing/Enrollment Sanctions, etc.).
Attachment I-B Medicare Advantage and Prescription Drug Compliance Program Effectiveness CO-Q	Question #27 Describe your role in implementing any recommendations made as a result of performance reviews?	This question was removed from the document.	None

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Attachment I-B Medicare Advantage and Prescription Drug Compliance Program Effectiveness CO-Q	Question #28 What processes are in place to communicate operational area concerns to the compliance department?	Changed “processes” to “mechanisms”.	Question #16 What mechanisms are in place to communicate operational area concerns/issues to the compliance department?
Attachment I-B Medicare Advantage and Prescription Drug Compliance Program Effectiveness CO-Q	Question #29 Can you provide us with specific examples when the compliance department initiated a review of procedures within an operational area based on a concern identified by the operational area?	This question was removed from the document.	None
Attachment I-B Medicare Advantage and Prescription Drug Compliance Program Effectiveness CO-Q	Question #30 How are you able to ensure that operational areas are fully reporting compliance issues to you and your staff?	This question was removed from the document.	None
Attachment I-B Medicare Advantage and Prescription Drug Compliance Program Effectiveness CO-Q	Question #31 Do you have any concerns about your oversight over operations given the existing process of identifying risks?	This question was removed from the document.	None
Attachment I-B Medicare Advantage and Prescription Drug Compliance Program Effectiveness CO-Q	Question #32 Describe the risk assessment process. How are risks associated with the Medicare line of business compiled and ranked?	This question was removed from the document.	None
Attachment I-B Medicare Advantage and Prescription Drug Compliance Program Effectiveness CO-Q	Question #33 How often are risks evaluated and/or updated?	This question was removed from the document.	None
Attachment I-B Medicare Advantage and Prescription Drug Compliance Program Effectiveness CO-Q	Question #34 Is this process the same for operational areas and FDRs? If FDRs are assessed separately, please describe that process.	This question was removed from the document.	None

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Attachment I-B Medicare Advantage and Prescription Drug Compliance Program Effectiveness CO-Q	None	Added a new question to the document.	Question #17 What have been major obstacles with executing an effective compliance program which you have had to overcome in your role as the Compliance Officer? How did you deal with them
Attachment I-B Medicare Advantage and Prescription Drug Compliance Program Effectiveness CO-Q	Question #36 Who has responsibility for ensuring your employees (including temporary workers and volunteers) and governing body members are checked monthly against the OIG/GSA exclusion lists?	This question was removed from the document.	None
Attachment I-B Medicare Advantage and Prescription Drug Compliance Program Effectiveness CO-Q	Question #37 Who has responsibility for ensuring your FDRs (and their employees) were checked monthly against the OIG/GSA exclusion lists?	This question was removed from the document.	None
Attachment I-B Medicare Advantage and Prescription Drug Compliance Program Effectiveness CO-Q	Question #38 How long after you receive reports of potential non-compliance do you initiate an investigation into the incident?	This question was removed from the document.	None
Attachment I-B Medicare Advantage and Prescription Drug Compliance Program Effectiveness CO-Q	Question #39 How long after you receive reports of potential FWA do you initiate an investigation into the incident? If FWA cases are handled through the Special Investigations Unit (SIU), please explain how the compliance department is updated on forwarded cases.	This question was removed from the document.	None
Attachment I-B Medicare Advantage and Prescription Drug Compliance Program Effectiveness CO-Q	Question #40 How do you document the results of your investigations?	This question was removed from the document.	None
Attachment I-B Medicare Advantage and Prescription Drug Compliance Program Effectiveness CO-Q	Question #41 What are your organization's biggest Medicare compliance and/or performance challenges at present?	This question was removed from the document.	None

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Attachment I-B Medicare Advantage and Prescription Drug Compliance Program Effectiveness CO-Q	Question #42 What is being done to address these challenges?	This question was removed from the document.	None
Attachment I-B Medicare Advantage and Prescription Drug Compliance Program Effectiveness CO-Q	Question #43 With respect to the compliance program, what keeps you up at night?	This question was removed from the document.	None
Attachment I-B Medicare Advantage and Prescription Drug Compliance Program Effectiveness CO-Q	None	Added a new question to the document.	Question #19 What suggestions or changes would you make to encourage transparency and strengthen the communication between your organization and CMS (e.g. Central Office, Regional Office, and Account Manager) as it relates to compliance issues?
Attachment I-B Medicare Advantage and Prescription Drug Compliance Program Effectiveness CO-Q	Question #45 Were you surprised by this CMS audit and what do you expect to see regarding the final results of this audit?	This question was removed from the document.	None
Attachment I-C Medicare Advantage and Prescription Drug Compliance Program Effectiveness Organizational Structure and Governance PPT Template	None	Added a new section to the template for sponsor's to provide an overview of the organization's standardized processes, tools and controls used to conduct the day-to-day oversight of compliance and FWA issues that may impact Medicare business operations. This information is critical for the tracer evaluation portion of the CPE audit.	Compliance Program Infrastructure and Process Overview

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Attachment I-D Medicare Advantage and Prescription Drug Compliance Program Effectiveness FDR Oversight Questionnaire FDR-Q	This questionnaire will assist CMS with understanding how the individual who is responsible for the oversight of FDRs is vested in the day-to-day operations of the Medicare compliance program and the processes for working with key business operations and reporting to senior management and oversight bodies on the activities and status of the Medicare program. We recognize that your time is valuable and appreciate your availability to provide responses to our questions regarding the compliance program.	Added clarifying language to reflect the purpose of the questionnaire and how to record responses for multiple individuals.	This questionnaire will assist CMS with understanding the sponsoring organization's accountabilities and oversight of its delegated entities to ensure their compliance with Medicare program requirements. The responses to these questions may be discussed during the onsite portion of the CPE audit. We recognize that your time is valuable and appreciate your availability to provide responses to our questions regarding the compliance program. If multiple individuals are responsible for the operations and oversight of first-tier, downstream and related entities (e.g. Corporate Compliance Officer, Delegated Entity Compliance Officer, Vendor Management Group, etc.) and have different responses to the questions, please consolidate responses and incorporate into one document.
Attachment I-D Medicare Advantage and Prescription Drug Compliance Program Effectiveness FDR Oversight Questionnaire FDR-Q	Question #1 How long have you been employed at [Insert name of MA/PD Sponsor]?	Modified the question.	Question #1 How long have you been employed with the sponsor and been in involved with overseeing FDRs?
Attachment I-D Medicare Advantage and Prescription Drug Compliance Program Effectiveness FDR Oversight Questionnaire FDR-Q	Question #3 How long have you been in your current position? Who do you report to?	This question was removed from the document.	None
Attachment I-D Medicare Advantage and Prescription Drug Compliance Program Effectiveness FDR Oversight Questionnaire FDR-Q	Question #4 Describe your day-to-day responsibilities as the [Manager/Director] of [MA/PD]'s Vendor Oversight Program?	This question was removed from the document.	None

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Attachment I-D Medicare Advantage and Prescription Drug Compliance Program Effectiveness FDR Oversight Questionnaire FDR-Q	None	Added a new question to the document.	Question #3 Are delegated entities managed by one individual or a group of individuals/departments?
Attachment I-D Medicare Advantage and Prescription Drug Compliance Program Effectiveness FDR Oversight Questionnaire FDR-Q	None	Added a new question to the document.	Question #4 Provide a general overview of the delegated entity oversight program.
Attachment I-D Medicare Advantage and Prescription Drug Compliance Program Effectiveness FDR Oversight Questionnaire FDR-Q	Question #5 Do you have policies and procedures that document your oversight of FDRs?	This question was removed from the document.	None
Attachment I-D Medicare Advantage and Prescription Drug Compliance Program Effectiveness FDR Oversight Questionnaire FDR-Q	Question #8 Who or what operational area(s) is responsible for initiating the contracts for Medicare Parts C/D administrative or health care functions delegated to FDRs?	Modified the question.	Question #7 Who or which business operations are involved with the pre-contractual assessment to ensure contractual and regulatory obligations are met.
Attachment I-D Medicare Advantage and Prescription Drug Compliance Program Effectiveness FDR Oversight Questionnaire FDR-Q	Question #9 Who is responsible for ensuring FDRs comply with the terms of their contract, including complying with Medicare program requirements?	Modified the question.	Question #8 Once the contract has been initiated with the delegated entity, who or which business operations are responsible for tracking and monitoring the FDRs performance and day to day oversight for compliance issues?

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Attachment I-D Medicare Advantage and Prescription Drug Compliance Program Effectiveness FDR Oversight Questionnaire FDR-Q	Question #10 Have you clearly defined administrative or health care services, including the roles and responsibilities of each FDR?	This question was removed from the document.	None
Attachment I-D Medicare Advantage and Prescription Drug Compliance Program Effectiveness FDR Oversight Questionnaire FDR-Q	Question #11 Please describe the process for distrusting compliance policies and procedures and the Code of Conduct to FDRs.	This question was removed from the document.	None
Attachment I-D Medicare Advantage and Prescription Drug Compliance Program Effectiveness FDR Oversight Questionnaire FDR-Q	Question #12 Please describe your interactions and routine communications with the Compliance Officer and Compliance Department.	This question was removed from the document.	None
Attachment I-D Medicare Advantage and Prescription Drug Compliance Program Effectiveness FDR Oversight Questionnaire FDR-Q	None	Added a new question to the document.	Question #9 Describe the mechanisms used for oversight activities (e.g. structure, risk assessment, specialized teams focused on specific functions, etc.)
Attachment I-D Medicare Advantage and Prescription Drug Compliance Program Effectiveness FDR Oversight Questionnaire FDR-Q	Question #13 What types of communications exist between the two of you regarding Medicare requirements, policy updates, performance concerns or issues with FDRs, specifically the first-tier entities such as your PBM, enrollment/membership functions, coverage or claims adjudication, network management, etc.?	Modified the question.	Question #10 Describe specific examples of the types of communications that exist between the Compliance Department and FDR Oversight regarding Medicare requirements, policy updates, performance concerns or issues with FDRs, specifically the first-tier entities such as your PBM, enrollment/membership functions, coverage or claims adjudication, network management, etc.?

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Attachment I-D Medicare Advantage and Prescription Drug Compliance Program Effectiveness FDR Oversight Questionnaire FDR-Q	Question #17 How do you ensure FDRs are trained appropriately on CMS's rules, regulations and policy for the administrative or health care service performed on the plan sponsor's behalf?	Modified the question.	Question #13 How do you share information or train FDRs on your organization's culture, compliance and productivity expectations, CMS regulations, and policy for the Medicare function performed on the sponsoring organization's behalf?
Attachment I-D Medicare Advantage and Prescription Drug Compliance Program Effectiveness FDR Oversight Questionnaire FDR-Q	Question #18 How do you ensure your FDRs (and the appropriate FDR employees) are completing annual general compliance training and fraud, waste and abuse training as required by CMS? Do you advise FDRs which roles or functions within their organization are subject to the compliance training requirements?	Modified the question.	Question #14 Describe the training, education and communication program for FDRs (e.g. roles and responsibilities, compliance and FWA training, job-specific, exchange of information, compliance disclosures and failures, etc.).
Attachment I-D Medicare Advantage and Prescription Drug Compliance Program Effectiveness FDR Oversight Questionnaire FDR-Q	Question #19 How do you communicate clear roles, responsibilities, and expectations to your FDRs in terms of performance and compliance with CMS requirements?	This question was removed from the document.	None
Attachment I-D Medicare Advantage and Prescription Drug Compliance Program Effectiveness FDR Oversight Questionnaire FDR-Q	Question #20 Describe how your organization governs the exchange of information with FDRs, including performance monitoring, compliance disclosures and failures, and corrective action requirements?	This question was removed from the document.	None
Attachment I-D Medicare Advantage and Prescription Drug Compliance Program Effectiveness FDR Oversight Questionnaire FDR-Q	Question #21 What formal processes do you have to support the sharing of information, including a centralized repository of information for process flows, assumptions, change requests, etc.?	This question was removed from the document.	None

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Attachment I-D Medicare Advantage and Prescription Drug Compliance Program Effectiveness FDR Oversight Questionnaire FDR-Q	Question #22 What methods do you have to receive periodic monitoring reports from FDRs?	Modified the question.	Question #15 Provide examples of the types of periodic monitoring reports your organization receives from FDRs.
Attachment I-D Medicare Advantage and Prescription Drug Compliance Program Effectiveness FDR Oversight Questionnaire FDR-Q	Question #23 Does your strategy for monitoring and auditing your first tier entities include: a. Ensuring that they are in compliance with Medicare Parts C and D requirements? b. Ensuring that they are monitoring their downstream entities' compliance?	Modified the question.	Question #16 Describe the strategy for monitoring and auditing your first tier entities for compliance regulatory requirements, downstream oversight, and implementation of corrective actions.
Attachment I-D Medicare Advantage and Prescription Drug Compliance Program Effectiveness FDR Oversight Questionnaire FDR-Q	Question #24 Does your monitoring and auditing work plan include the number of first tier entities that will be audited and how the entities will be identified for auditing?	This question was removed from the document.	None
Attachment I-D Medicare Advantage and Prescription Drug Compliance Program Effectiveness FDR Oversight Questionnaire FDR-Q	Question #25 What procedures do you have to ensure that your FDR's are not excluded from participation in Federal health care programs? Does your system include review of the OIG and GSA exclusion lists prior to hiring or contracting and *monthly* thereafter for FDRs and their employees either by you, your first entities, or the downstream entities themselves?	This question was removed from the document.	None
Attachment I-D Medicare Advantage and Prescription Drug Compliance Program Effectiveness FDR Oversight Questionnaire FDR-Q	Question #26 How do you ensure that needed corrective actions are taken by first tier entities?	Modified the question.	Question #17 What happens if a FDR fails to satisfactorily implement a corrective action plan or commits a serious act of noncompliance with Medicare requirement that affects enrollees from receiving their health care or drug benefit appropriately or timely?

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Attachment I-D Medicare Advantage and Prescription Drug Compliance Program Effectiveness FDR Oversight Questionnaire FDR-Q	Question #27 How do you ensure that noncompliance or FWA committed by FDR's is well-documented and includes ramifications should the FDR fail to satisfactorily implement the corrective action plan?	This question was removed from the document.	None
Attachment I-D Medicare Advantage and Prescription Drug Compliance Program Effectiveness FDR Oversight Questionnaire FDR-Q	Question #28 Do you maintain thorough documentation of all deficiencies identified and the corrective actions taken?	This question was removed from the document.	None
Attachment I-D Medicare Advantage and Prescription Drug Compliance Program Effectiveness FDR Oversight Questionnaire FDR-Q	Question #29 Do you continue to monitor FDR corrective actions after their implementation to ensure that they are effective?	This question was removed from the document.	None
Attachment I-D Medicare Advantage and Prescription Drug Compliance Program Effectiveness FDR Oversight Questionnaire FDR-Q	Question #30 Please discuss the performance of some of your FDRs responsible for critical, high-risk functions and any compliance/FWA challenges or issues experienced in the past 12 months? (e.g., PBM, sales brokers, entities with direct member contact, provider networks, etc.)	Modified the question.	Question #18 What are a few of the challenges or issues with effectively overseeing FDRs your organization has experienced within the audit review period (e.g., PBM, sales brokers, entities with direct member contact, provider networks, etc.).
Attachment I-D Medicare Advantage and Prescription Drug Compliance Program Effectiveness FDR Oversight Questionnaire FDR-Q	Question #31 What are the company's top 5 opportunities for improvement with overseeing FDRs performance and compliance with Medicare C/D program requirements?	Modified the question.	Question #19 List a few of your accomplishments for FDR oversight during the audit review period? What are your priorities for delegation for the next two years?

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Attachment I-D Medicare Advantage and Prescription Drug Compliance Program Effectiveness FDR Oversight Questionnaire FDR-Q	None	Added this question to the document.	Question #21 Do you have any comments or questions for CMS?
Attachment I-E Medicare Advantage and Prescription Drug Compliance Program Effectiveness SIU/FWA Prevention and Detection Questionnaire FWA-Q	This questionnaire will assist CMS with understanding how the individual responsible for the SIU or FWA prevention and detection staff is vested in the day-to-day operations of the Medicare compliance program and the processes for working with key business operations and reporting to senior management and oversight bodies on the activities and status of the Medicare program. We recognize that your time is valuable and appreciate your availability to provide responses to our questions regarding the compliance program.	Added clarifying language to reflect the purpose of the questionnaire and how to record responses for multiple individuals.	This questionnaire will assist CMS with understanding the sponsoring organization's program to prevent, detect and correct suspected fraud, waste and abuse for their Medicare line of business. The responses to these questions may be discussed during the onsite portion of the CPE audit. We recognize that your time is valuable and appreciate your availability to provide responses to our questions regarding the compliance program. If multiple individuals are responsible for the operations and oversight of first-tier, downstream and related entities (e.g. Corporate Compliance Officer, SIU Director, Ethics and Integrity Officer, Investigators, etc.) and have different responses to the questions, please consolidate responses and incorporate into one document.
Attachment I-E Medicare Advantage and Prescription Drug Compliance Program Effectiveness SIU/FWA Prevention and Detection Questionnaire FWA-Q	Question #1 How long have you been employed at [Insert Name of MA/PD Sponsor]?	Modified the question.	Question #1 How long have you been employed with the sponsor and been in involved with FWA prevention and detection activities?
Attachment I-E Medicare Advantage and Prescription Drug Compliance Program Effectiveness SIU/FWA Prevention and Detection Questionnaire FWA-Q	Question #2 Briefly describe your day-to-day responsibilities.	Removed this question from the document.	None
Attachment I-E Medicare Advantage and Prescription Drug Compliance Program Effectiveness SIU/FWA Prevention and Detection Questionnaire FWA-Q	Question #3 How are compliance expectations with respect to FWA operations communicated to employees that work in the SIU or FWA department?	Removed this question from the document.	None

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Attachment I-E Medicare Advantage and Prescription Drug Compliance Program Effectiveness SIU/FWA Prevention and Detection Questionnaire FWA-Q	None	Added this question to the document.	Question #2 Have you held any positions in the company, prior to being the person or a part of the team responsible for the SIU and/or FWA prevention/detection activities?
Attachment I-E Medicare Advantage and Prescription Drug Compliance Program Effectiveness SIU/FWA Prevention and Detection Questionnaire FWA-Q	None	Added this question to the document.	Question #3 Is FWA managed by one individual or a team/department such as the compliance department or special investigations unit (SIU)?
Attachment I-E Medicare Advantage and Prescription Drug Compliance Program Effectiveness SIU/FWA Prevention and Detection Questionnaire FWA-Q	Question #4 Briefly describe the structure and operations of the SIU.	Modified the question.	Question #4 Provide a general overview of the unit/department responsible for conducting surveillance and methods of investigation relating to potential FWA (e.g. number of personnel, types of detection and prevention activities, etc.)
Attachment I-E Medicare Advantage and Prescription Drug Compliance Program Effectiveness SIU/FWA Prevention and Detection Questionnaire FWA-Q	Question #5 If this wasn't already addressed in question #4, is there a separate SIU **or** are the responsibilities generally conducted by a SIU handled by the compliance department?	This question was removed from the document.	None
Attachment I-E Medicare Advantage and Prescription Drug Compliance Program Effectiveness SIU/FWA Prevention and Detection Questionnaire FWA-Q	Question #6 How large is the SIU?	This question was removed from the document.	None

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Attachment I-E Medicare Advantage and Prescription Drug Compliance Program Effectiveness SIU/FWA Prevention and Detection Questionnaire FWA-Q	Question #7 How many people are dedicated to FWA identification, detection, and investigation?	This question was removed from the document.	None
Attachment I-E Medicare Advantage and Prescription Drug Compliance Program Effectiveness SIU/FWA Prevention and Detection Questionnaire FWA-Q	Question #8 About what percentage of the workload is spent on Medicare?	This question was removed from the document.	None
Attachment I-E Medicare Advantage and Prescription Drug Compliance Program Effectiveness SIU/FWA Prevention and Detection Questionnaire FWA-Q	Question #9 Describe the communication and coordination between the SIU and compliance department.	Modified the question.	Question #5 Describe the working relationship between the compliance department and SIU as it relates to the compliance program.
Attachment I-E Medicare Advantage and Prescription Drug Compliance Program Effectiveness SIU/FWA Prevention and Detection Questionnaire FWA-Q	Question #10 Is there a hotline available to anonymously report noncompliance and/or FWA issues?	Modified the question.	Question #6 Describe a few of the mechanisms that exist for employees, providers, members and FDRs to report compliance, ethics and FWA concerns and how are they advertised internally and externally. Please indicate if multiple hotline numbers are used to report various categories of compliance and FWA inquiries.
Attachment I-E Medicare Advantage and Prescription Drug Compliance Program Effectiveness SIU/FWA Prevention and Detection Questionnaire FWA-Q	Question #11 If there is a voicemail capacity on the hotline, how often do you check for messages?	This question was removed from the document.	None

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Attachment I-E Medicare Advantage and Prescription Drug Compliance Program Effectiveness SIU/FWA Prevention and Detection Questionnaire FWA-Q	Question #12 Are there separate hotlines numbers for compliance or do you each share one?	This question was removed from the document.	None
Attachment I-E Medicare Advantage and Prescription Drug Compliance Program Effectiveness SIU/FWA Prevention and Detection Questionnaire FWA-Q	Question #13 How do you ensure the hotline is anonymous (e.g. Does your phone show Caller ID?)	This question was removed from the document.	None
Attachment I-E Medicare Advantage and Prescription Drug Compliance Program Effectiveness SIU/FWA Prevention and Detection Questionnaire FWA-Q	Question #14 If the hotline is handled by the SIU, please answer 13a – 13d: a. How many referrals have there been within the past twelve months? b. If there is a voicemail capacity on the hotline, how often do you check for messages? c. How is the hotline advertised? d. Is it available externally and internally?	This question was removed from the document.	None
Attachment I-E Medicare Advantage and Prescription Drug Compliance Program Effectiveness SIU/FWA Prevention and Detection Questionnaire FWA-Q	Question #15 If the hotline is **outsourced**, please answer 14a – 14c: a. To whom is the incoming information referred to: SIU or compliance? b. If compliance, how does the SIU become informed of potential FWA issues? c. How often is the information referred from the outsourced party to the SIU or to Compliance?	This question was removed from the document.	None
Attachment I-E Medicare Advantage and Prescription Drug Compliance Program Effectiveness SIU/FWA Prevention and Detection Questionnaire FWA-Q	Question #16 Besides a hotline, how else can employees or FDRs report to you?	This question was removed from the document.	None

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Attachment I-E Medicare Advantage and Prescription Drug Compliance Program Effectiveness SIU/FWA Prevention and Detection Questionnaire FWA-Q	Question #17 How are reporting mechanisms publicized?	This question was removed from the document.	None
Attachment I-E Medicare Advantage and Prescription Drug Compliance Program Effectiveness SIU/FWA Prevention and Detection Questionnaire FWA-Q	None	Added this question to the document.	Question #7 How many reports did the hotline(s) receive during the audit review period? If multiple hotline numbers to report various categories of compliance and FWA inquiries, please separate responses for each hotline number.
Attachment I-E Medicare Advantage and Prescription Drug Compliance Program Effectiveness SIU/FWA Prevention and Detection Questionnaire FWA-Q	None	Added this question to the document.	Question #8 From your perspective, does the number of calls received demonstrate the effectiveness of your reporting mechanisms?
Attachment I-E Medicare Advantage and Prescription Drug Compliance Program Effectiveness SIU/FWA Prevention and Detection Questionnaire FWA-Q	Question #18 Are investigations handled by the SIU?	This question was removed from the document.	None
Attachment I-E Medicare Advantage and Prescription Drug Compliance Program Effectiveness SIU/FWA Prevention and Detection Questionnaire FWA-Q	Question #19 Have you found it challenging to complete investigations due to resource or time constraints?	This question was removed from the document.	None

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Attachment I-E Medicare Advantage and Prescription Drug Compliance Program Effectiveness SIU/FWA Prevention and Detection Questionnaire FWA-Q	Question #20 Do you refer cases to the NBI MEDIC?	This question was removed from the document.	None
Attachment I-E Medicare Advantage and Prescription Drug Compliance Program Effectiveness SIU/FWA Prevention and Detection Questionnaire FWA-Q	Question #21 When do you make a determination to refer a case to the NBI MEDIC?	This question was removed from the document.	None
Attachment I-E Medicare Advantage and Prescription Drug Compliance Program Effectiveness SIU/FWA Prevention and Detection Questionnaire FWA-Q	Question #22 Are potential fraud cases referred to the NBI MEDIC and/or law enforcement?	This question was removed from the document.	None
Attachment I-E Medicare Advantage and Prescription Drug Compliance Program Effectiveness SIU/FWA Prevention and Detection Questionnaire FWA-Q	Question #23 How many potential fraud cases have been referred over the past 12 months?	This question was removed from the document.	None
Attachment I-E Medicare Advantage and Prescription Drug Compliance Program Effectiveness SIU/FWA Prevention and Detection Questionnaire FWA-Q	Question #24 How were these allegations discovered? (e.g., proactive data mining, monitoring, reported internally or from beneficiaries?)	This question was removed from the document.	None

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Attachment I-E Medicare Advantage and Prescription Drug Compliance Program Effectiveness SIU/FWA Prevention and Detection Questionnaire FWA-Q	Question #25 What is the status of the fraud cases referred to either the NBI MEDIC or to law enforcement, but now have been returned back to the SIU?	This question was removed from the document.	None
Attachment I-E Medicare Advantage and Prescription Drug Compliance Program Effectiveness SIU/FWA Prevention and Detection Questionnaire FWA-Q	Question #26 Does the SIU receive many requests from the NBI MEDIC or law enforcement for additional information?	This question was removed from the document.	None
Attachment I-E Medicare Advantage and Prescription Drug Compliance Program Effectiveness SIU/FWA Prevention and Detection Questionnaire FWA-Q	Question #27 Who handles Part D specific investigations?	This question was removed from the document.	None
Attachment I-E Medicare Advantage and Prescription Drug Compliance Program Effectiveness SIU/FWA Prevention and Detection Questionnaire FWA-Q	Question #28 Do the SIU or FWA professionals attend any health care task force meetings, at US Attorney's offices, for example?	This question was removed from the document.	None
Attachment I-E Medicare Advantage and Prescription Drug Compliance Program Effectiveness SIU/FWA Prevention and Detection Questionnaire FWA-Q	Question #29 How often do you attend and when was the last meeting you attended?	This question was removed from the document.	None

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Attachment I-E Medicare Advantage and Prescription Drug Compliance Program Effectiveness SIU/FWA Prevention and Detection Questionnaire FWA-Q	Question #30 Do the SIU or FWA professionals attend the quarterly O&E MEDIC Fraud, Waste and Abuse Training Meetings, or webinars?	This question was removed from the document.	None
Attachment I-E Medicare Advantage and Prescription Drug Compliance Program Effectiveness SIU/FWA Prevention and Detection Questionnaire FWA-Q	Question #31 Does the SIU conduct any of the internal FWA training to employees, members of the Board of Directors, or FDRs? a. If yes, what method of training is used? If no, do you provide any of the materials if the training is conducted by another component within the company?	This question was removed from the document.	None
Attachment I-E Medicare Advantage and Prescription Drug Compliance Program Effectiveness SIU/FWA Prevention and Detection Questionnaire FWA-Q	Question #32 How do you track that employees complete the CMS Medicare Parts C/D FWA training on annual basis?	This question was removed from the document.	None
Attachment I-E Medicare Advantage and Prescription Drug Compliance Program Effectiveness SIU/FWA Prevention and Detection Questionnaire FWA-Q	None	This question was added to the document.	Question #9 Describe proactive measures to investigate suspicions of FWA and inappropriate payments made by the sponsoring organization.
Attachment I-E Medicare Advantage and Prescription Drug Compliance Program Effectiveness SIU/FWA Prevention and Detection Questionnaire FWA-Q	None	This question was added to the document.	Question #10 How does the organization engage participation from the NBI MEDIC, law enforcement and other business partners on suspected FWA cases or investigations?

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Attachment I-E Medicare Advantage and Prescription Drug Compliance Program Effectiveness SIU/FWA Prevention and Detection Questionnaire FWA-Q	None	This question was added to the document.	Question #11 How many suspected FWA cases were referred to the NBI MEDIC or law enforcement agency within the audit review period?
Attachment I-E Medicare Advantage and Prescription Drug Compliance Program Effectiveness SIU/FWA Prevention and Detection Questionnaire FWA-Q	None	This question was added to the document.	Question #12 Describe the triage process for cases referred to the SIU for fraud investigation, including timeframes associated with the intake and validation functions.
Attachment I-E Medicare Advantage and Prescription Drug Compliance Program Effectiveness SIU/FWA Prevention and Detection Questionnaire FWA-Q	Question #33 How is data analysis conducted?	Modified the question	Question #13 Describe how data analytics or data analysis software are used to monitor potential FWA activity and identify unusual patterns in the delivery of Medicare Parts C and/or D benefits (e.g. queries for pharmacy patterns, provider billing, drug utilization, etc.).
Attachment I-E Medicare Advantage and Prescription Drug Compliance Program Effectiveness SIU/FWA Prevention and Detection Questionnaire FWA-Q	Question #34 Is the data analysis conducted by the SIU or another department?	This question was removed from the document.	None
Attachment I-E Medicare Advantage and Prescription Drug Compliance Program Effectiveness SIU/FWA Prevention and Detection Questionnaire FWA-Q	Question #35 Are you using The Predictive Learning Analytics Tracking Outcome (PLATO)? • PLATO is a web-based application tool made available by CMS to the plans in the summer of 2015 to present fraud and abuse lead information visually to Medicare Part D plan sponsors in detecting and prevent fraud, waste and abuse.	Modified the question.	Question #15 Does the organization use the web-based application tool, The Predictive Learning Analytics Tracking Outcome (PLATO), made available by CMS? Explain whether the use of PLATO has been effective for your organization?

Current Section in CMS-10191	Original Language	Clarification or Change	Revised Language
Attachment I-E Medicare Advantage and Prescription Drug Compliance Program Effectiveness SIU/FWA Prevention and Detection Questionnaire FWA-Q	Question #36 Has the use of PLATO been effective? If yes or no, please explain.	This question was removed from the document.	None
Attachment I-E Medicare Advantage and Prescription Drug Compliance Program Effectiveness SIU/FWA Prevention and Detection Questionnaire FWA-Q	Question #37 Are routine queries run to determine FWA for your Medicare C and/or D plans?	This question was removed from the document.	None
Attachment I-E Medicare Advantage and Prescription Drug Compliance Program Effectiveness SIU/FWA Prevention and Detection Questionnaire FWA-Q	Question #38 What types of queries are run?	This question was removed from the document.	None
Attachment I-E Medicare Advantage and Prescription Drug Compliance Program Effectiveness SIU/FWA Prevention and Detection Questionnaire FWA-Q	Question #39 Have these queries have been effective in preventing FWA? (e.g. pharmacy patterns, provider billing, drug utilization)	This question was removed from the document.	None
Attachment I-E Medicare Advantage and Prescription Drug Compliance Program Effectiveness SIU/FWA Prevention and Detection Questionnaire FWA-Q	Question #40 Are you familiar with the HEAT Task Force cities? Does your organization operate or have Medicare members that reside in any of these cities? • "HEAT" is the joint HHS-DOJ Health Care Fraud Prevention and Enforcement Action Team. Current HEAT cities are: Baton Rouge - Louisiana, Brooklyn - New York, Chicago - Illinois, Dallas - Texas, Detroit - Michigan, Houston - Texas, Los Angeles - California, Miami – Florida, Tampa Bay – Florida.	Modified the question.	Question #16 Provide an overview that describes the organization's monitoring activities in the HEAT Medicare Strike Force cities. HEAT is the joint HHS-DOJ Health Care Fraud Prevention and Enforcement Action Team. The list of the nine cities can be found at: https://www.stopmedicarefraud.gov/aboutfraud/heattaskforce/

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Attachment I-E Medicare Advantage and Prescription Drug Compliance Program Effectiveness SIU/FWA Prevention and Detection Questionnaire FWA-Q	Question #41 Describe the focus of your organization's monitoring for FWA placed on the HEAT cities?	This question was removed from the document.	None
Attachment I-E Medicare Advantage and Prescription Drug Compliance Program Effectiveness SIU/FWA Prevention and Detection Questionnaire FWA-Q	Question #43 What analyses are performed of the reports?	This question was removed from the document.	None
Attachment I-E Medicare Advantage and Prescription Drug Compliance Program Effectiveness SIU/FWA Prevention and Detection Questionnaire FWA-Q	Question #44 How often are these reports provided and who analyzes the reports?	This question was removed from the document.	None
Attachment I-E Medicare Advantage and Prescription Drug Compliance Program Effectiveness SIU/FWA Prevention and Detection Questionnaire FWA-Q	Question #45 What are the top 3 trends or issues discovered during the review of the PBM reports?	This question was removed from the document.	None
Attachment I-E Medicare Advantage and Prescription Drug Compliance Program Effectiveness SIU/FWA Prevention and Detection Questionnaire FWA-Q	Question #46 How does the SIU keep current on potential FWA trends in Medicare C and/or D program?	This question was removed from the document.	None

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Attachment I-E Medicare Advantage and Prescription Drug Compliance Program Effectiveness SIU/FWA Prevention and Detection Questionnaire FWA-Q	Question #47 How is that information disseminated to the SIU staff, compliance department, and senior leadership (e.g., CEO, reported to the board)?	This question was removed from the document.	None
Attachment I-E Medicare Advantage and Prescription Drug Compliance Program Effectiveness SIU/FWA Prevention and Detection Questionnaire FWA-Q	Question #48 How are the fraud alerts issued through CMS' Health Plan Management System (HPMS) handled?	Modified the question	Question #17 How are the CMS fraud alerts issued through the Health Plan Management System (HPMS) incorporated into FWA prevention and detection monitoring and audit activities?
Attachment I-E Medicare Advantage and Prescription Drug Compliance Program Effectiveness SIU/FWA Prevention and Detection Questionnaire FWA-Q	Question #49 When you receive notifications from CMS concerning FWA studies, are you incorporating the findings into your monitoring and auditing work plans?	This question was removed from the document.	None
Attachment I-E Medicare Advantage and Prescription Drug Compliance Program Effectiveness SIU/FWA Prevention and Detection Questionnaire FWA-Q	Question #50 If findings from CMS FWA studies are incorporated into monitoring and auditing work plans, please answer 48a & 48b: a. How is this done? b. How soon does the monitoring occur once you are notified of the study?	This question was removed from the document.	None
Attachment I-E Medicare Advantage and Prescription Drug Compliance Program Effectiveness SIU/FWA Prevention and Detection Questionnaire FWA-Q	None	Added this question to the document.	Question #18 Would you like to share any best practices that may assist others with succeeding in preventing, identifying, and controlling FWA practices?

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Attachment I-E Medicare Advantage and Prescription Drug Compliance Program Effectiveness SIU/FWA Prevention and Detection Questionnaire FWA-Q	None	Added this question to the document.	Question #19 Highlight a few accomplishments of the FWA operations/SIU during the audit review period.
Attachment II – Formulary and Benefit Administration Audit Process and Data Request Audit Purpose and General Guidelines Purpose	To evaluate performance in the three areas outlined below related to Part D Formulary and Benefit Administration (FA).	Changed wording from "below" to "in this protocol."	To evaluate performance in the three areas outlined in this protocol related to Part D Formulary and Benefit Administration (FA).
Attachment II – Formulary and Benefit Administration Audit Process and Data Request Audit Purpose and General Guidelines Review Period Transition Rejected Claims – New Contract Year	• Sponsors with ≥ 100,000 enrollees: All rejected claims with dates of service for January 2017. • Sponsors with < 100,000 enrollees: All rejected claims with dates of service for January and February 2017.	Revised language to remove year specific references.	• Sponsors with ≥ 100,000 enrollees: All rejected claims with dates of service for January of the audit year. • Sponsors with < 100,000 enrollees: All rejected claims with dates of service for January and February of the audit year.

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Attachment II – Formulary and Benefit Administration Audit Process and Data Request Audit Purpose and General Guidelines Review Period Transition Rejected Claims – Previous Contract Year	• Beneficiaries with effective enrollment dates of November or December 2016: All rejected claims with dates of service for November and December 2016.	Revised language to remove year specific references.	• Beneficiaries with effective enrollment dates of November or December of the contract year immediately prior to the audit year: All rejected claims with dates of service for November and December of the contract year immediately prior to the audit year.
Attachment II – Formulary and Benefit Administration Audit Process and Data Request Audit Purpose and General Guidelines Review Period Transition Prescription Drug Event (PDE) Data	• Beneficiaries in both of the Rejected Claims Transition universes (new and previous contract year): All final action PDEs accepted by CMS with dates of service September – December 2016.	Changed language to clarify that the PDEs should be for what was submitted in either of the Rejected Claims Transition Universes and revised language to remove year specific references.	• Beneficiaries submitted in either of the Rejected Claims Transition universes (new and previous contract year): All final action PDEs accepted by CMS with dates of service September – December of the contract year immediately prior to the audit year.

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Attachment II – Formulary and Benefit Administration Audit Process and Data Request Audit Purpose and General Guidelines Review Period Transition New Members	• Sponsors with ≥ 100,000 enrollees: o All CY 2016 beneficiaries with an effective enrollment date of November 2016 or December 2016 regardless of whether they continued in the same plan in CY 2017. o All CY 2017 beneficiaries with an effective enrollment date of January 2017. • Sponsors with < 100,000 enrollees: o All CY 2016 beneficiaries with an effective enrollment date of November 2016 or December 2016 regardless of whether they continued in the same plan in CY 2017. o All CY 2017 beneficiaries with an effective enrollment date of January 2017 or February 2017.	Revised language to remove year specific references.	• Sponsors with ≥ 100,000 enrollees: o All beneficiaries with an effective enrollment date of November or December of the contract year immediately prior to the audit year regardless of whether they continued in the same plan during the audit year. o All beneficiaries with an effective enrollment date of January of the audit year. • Sponsors with < 100,000 enrollees: o All beneficiaries with an effective enrollment date of November or December of the contract year immediately prior to the audit year regardless of whether they continued in the same plan in the audit year. o All beneficiaries with an effective enrollment date of January or February of the audit year.
Attachment II – Formulary and Benefit Administration Audit Process and Data Request Universe Preparation & Submission Responding to Universe Requests	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.	Changed wording from "3rd" to "third."	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.
Attachment II – Formulary and Benefit Administration Audit Process and Data Request Universe Preparation & Submission Pull Universes	The universes collected for the FA program area test whether the sponsor has deficiencies related to the appropriate point-of-sale claims adjudication.	Changed wording from "the FA" to "this."	The universes collected for this program area test whether the sponsor has deficiencies related to the appropriate point-of-sale claims adjudication.

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Attachment II – Formulary and Benefit Administration Audit Process and Data Request Universe Preparation & Submission Pull Universes	NOTE: For each respective universe, the sponsor should include all cases that match the description for that universe for all contracts and PBPs in its organization as identified in the audit engagement letter (e.g., all rejected claims for all contracts and PBPs in your organization that were received during the review period).	Provided clarification to specify that rejected claims for all contracts and PBPs in an organization for dates of service that fall within the review period.	NOTE: For each respective universe, the sponsor should include all cases that match the description for that universe for all contracts and PBPs in its organization as identified in the audit engagement letter (e.g., all rejected claims for all contracts and PBPs in your organization for dates of service that fall within the applicable review period).
Attachment II – Formulary and Benefit Administration Audit Process and Data Request Audit Elements Formulary Administration and Transition Review Sample Case Documentation	The sponsor will need access to the following information during the live webinar and may be requested to produce screenshots. The screenshots must be provided to CMS via a Microsoft® Word or PDF document. The sponsor must provide a legend that directs CMS to the requested information on the screenshot. At a minimum, the first shot of each screen type must clearly indicate where the requested information resides on the screen. The sponsor may include additional documentation not requested, including but not limited to a narrative summary of the case, to provide additional detail or clarity. Requested information will include:	Made consistent with other protocols, deleted repetitive text, and clarified information regarding reviewing documentation during audit.	The sponsor will need access to the following documents during the live audit webinar and may be requested to produce screenshots of any of the following:
Attachment II – Formulary and Benefit Administration Audit Process and Data Request Audit Elements Formulary Administration and Transition Review Sample Case Documentation	• Days' supply • Comment log associated with the rejected claim. • [*Formulary only*] A history of all CY 2017 rejected claims for the same drug (brand name, dosage form, route of administration). • [*Transition only*] A history of CY 2016 and/or 2017 rejected claims for the same drug (brand name, dosage form, route of administration).	Removed the possessive character from days. Added clarification regarding the comment log which displays the pharmacy messages and documentation may pertain to the history for all rejected and paid claims. Revised language to remove year specific references.	• Days supply • Comment log associated with the rejected claim that displays the pharmacy messages. • [*Formulary only*] A history of all rejected and paid claims for the same drug (brand name, dosage form, route of administration) during the audit year. • [*Transition only*] A history of rejected and paid claims for the same drug (brand name, dosage form, route of administration) from the audit year and/or the previous contract year.

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Attachment II – Formulary and Benefit Administration Audit Process and Data Request Audit Elements Transition Select Sample Cases	**Continuing members:** The sample will consist of rejected claims related to cross-year formulary changes between 2016 and 2017 (e.g., formulary deletions).	Revised language to remove year specific references.	**Continuing members:** The sample will consist of rejected claims related to cross-year formulary changes between the audit year and the previous contract year (e.g., formulary deletions).
Attachment II – Formulary and Benefit Administration Audit Process and Data Request Website Select Sample Contracts and Cases	Contract selection will be made in the following order: PDP contract, if none then → MAPD contract, if none then → EGWP contract.	Inserted MMP contract into the selection order.	Contract selection will be made in the following order: PDP or if applicable, MMP contract, if none then → MAPD contract, if none then → EGWP contract.
Attachment II – Formulary and Benefit Administration Audit Process and Data Request Tables 1 and 2 - Introductory Text	**Bullet 1**: Include all rejected claims adjudicated by the sponsor for the applicable timeframe.	Specified that rejected claims should include dates of service that fall within the applicable review period timeframe and universes should also include members enrolled in employer plans and MMPs.	**Bullet 1**: Include all rejected claims with dates of service that fall within the applicable review period timeframe (including members enrolled in employer plans and Medicare-Medicaid Plans (MMPs)).
Attachment II – Formulary and Benefit Administration Audit Process and Data Request Table 3 - Introductory Text	**Bullet 1**: Include all rejected claims adjudicated by the sponsor with dates of service for November and December 2016, for beneficiaries with effective enrollment dates of November or December 2016. **Bullet 2**: Exclude rejected claims for beneficiaries with effective enrollment dates other than November or December 2016.	Universes should also include members enrolled in employer plans and MMPs. Revised language to remove year specific references.	**Bullet 1**: Include all rejected claims with dates of service for November and December of the contract year immediately prior to the audit year, for beneficiaries with effective enrollment dates of November or December of that contract year (including members enrolled in employer plans and Medicare-Medicaid Plans (MMPs)). **Bullet 2**: Exclude rejected claims for beneficiaries with effective enrollment dates other than November or December of the contract year immediately prior to the audit year.

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Attachment II – Formulary and Benefit Administration Audit Process and Data Request Table 4 - Introductory Text	• Include all final action PDEs accepted by CMS with dates of service in September – December of 2016. • Include PDEs only for beneficiaries in the Rejected Claims Transition Universes (RCT-N and RCT-P).	Changed language to clarify that the PDEs should be for what was submitted in either of the Rejected Claims Transition Universes, universes should also include members enrolled in employer plans and MMPs, and revised language to remove year specific references.	• Include all final action PDEs accepted by CMS with dates of service in September – December of the contract year immediately prior to the audit year. o Include PDEs only for beneficiaries submitted in either of the Rejected Claims Transition Universes (RCT-N and RCT-P) (including members enrolled in employer plans and Medicare-Medicaid Plans (MMPs)).
Attachment II – Formulary and Benefit Administration Audit Process and Data Request Table 5 - Introductory Text	o For sponsors with ≥ 100,000 enrollees include: ▪ All CY 2016 beneficiaries with an effective enrollment date of November 2016 or December 2016 regardless of whether they continued in the same plan in CY 2017. ▪ All CY 2017 beneficiaries with an effective enrollment date of January 2017. o For sponsors with < 100,000 enrollees: ▪ All CY 2016 beneficiaries with an effective enrollment date of November 2016 or December 2016 regardless of whether they continued in the same plan in CY 2017. ▪ All CY 2017 beneficiaries with an effective enrollment date of January 2017 or February 2017.	Revised language to remove year specific references.	o For sponsors with ≥ 100,000 enrollees include: ▪ All beneficiaries with an effective enrollment date of November or December of the contract year immediately prior to the audit year regardless of whether they continued in the same plan in the audit year. ▪ All beneficiaries with an effective enrollment date of January of the audit year. o For sponsors with < 100,000 enrollees: ▪ All beneficiaries with an effective enrollment date of November or December of the contract year immediately prior to the audit year regardless of whether they continued in the same plan in the audit year. ▪ All beneficiaries with an effective enrollment date of January or February of the audit year.
Attachment II – Formulary and Benefit Administration Audit Process and Data Request Tables 1, 2, 3, 4, and 5 - Column ID B	**Field Length**: 100	Changed field length.	**Field Length:** 50

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Attachment II – Formulary and Benefit Administration Audit Process and Data Request Tables 1, 2, 3, 4, and 5 - Column ID C	**Field Length**: 100	Changed field length.	**Field Length**: 50
Attachment II – Formulary and Benefit Administration Audit Process and Data Request Tables 1, 2, 3, and 5 - Column ID E	**Description**: Effective date of enrollment for the beneficiary. Submit in CCYY/MM/DD format (e.g., 2016/01/01).	Specified enrollment date should be at the PBP level.	**Description**: Effective date of enrollment for the beneficiary (PBP level).
Attachment II – Formulary and Benefit Administration Audit Process and Data Request Tables 1, 2, 3, and 5 - Column ID F	**Description**: Effective date of disenrollment for the beneficiary.	Specified disenrollment date should be at the PBP level.	**Description**: Effective date of disenrollment for the beneficiary (PBP level).
Attachment II – Formulary and Benefit Administration Audit Process and Data Request Tables 1, 2, and 3 - Column ID J Table 4 - Column ID H	**Description**: 11-Digit National Drug Code When no NDC is available enter the applicable Uniform Product Code (UPC) or Health Related Item Code (HRI). Do not include any spaces, hyphens or other special characters.	Provided clarification for how to populate this field for multi ingredient compound claims.	**Description**: 11-Digit National Drug Code When no NDC is available enter the applicable Uniform Product Code (UPC) or Health Related Item Code (HRI). Do not include any spaces, hyphens or other special characters. For multi-ingredient compound claims, include the drug information that matches the NDC of the most expensive Part D covered drug.
Attachment II – Formulary and Benefit Administration Audit Process and Data Request Tables 1, 2, 3 - Column ID M Table 4 - Column ID J	**Field Length**: 10 **Description**: Number of drug dosage units entered in the claim (e.g., 30 [tablets], 0.42 [milliliters of liquid]).	Changed field length and provided clarification for how to populate this field.	**Field Length**: 11 **Description**: Number of drug dosage units entered in the claim (e.g., 30 [tablets], 0.42 [milliliters of liquid]), including decimal values, when applicable. Units of measurement should not to be reported.

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Attachment II – Formulary and Benefit Administration Audit Process and Data Request Tables 1, 2, 3 - Column ID N Table 4 - Column ID K	**Field Name**: Claim Days' Supply **Description**: Days' supply of the drug entered on the claim (e.g., 30 [days]).	Removed the possessive character from the field name and provided clarification for how to populate this field.	**Field Name**: Claim Days Supply **Description**: Days supply of the drug entered on the claim (e.g., 30 [days]). Units of measurement should not to be reported.
Attachment II – Formulary and Benefit Administration Audit Process and Data Request Tables 1, 2, and 3 - Column ID R	**Description**: Answer "NA" in the Reject Reason Code field for pharmacy messages included in column S not paired with a reject reason code.	Clarified language for pharmacy messages that are not paired with a reject reason code.	**Description**: Answer "NA" in the Reject Reason Code field for pharmacy messages included in column S that are not paired with a reject reason code.
Attachment II – Formulary and Benefit Administration Audit Process and Data Request Tables 1, 2, and 3 - Column ID S	None	Added a third note about when pharmacy messaging is not linked with a corresponding reject code.	**Description**: ***In the event that specific pharmacy messages are not linked with a corresponding reject code, include all pharmacy messages in this field and repeat for each reject reason code submitted.
Attachment II – Formulary and Benefit Administration Audit Process and Data Request Tables 2 and 3 -Column ID P	**Description**: Pharmacy service type as submitted by the pharmacy. Answer "UNK" if this field is left blank by the pharmacy.	Specified that pharmacy service type should be as submitted by the pharmacy on the claim.	**Description**: Pharmacy service type as submitted by the pharmacy on the claim. Answer "UNK" if this field is left blank by the pharmacy.

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Attachment II – Formulary and Benefit Administration Audit Process and Data Request Formulary and Benefit Administration Impact Analysis Number of Days Beneficiary Went Without Target Medication (Column ID AB)	Number of Days Beneficiary Went Without Target Medication - Enter N/A if never received.	Provided clarification that sponsors should use either target or related medications when populating this field.	Number of Days Beneficiary Went Without Medication (Target or Related) - Enter N/A if never received.
Attachment III CDAG Audit Process and Data Request Audit Purpose and General Guidelines Review Period	The review period will be decided based on your organization's total enrollment. CMS reserves the right to expand the review period to ensure sufficient universe size. • Plans with <50,000 enrollees: The review period will be the 3 month period preceding and including the date of the audit engagement letter. • Plans with >50,000 but <250,000 enrollees: The review period will be the 2 month period preceding and including the date of the audit engagement letter. • Plans with >250,000 enrollees: The review period will be the 1 month period preceding and including the date of the audit engagement letter.	Added a note about call log universe size being included in the appendix.	Note: The audit review period for the Call Logs - Part D universe (Table 16) is specified in the audit universe record layout and the audit review period varies depending on organization size.
Attachment III CDAG Audit Process and Data Request Universe Preparation & Submission Pull Universes	Sponsors will provide universes … as well as a call log of all calls received by the sponsor during the audit period relating to their Part D benefit.	Clarified that call logs will be calls from enrollees and/or their representatives.	Sponsors will provide universes… as well as a call log of all calls received by the sponsor from enrollees or their representatives relating to their Part D benefit.

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Attachment III CDAG Audit Process and Data Request Universe Preparation & Submission Pull Universes	For each respective universe, the sponsor should include all cases that match the description for that universe for all contracts and Plan Benefit Packages (PBPs) in its organization as identified in the audit engagement letter (e.g., all standard tiering exception CDs for all contracts and PBPs in your organization).	Added a comment directing people to the record layouts for specific instructions on populating universes.	Instructions for what should be included in each universe are listed above the tables listed in Appendix A. For each respective universe, the sponsor should include all cases that match the description for that universe for all contracts and Plan Benefit Packages (PBPs) in its organization as identified in the audit engagement letter (e.g., all standard tiering exception CDs for all contracts and PBPs in your organization).
Attachment III CDAG Audit Process and Data Request Appropriateness of Clinical Decision Making Apply Compliance Standard Clinical Appropriateness/ Denials	3.2.4 Was the reconsideration reviewed by a different physician with expertise in the field of medicine that is appropriate for the services at issue?	Changed “reconsideration” to “redetermination” to be consistent with Part D terminology.	3.2.4 Was the redetermination reviewed by a different physician with expertise in the field of medicine that is appropriate for the services at issue?
Attachment III CDAG Audit Process and Data Request Appropriateness of Clinical Decision Making Apply Compliance Standard Clinical Appropriateness/ Denials	3.2.8. Did the beneficiary receive a therapeutic alternative or other formulary medication?	Removed compliance standard.	None

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Attachment III CDAG Audit Process and Data Request Grievances and Misclassification of Requests Select Sample Cases	CMS will select a targeted sample of 10 total grievances: 7 from the standard grievances record layout and 3 from the expedited grievances record layout (Appendix A, Tables 14 and 15). The sample will consist of oral and written grievances. CMS will also select a targeted sample of 10 calls from the sponsor's Part D call logs (Table 16).	Clarified sampling when there are no expedited grievances.	CMS will select a targeted sample of 10 total grievances: 7 from the standard grievances record layout and 3 from the expedited grievances record layout (Appendix A, Tables 14 and 15). If the sponsor does not have enough expedited grievances, the auditors will sample additional cases from the standard grievance universe. CMS will also select a targeted sample of 10 calls from the sponsor's Part D call logs universe.
Attachment III CDAG Audit Process and Data Request Grievances and Misclassification of Requests Review Sample Case Documentation For Grievances	Copy of all notices, letters, call logs, or other documentation showing when the sponsor sent acknowledgement of grievance receipt to the beneficiary and/or requested additional information from the beneficiary and/or their representative date/time stamp of the request. If request was made via phone call, copy of call log detailing what was communicated to the enrollee.	Deleted the reference to sending an acknowledgment of grievance receipt.	Copy of all notices, letters, call logs, or other documentation showing when the sponsor received the grievance and/or requested additional information from the beneficiary and/or their representative date/time stamp of the request. If request was made via phone call, copy of call log detailing what was communicated to the enrollee.
Attachment III CDAG Audit Process and Data Request Grievances and Misclassification of Requests Apply Compliance Standard	3.1 Was the case or call correctly classified, and if not, was it quickly transferred to the appropriate process?	Clarified that "case" can mean "grievance".	3.1 Was the case (e.g. grievance) or call correctly classified, and if not, was it quickly transferred to the appropriate process?
Attachment III CDAG Audit Process and Data Request Record Layout Instructions	Please use a comma (,) to separate multiple values within one field if there is more than one piece of information for a specific field. Please ensure that all cases in your universes are in one standardized time zone.	Deleted the requirement that all universes be submitted in one standardized time zone, and added instructions that the time zone be consistent for each case (based on when the case was received).	Please use a comma (,) to separate multiple values within one field if there is more than one piece of information for a specific field. Please ensure that all case information (dates and times) are included in the specific time zone that the case was received.

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Attachment III CDAG Audit Process and Data Request Record Layout Instructions	There is a maximum of 4,000 characters per record row.	Added clarification on 4,000 character count and made consistent with ODAG protocol.	There is a maximum of 4,000 characters per record row and spaces count toward this 4,000 character limit.
Attachment III CDAG Audit Process and Data Request Tables 1,2,4 and 5 - Column ID G	Patient residence code for the beneficiary as submitted on the coverage determination or as submitted by the pharmacy on the rejected claim that led to the coverage determination. Answer "UNK" if the patient residence is unknown.	Changed this field to assess whether the beneficiary was residing in a long term care facility. Changed field name and description.	Indicate whether the beneficiary was identified as residing in a long term care facility when the coverage determination was received. Valid values are: Y = Yes N = No U = Unknown
Attachment III CDAG Audit Process and Data Request Tables 1,2,4,5,9 and 10 - Column ID J Tables 3,6 and 7 - Column ID H Table 8 - Column ID I	None	Made consistent with ODAG and added AOR fields into record layouts.	**Description**: Yes (Y)/ No (N) indicator of whether the request was made by a representative or someone claiming to be a representative.
Attachment III CDAG Audit Process and Data Request Tables 1,2,4,5,9 and 10 - Column ID K Tables 3,6 and 7 - Column ID I Table 8 - Column ID J	None	Made consistent with ODAG and added AOR fields into record layouts.	**Description**: Date the Appointment of Representative (AOR) form or other appropriate documentation received by the sponsor. Submit in CCYY/MM/DD format (e.g., 2015/01/01). Answer None if no AOR was received. Answer NA if no AOR form was required.

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Attachment III CDAG Audit Process and Data Request Tables 1,2,4,5,9 and 10 Column ID L Table 8 - Column ID K	None	Made consistent with ODAG and added AOR fields into record layouts.	**Description**: Time the Appointment of Representative (AOR) form or other appropriate documentation received by the sponsor. Submit in HH:MM:SS format (e.g., 23:45:59). Answer None if no AOR was received. Answer NA if no AOR form was required.
Attachment III CDAG Audit Process and Data Request Table 3 - Column ID P Table 7 - Column ID T Table 12 - Column ID M	**Description**: Date check or reimbursement provided to the enrollee (i.e., mailed to the enrollee). Submit in CCYY/MM/DD format (e.g., 2017/01/01). Answer NA if the request was not approved, or if check was not provided.	Added an option to enter NRD if no reimbursement was due to the enrollee when a request was approved.	**Description**: Date check or reimbursement provided to the enrollee (i.e., mailed to the enrollee). Submit in CCYY/MM/DD format (e.g., 2017/01/01). Enter NRD if the request was approved but no reimbursement was due to the enrollee. Answer NA if the request was not approved.
Attachment III CDAG Audit Process and Data Request Table 5 - Column ID V Table 7 - Column ID O Table 8 - Column ID S	**Field Length**: 16	Changed character field length from 16 to 20 to be consistent with other tables.	**Field Length**: 20
Attachment III CDAG Audit Process and Data Request Table 6 - Column ID R Table 7 - Column ID Q Table 8 - Column ID U	**Description**: Yes (Y)/No (N) indicator of review by physician if case was denied for lack of medical necessity. Answer NA if the request was not denied for lack of medical necessity or not denied (e.g., approved).	Added "CD" into Field Name. Changed "case" to "the coverage determination" to clarify that the review by a physician on redetermination is triggered by the initial coverage determination being denied for lack of medical necessity.	**Description**: Yes (Y)/No (N) indicator of review by physician if the coverage determination was denied for lack of medical necessity. Answer NA if the request was not denied for lack of medical necessity or not denied (e.g., approved).
Attachment III CDAG Audit Process and Data Request Table 14 - Column ID J Table 15 - Column ID K	**Field Name**: Issue Description	Changed field name to "Grievance/Complaint Description" to be consistent with ODAG.	**Field Name**: Grievance/ Complaint Description

Current Section in CMS-10191	Original Language	Clarification or Change	Revised Language
Attachment III CDAG Audit Process and Data Request Table 14 - Column ID J and Q Table 15 - Column ID K and P	**Field Length**: 1500	Expanded the field lengths to 1800 and made consistent with ODAG grievance field lengths.	**Field Length**: 1800
Attachment III CDAG Audit Process and Data Request Table 15: Column ID I	**Field Length**: 40	Changed to 7 characters to match the standard grievance table.	**Field Length**: 7
Attachment III CDAG Audit Process and Data Request Table 15 - Column ID J	**Description**: Describe the category of the grievance/complaint. If this grievance was over the plan's refusal to expedite a request, indicate Refusal to Expedite in this field. If the grievance was over another issue, please use the following categories: Enrollment/Disenrollment; Plan Benefits; Pharmacy Access; Marketing; Customer Service; Coverage Determinations/ Redetermination Process; Quality of Care; CMS Issues; or; Other.	Removed the categories not relevant to expedited grievances but left sponsors an option to put "other" if the organization chooses to expedite grievances for other reasons.	**Description**: Describe the category of the grievance/complaint. If this grievance was over the plan's refusal to expedite a request, indicate Refusal to Expedite in this field. If the sponsor expedited a grievance for any other issue, please indicate "other".

Current Section in CMS-10191	Original Language	Clarification or Change	Revised Language
Attachment III CDAG Audit Process and Data Request Table 16 - Introduction bullets and description of pull instructions for call logs	• Include all calls received by your organization (or another entity) that relate to your Medicare Part D line of business. • Exclude any calls not relating to your Part D business (i.e., Medicare advantage, commercial). • Submit all calls based on the date the call was received by your organization, PBM or other entity.	Added more instructions on how to pull call logs. Made the record layout a recommendation (not required for formatting). Narrowed the universe for calls to range from 2 to 4 weeks depending on organization size. Additionally, limiting calls to incoming calls from enrollees and representatives (e.g., calls to the customer service line(s). Excluding calls from prescribers.	**NOTE:** Sponsors are not required to submit the information below in the format provided by the record layout as long as the information provided is sufficient for CMS review. • Include all incoming calls received by your organization (or another entity) from Part D enrollees and/or their representatives that relate to your Medicare Part D line of business (i.e., calls made to your customer service line(s)). • Exclude any calls not relating to your Part D business (i.e., Medicare advantage, commercial). • Exclude provider/ prescriber calls, or any calls not from an enrollee/ representative. • Submit all calls based on the date the call was received by your organization, PBM or other entity using the following criteria: • Plans with <50,000 enrollees: Plans should submit calls for the first 2-weeks of the audit review period as defined above in the Audit Purpose and General Guidelines. • Plans with >50,000 but <250,000 enrollees: Plans should submit calls for the first 3-weeks of the audit review period as defined above in the Audit Purpose and General Guidelines. • Plans with >250,000 enrollees: Plans should submit calls for the first 4-weeks of the audit review period as defined above in the Audit Purpose and General Guidelines.
Attachment III CDAG Audit Process and Data Request Table 16 - Column IDs A, B, and C	**Column ID A Field Length**: 30 **Column ID B Field Length**: 30 **Column ID C Field Length**: 8	Changed these fields to be consistent with the character lengths in other tables.	**Column ID A Field Length**: 50 **Column ID B Field Length**: 50 **Column ID C Field Length**: 10
Attachment III CDAG Audit Process and Data Request Table 16 - Column IDs J and K	**Column ID J Field Length**: 2000 **Column ID K Field Length**: 1000	Changed field lengths to increase the outcome of call field and make the fields as large as possible (and consistent as possible).	**Field Length**: 1800

Current Section in CMS-10191	Original Language	Clarification or Change	Revised Language
Attachment III-A_CDAG Supplemental Questions Question 4	If response to #6 is yes, please attach the portion of your policy that specifically address this question.	This should have referred back to question 3	If response to #3 is yes, please attach the portion of your policy that specifically addresses this question.
Attachment IV – Part C Organization Determinations, Appeals, and Grievances (ODAG) Audit Process and Data Request Review Period	None	Added note to clarify the Call Log universe audit review period is different than the overall ODAG audit review period	**Note:** The audit review period for the Call Logs - Part C universe (Table 14) is specified in the audit universe record layout and the audit review period varies depending on organization size.
Attachment IV – Part C Organization Determinations, Appeals, and Grievances (ODAG) Audit Process and Data Request Timeliness Test Compliance Standards	See SOD, EOD, SREC, EREC and PREC timeframes.	Added Claims and DMR universes as compliance standards for the Dismissals universe (Table 13 – DIS).	See SOD, EOD, Claims, DMR, SREC, EREC and PREC timeframes.
Attachment IV – Part C Organization Determinations, Appeals, and Grievances (ODAG) Audit Process and Data Request	None	Added page number.	Page 8 of 53
Attachment IV – Part C Organization Determinations, Appeals, and Grievances (ODAG) Audit Process and Data Request Select Sample Cases	CMS will select a targeted sample of 10 total grievances: 7 from the standard grievances record layout and 3 from the expedited grievances record layout (Appendix A, Tables 11 and 12). The sample will consist of oral and written grievances. CMS will also select a targeted sample of 10 calls from the sponsor's Part C Call Logs (Table 14).	Clarified CMS' sampling approach to include clarify sampling process.	CMS will select a targeted sample of 10 total grievances: 7 from the standard grievances record layout and 3 from the expedited grievances record layout (Appendix A, Tables 11 and 12). If the sponsor does not have enough expedited grievances, the auditors sample additional cases from the standard grievance universe. CMS will also select a targeted sample of 10 calls from the sponsor's Part C Call Log universe (Table 14).

Current Section in CMS-10191	Original Language	Clarification or Change	Revised Language
Attachment IV – Part C Organization Determinations, Appeals, and Grievances (ODAG) Audit Process and Data Request Clinical Appropriateness/Denials	3.2.3. Was the request reviewed by a physician or other appropriate health care professional with sufficient medical and other expertise including knowledge of Medicare coverage criteria?	Removed duplicate compliance standard #3.2.3	None
Attachment IV – Part C Organization Determinations, Appeals, and Grievances (ODAG) Audit Process and Data Request Clinical Appropriateness/Denials	3.2.10. Did the enrollee get a clinically equivalent or alternate service?	Clarified that this compliance standard may not be applicable for all circumstances.	3.2.10. Did the enrollee get a clinically equivalent or alternate service, if applicable?
Attachment IV – Part C Organization Determinations, Appeals, and Grievances (ODAG) Audit Process and Data Request Sample Case Results	CMS will test each of the 20 cases (10 grievances and 10 calls). If CMS requirements are not met, conditions (findings) are cited. If CMS requirements are met, no conditions (findings) are cited.	Clarified CMS' sampling approach.	CMS will test each of the 20 cases (10 to 15 grievances and 10 calls). If CMS requirements are not met, conditions (findings) are cited. If CMS requirements are met, no conditions (findings) are cited.
Attachment IV – Part C Organization Determinations, Appeals, and Grievances (ODAG) Audit Process and Data Request Record Layout Instructions	Please use a comma (,) to separate multiple values within one field if there is more than one piece of information for a specific field. Please ensure that all cases in your universes are in one standardized time zone.	Revised time zone standards to be based on where the request was received.	Please use a comma (,) to separate multiple values within one field if there is more than one piece of information for a specific field. Please ensure that all cases in your universes are populated based on the time zone where the request was received.

Current Section in CMS-10191	Original Language	Clarification or Change	Revised Language
Attachment IV – Part C Organization Determinations, Appeals, and Grievances (ODAG) Audit Process and Data Request Table 1 - Introductory Text	**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.	Clarified that spaces count toward the character limits.	**Note:** There is a maximum of 4,000 characters per record row and spaces count toward this 4,000 character limit. Therefore, should additional characters be needed for a variable, enter this information on the next record at the appropriate start position.
Attachment IV – Part C Organization Determinations, Appeals, and Grievances (ODAG) Audit Process and Data Request Table 1 - Introductory Text	**Bullet 2**: Exclude payment requests, withdrawn requests, all requests processed as expedited organization determinations, concurrent review for inpatient hospital and SNF services, post-service reviews, notification of admission, requests for extensions of previously approved services, duplicate claims and payment adjustments to claims, claims that are denied for invalid billing codes, billing errors, denied claims for bundled or separately payable items, denied claims for beneficiaries who are not enrolled on the date of service, and claims denied due to recoupment of payment	Revised types of excluded cases.	**Bullet 2**: Exclude payment requests, dismissals, reopenings, withdrawn requests and all requests processed as expedited organization determinations.
Attachment IV – Part C Organization Determinations, Appeals, and Grievances (ODAG) Audit Process and Data Request Table 1 – Column ID J Table 2 – Column ID K Table 3 – Column ID J Table 4 – Column ID J Table 5 – Column ID J Table 6 – Column ID K Table 7 – Column ID H Table 8 – Column ID G Table 9 – Column ID G Table 10 – Column ID G	**Description**: Provide the enrollee diagnosis/diagnoses ICD-10 codes related to this request. If the ICD codes are unavailable, provide a description of the diagnosis, or for drugs provide the 11 digit National Drug Code (NDC).	Revised field description	**Description**: Provide the enrollee diagnosis/diagnoses ICD-10 codes related to this request. If the ICD codes are unavailable, provide a description of the diagnosis, or for drugs provide the 11 digit National Drug Code (NDC) as well as the ICD-10 code related to the request.

Current Section in CMS-10191	Original Language	Clarification or Change	Revised Language
Attachment IV – Part C Organization Determinations, Appeals, and Grievances (ODAG) Audit Process and Data Request Table 1 – Column ID N Table 5 – Column ID N	**Field Name**: Subsequent expedited request **Description**: If a request was made after the organization determination to expedite the request, indicate who made the subsequent request to expedite the request: contract provider (CP), non-contract provider (NCP), beneficiary (B), beneficiary's representative (BR) or sponsor (S). Answer NA if no expedited timeframe was requested.	Revised field name. Revised field description to remove "contract provider" and "sponsor" as valid responses.	**Field Name**: Request for expedited timeframe **Description**: If a request was made after the organization determination to expedite the request, indicate who made the subsequent request to expedite the request: non-contract provider (NCP), beneficiary (B), beneficiary's representative (BR). Answer NA if no expedited timeframe was requested.
Attachment IV – Part C Organization Determinations, Appeals, and Grievances (ODAG) Audit Process and Data Request Table 2 - Introductory Text	**Bullet 2**: Exclude payment requests, withdrawn requests, all requests processed as expedited organization determinations, concurrent review for inpatient hospital and SNF services, post-service reviews, notification of admission, requests for extensions of previously approved services, duplicate claims and payment adjustments to claims, claims that are denied for invalid billing codes, billing errors, denied claims for bundled or separately payable items, denied claims for beneficiaries who are not enrolled on the date of service, and claims denied due to recoupment of payment	Revised types of excluded cases.	**Bullet 2**: Exclude payment requests, dismissals, reopenings, withdrawn requests and all requests processed as standard organization determinations.
Attachment IV – Part C Organization Determinations, Appeals, and Grievances (ODAG) Audit Process and Data Request Table 2 – Column ID I Table 6 – Column ID I	**Description**: Provide the date the request was received by your organization. Submit in CCYY/MM/DD format (e.g., 2015/01/01).	Added a note to clarify how subsequently expedited requests should be populated.	**Description**: Provide the date the request was received by your organization. Submit in CCYY/MM/DD format (e.g., 2015/01/01). Note: If the request was received as a standard organization determination request, but later expedited, enter the date of the request to expedite the organization determination.
Attachment IV – Part C Organization Determinations, Appeals, and Grievances (ODAG) Audit Process and Data Request Table 2 – Column ID J Table 6 – Column ID J	**Description**: Provide the time the request was received by your organization. Submit in HH:MM:SS military time format (e.g., 23:59:59).	Added a note to clarify how subsequently expedited requests should be populated.	**Description**: Provide the time the request was received by your organization. Submit in HH:MM:SS military time format (e.g., 23:59:59). Note: If the request was received as a standard organization determination request, but later expedited, enter the time of the request to expedite the organization determination.

Current Section in CMS-10191	Original Language	Clarification or Change	Revised Language
Attachment IV – Part C Organization Determinations, Appeals, and Grievances (ODAG) Audit Process and Data Request Table 2 – Column ID N Table 6 – Column ID O	**Field Name**: Was the request made under the standard timeframe but processed by the plan under the expedited timeframe?	This field has been removed in its entirety. All Column ID IDs shift up one letter beginning with Column ID N in Table 2 and Column ID O in Table 6.	None
Attachment IV – Part C Organization Determinations, Appeals, and Grievances (ODAG) Audit Process and Data Request Table 2 – Column ID N	**Column ID O Field Name:** Subsequent expedited request **Description**: If a request was made after the organization determination to expedite the request, indicate who made the subsequent request to expedite the request: contract provider (CP), non-contract provider (NCP), beneficiary (B), beneficiary's representative (BR) or sponsor (S). Answer NA if no expedited timeframe was requested.	Modified Column ID and added clarification that "NA" is appropriate where no subsequent expedited timeframe was requested.	**Column ID N Field Name:** Subsequent expedited request **Description**: If a request was made after the organization determination to expedite the request, indicate who made the subsequent request to expedite the request: contract provider (CP), non-contract provider (NCP), beneficiary (B), beneficiary's representative (BR) or sponsor (S). Answer NA if no subsequent expedited timeframe was requested.
Attachment IV – Part C Organization Determinations, Appeals, and Grievances (ODAG) Audit Process and Data Request Table 2 Column ID	**Field Name and Column ID:** Was a timeframe extension taken? (Column ID P) If an extension was taken, did the sponsor notify the member of the reason(s) for the delay and of their right to file an expedited grievance? (Column ID Q) Request Disposition (Column ID R) Date of sponsor decision (Column ID S) Time of sponsor decision (Column ID T) Was the request denied for lack of medical necessity? (Column ID U) If denied for lack of medical necessity, was the review completed by a physician or other appropriate health care professional? (Column ID V) Date oral notification provided to enrollee (Column ID W) Time oral notification provided to enrollee (Column ID X) Date written notification provided to enrollee (Column ID Y) Time written notification provided to enrollee (Column ID Z)	Changed column IDs	**Field Name and Column ID:** Was a timeframe extension taken? (Column ID O) If an extension was taken, did the sponsor notify the member of the reason(s) for the delay and of their right to file an expedited grievance? (Column ID P) Request Disposition (Column ID Q) Date of sponsor decision (Column ID R) Time of sponsor decision (Column ID S) Was the request denied for lack of medical necessity? (Column ID T) If denied for lack of medical necessity, was the review completed by a physician or other appropriate health care professional? (Column ID U) Date oral notification provided to enrollee (Column ID V) Time oral notification provided to enrollee (Column ID W) Date written notification provided to enrollee (Column ID X) Time written notification provided to enrollee (Column ID Y)

Current Section in CMS-10191	Original Language	Clarification or Change	Revised Language
	Date service authorization entered/effectuated in the sponsor's system (Column ID AA) Time service authorization entered/effectuated in the sponsor's system (Column ID AB) AOR receipt date (Column ID AC) AOR receipt time (Column ID AD) First Tier, Downstream, and Related Entity (Column ID AE)		Date service authorization entered/effectuated in the sponsor's system (Column ID Z) Time service authorization entered/effectuated in the sponsor's system (Column ID AA) AOR receipt date (Column ID AB) AOR receipt time (Column ID AC) First Tier, Downstream, and Related Entity (Column ID AD)
Attachment IV – Part C Organization Determinations, Appeals, and Grievances (ODAG) Audit Process and Data Request Table 4 – Column M Table 5 – Column ID Q Table 6 – Column ID R Table 7 – Column ID K	**Field Length**: 36	Revised field length to account for spaces.	**Field Length**: 41
Attachment IV – Part C Organization Determinations, Appeals, and Grievances (ODAG) Audit Process and Data Request Table 3 - Introductory Text	**Bullet 2**: Exclude all requests processed as direct member reimbursements, duplicate claims and payment adjustments to claims, reopenings, claims denied for invalid billing codes, denied claims for beneficiaries who are not enrolled on the date of service and claims denied due to recoupment of payment	Revised types of excluded cases.	**Bullet 2**: Exclude all requests processed as direct member reimbursements, dismissals, duplicate claims and payment adjustments to claims, reopenings, claims denied for invalid billing codes, denied claims for beneficiaries who are not enrolled on the date of service and claims denied due to recoupment of payment.
Attachment IV – Part C Organization Determinations, Appeals, and Grievances (ODAG) Audit Process and Data Request Table 3 - Introductory Text	**Bullet 3**: Submit payment organization determinations (claims) based on the date the claim was paid or denied, or should have been paid or denied (the date the request was initiated may fall outside of the review period).	Clarified the dates for submitting the universe are based on the date the claim was paid or the notification date of the denial.	**Bullet 3**: Submit payment organization determinations (claims) based on the date the claim was paid, or should have been paid, or the notification date of the denial, or the date the denial notification should have been sent (the date the request was initiated may fall outside of the review period).

Current Section in CMS-10191	Original Language	Clarification or Change	Revised Language
Attachment IV – Part C Organization Determinations, Appeals, and Grievances (ODAG) Audit Process and Data Request Table 3 - Column ID H	**Description**: Yes/No indicator flag to indicate whether the claim is clean (Y) or unclean (N). Answer NA for untimely requests that are still open.	Added clarification that a response of "NA" is appropriate where the clean status has not yet been determined.	**Description**: Yes/No indicator flag to indicate whether the claim is clean (Y) or unclean (N). Answer NA for untimely requests that are still open or if clean status has not yet been determined.
Attachment IV – Part C Organization Determinations, Appeals, and Grievances (ODAG) Audit Process and Data Request Table 3 - Column ID N	**Field Name**: Date the claim was paid or denied **Description**: Date the claim was paid or denied. Submit in CCYY/MM/DD format (e.g., 2015/01/01). Answer NA for untimely cases that are still open.	Clarified that this field is only for the date a claim is paid	**Field Name**: Date the claim was paid **Description**: Date the claim was paid. Submit in CCYY/MM/DD format (e.g., 2015/01/01). Answer DENIED for claims that were denied. Answer NA for untimely cases that are still open.
Attachment IV – Part C Organization Determinations, Appeals, and Grievances (ODAG) Audit Process and Data Request Table 3 - Column ID R	**Description**: Date written notification provided to enrollee. The term "provided" means when the letter left the sponsor's establishment by US Mail, fax, or electronic communication. Do not enter the date a letter is generated or printed within the sponsor's organization. Submit in CCYY/MM/DD format (e.g., 2015/01/01). Answer Pending if written notification has not yet been provided, but is anticipated to be provided in a forthcoming EOB notice. Answer NA if no written notification provided to the enrollee.	Clarified that this field is applicable to both EOB and IDN notifications.	**Description**: Date written notification provided to enrollee. The term "provided" means when the EOB, IDN or letter left the sponsor's establishment by US Mail, fax, or electronic communication. Do not enter the date a letter is generated or printed within the sponsor's organization. Submit in CCYY/MM/DD format (e.g., 2015/01/01). Answer Pending if written notification has not yet been provided, but is anticipated to be provided in a forthcoming EOB or IDN notice. Answer NA if no written notification provided to the enrollee.
Attachment IV – Part C Organization Determinations, Appeals, and Grievances (ODAG) Audit Process and Data Request Table 4 - Introductory Text	**Bullet 2:** Exclude all requests processed as contract and non-contract provider claims.	Revised types of excluded cases.	**Bullet 2:** Exclude all requests processed as contract and non-contract provider claims, reopenings and dismissals.
Attachment IV – Part C Organization Determinations, Appeals, and Grievances (ODAG) Audit Process and Data Request Table 4 - Introductory Text	**Bullet 3**: Submit direct member reimbursement requests based on the date the reimbursement was issued or denied, or should have been issued or denied (the date the request was initiated may fall outside of the review period).	Clarified the dates for submitting the universe are based on the date the claim was paid or the notification date of the denial.	**Bullet 3**: Submit direct member reimbursement requests based on the date the reimbursement was issued, or should have been issued, or the notification date of the denial, or the date the denial notification should have been sent(the date the request was initiated may fall outside of the review period).

Current Section in CMS-10191	Original Language	Clarification or Change	Revised Language
Attachment IV – Part C Organization Determinations, Appeals, and Grievances (ODAG) Audit Process and Data Request Table 4 - Column ID N	**Field Name**: Date reimbursement was issued or denied **Description**: Date the sponsor issued payment to the member or provider (for approvals) or the date the sponsor denied the member's reimbursement request. Submit in CCYY/MM/DD format (e.g., 2015/01/01). Sponsors should answer NA for untimely cases that are still open.	Clarified that this field is only for the date a reimbursement is paid	**Field Name**: Date the reimbursement was paid **Description**: Date the sponsor issued payment to the member or provider. Submit in CCYY/MM/DD format (e.g., 2015/01/01). Answer DENIED for reimbursement requests that were denied. Sponsors should answer NA for untimely cases that are still open.
Attachment IV – Part C Organization Determinations, Appeals, and Grievances (ODAG) Audit Process and Data Request Table 4 - Column ID R	**Description**: Date enrollee notified that request was forwarded to the IRE due to denial or untimely decision. Submit in CCYY/MM/DD format (e.g., 2015/01/01). Answer NA if approved or not forwarded to IRE.	Added clarification that a response of "NA" is appropriate for organization determination requests.	**Description**: Date enrollee notified that request was forwarded to the IRE due to denial or untimely decision. Submit in CCYY/MM/DD format (e.g., 2015/01/01). Answer NA if approved, request was an organization determination or not forwarded to IRE.
Attachment IV – Part C Organization Determinations, Appeals, and Grievances (ODAG) Audit Process and Data Request Table 5 - Introductory Text	**Bullet 2:** Exclude all requests processed as expedited reconsiderations, withdrawn reconsideration requests, concurrent review for inpatient hospital and SNF services, post-service reviews, notification of admission, requests for extensions of previously approved services, duplicate claims and payment adjustments to claims, claims that are denied for invalid billing codes, billing errors, denied claims for bundled or separately payable items, denied claims for beneficiaries who are not enrolled on the date of service, and claims denied due to recoupment of payment	Revised types of excluded cases.	**Bullet 2:** Exclude all requests processed as expedited reconsiderations, dismissals, reopenings and withdrawn reconsideration requests.
Attachment IV – Part C Organization Determinations, Appeals, and Grievances (ODAG) Audit Process and Data Request Table 6 - Introductory Text	**Bullet 2:** Exclude all requests processed as standard reconsiderations, withdrawn reconsideration requests concurrent review for inpatient hospital and SNF services, post-service reviews, notification of admission, requests for extensions of previously approved services, duplicate claims and payment adjustments to claims, claims that are denied for invalid billing codes, billing errors, denied claims for bundled or separately payable items, denied claims for beneficiaries who are not enrolled on the date of service, and claims denied due to recoupment of payment	Revised types of excluded cases.	**Bullet 2:** Exclude all requests processed as standard reconsiderations, dismissals, reopenings and withdrawn reconsideration requests.

Current Section in CMS-10191	Original Language	Clarification or Change	Revised Language
Attachment IV – Part C Organization Determinations, Appeals, and Grievances (ODAG) Audit Process and Data Request Table 6 - Column ID N	**Description**: If an expedited timeframe was requested, indicate who requested the expedited reconsideration timeframe: contract provider (CP), non-contract provider (NCP), beneficiary (B), beneficiary's representative (BR) or sponsor (S). Answer NA if no expedited timeframe was requested. Answer BR if a contract provider submitted the expedited reconsideration request on behalf of an enrollee.	Removed "NA" as a valid response.	**Description**: If an expedited timeframe was requested, indicate who requested the expedited reconsideration timeframe: contract provider (CP), non-contract provider (NCP), beneficiary (B), beneficiary's representative (BR) or sponsor (S). Answer BR if a contract provider submitted the expedited reconsideration request on behalf of an enrollee.
Attachment IV – Part C Organization Determinations, Appeals, and Grievances (ODAG) Audit Process and Data Request Table 6 - Column IDs	**Field Name and Column ID:** Was a timeframe extension taken? (Column ID P) If an extension was taken, did the sponsor notify the member of the reason(s) for the delay and of their right to file an expedited grievance? (Column ID Q) Request Disposition (Column ID R) Date of sponsor decision (Column ID S) Time of sponsor decision (Column ID T) Was the request denied for lack of medical necessity? (Column ID U) If denied for lack of medical necessity, was the review completed by a physician or other appropriate health care professional? (Column ID V) If the request was denied for lack of medical necessity, was the reconsideration completed by a physician other than the person involved in making the initial OD? (Column ID W) Date oral notification provided to enrollee (Column ID X) Time oral notification provided to enrollee (Column ID Y) Date written notification provided to enrollee (Column ID Z) Time written notification provided to enrollee (Column ID AA) Date service authorization entered/effectuated in the sponsor's system (Column ID AB) Time service authorization entered/effectuated in the sponsor's system (Column ID AC) Date forwarded to IRE if denied or untimely (Column ID AD) If request denied or untimely, date enrollee notified request has been forwarded to IRE (Column ID AE) AOR receipt date (Column ID AF) AOR receipt time (Column ID AG) First Tier, Downstream, and Related Entity (Column ID AH)	Changed column IDs	**Field Name and Column ID:** Was a timeframe extension taken? (Column ID O) If an extension was taken, did the sponsor notify the member of the reason(s) for the delay and of their right to file an expedited grievance? (Column ID P) Request Disposition (Column ID Q) Date of sponsor decision (Column ID R) Time of sponsor decision (Column ID S) Was the request denied for lack of medical necessity? (Column ID T) If denied for lack of medical necessity, was the review completed by a physician or other appropriate health care professional? (Column ID U) If the request was denied for lack of medical necessity, was the reconsideration completed by a physician other than the person involved in making the initial OD? (Column ID V) Date oral notification provided to enrollee (Column ID W) Time oral notification provided to enrollee (Column ID X) Date written notification provided to enrollee (Column ID Y) Time written notification provided to enrollee (Column ID Z) Date service authorization entered/effectuated in the sponsor's system (Column ID AA) Time service authorization entered/effectuated in the sponsor's system (Column ID AB) Date forwarded to IRE if denied or untimely (Column ID AC) If request denied or untimely, date enrollee notified request has been forwarded to IRE (Column ID AD) AOR receipt date (Column ID AE) AOR receipt time (Column ID AF) First Tier, Downstream, and Related Entity (Column ID AG)

Current Section in CMS-10191	Original Language	Clarification or Change	Revised Language
Attachment IV – Part C Organization Determinations, Appeals, and Grievances (ODAG) Audit Process and Data Request Table 7 - Introductory Text	**Bullet 2:** Exclude all requests processed as direct member reimbursements and direct member reimbursement reconsideration requests, duplicate claims and payment adjustments to claims, reopenings, claims denied for invalid billing codes, denied claims for beneficiaries who are not enrolled on the date of service and claims denied due to recoupment of payment.	Revised types of excluded cases.	**Bullet 2:** Exclude all requests processed as direct member reimbursements and direct member reimbursement reconsideration requests, dismissals, reopenings, duplicate reconsideration requests and payment adjustments to reconsideration requests, reopenings, reconsideration requests denied for invalid billing codes, denied reconsideration requests for beneficiaries who are not enrolled on the date of service and reconsideration requests denied due to recoupment of payment.
Attachment IV – Part C Organization Determinations, Appeals, and Grievances (ODAG) Audit Process and Data Request Table 7 - Introductory Text	**Bullet 4**: If a claim has more than one line item, include all of the claim's line items in a single row and enter the multiple line items as a single claim.	Clarified that this universe applies to reconsideration requests.	**Bullet 4**: If a reconsideration request has more than one line item, include all of the request's line items in a single row and enter the multiple line items as a single request.
Attachment IV – Part C Organization Determinations, Appeals, and Grievances (ODAG) Audit Process and Data Request Table 7 – Column ID L	**Field Name**: Date the claim was paid or denied **Description**: Date the claim was paid or the date the denied claim was upheld, which may be the IRE auto-forward date. Submit in CCYY/MM/DD format (e.g., 2015/01/01). Sponsors should answer NA for untimely cases that are still open.	Revised field name. Revised field description to clarify it is applicable to reconsideration requests.	**Field Name**: Date the reconsideration request was paid or denied **Description**: Date the reconsideration request was paid or the date the denied claim was upheld, which may be the IRE auto-forward date. Submit in CCYY/MM/DD format (e.g., 2015/01/01). Sponsors should answer NA for untimely cases that are still open.
Attachment IV – Part C Organization Determinations, Appeals, and Grievances (ODAG) Audit Process and Data Request Table 7 – Column ID M	**Field Name**: Was interest paid on the claim? **Description**: Yes (Y)/No (N) indicator of whether interest was paid on the claim.	Revised field name. Revised field description to clarify it is applicable to reconsideration requests.	**Field Name**: Was interest paid on the reconsideration request? **Description**: Yes (Y)/No (N) indicator of whether interest was paid on the reconsideration request.
Attachment IV – Part C Organization Determinations, Appeals, and Grievances (ODAG) Audit Process and Data Request Table 8 – Column ID L	**Description**: Provide the time the sponsor received the IRE overturn decision. Submit in HH:MM:SS military time format (e.g., 23:59:59).	Added clarification that a response of "NA" is appropriate for standard requests.	**Description**: Provide the time the sponsor received the IRE overturn decision. Submit in HH:MM:SS military time format (e.g., 23:59:59). Answer NA the request was not expedited.

Current Section in CMS-10191	Original Language	Clarification or Change	Revised Language
Attachment IV – Part C Organization Determinations, Appeals, and Grievances (ODAG) Audit Process and Data Request Table 8 – Column ID N	**Description**: Time effectuated in the sponsor's system. Submit in HH:MM:SS military time format (e.g., 23:59:59).	Added clarification that a response of "NA" is appropriate for standard requests.	**Description**: Time effectuated in the sponsor's system. Submit in HH:MM:SS military time format (e.g., 23:59:59). Answer NA the request was not expedited.
Attachment IV – Part C Organization Determinations, Appeals, and Grievances (ODAG) Audit Process and Data Request Table 10 – Column ID J	**Description**: Indicate whether the pre-service request was processed under the expedited (E) timeframe or standard (S) timeframe.	Added clarification that a response of "NA" is appropriate for standard requests.	**Description**: Indicate whether the pre-service request was processed under the expedited (E) timeframe or standard (S) timeframe. Answer NA for payment requests.
Attachment IV – Part C Organization Determinations, Appeals, and Grievances (ODAG) Audit Process and Data Request Table 11 Introductory Text	**Bullet 2**: Exclude all requests processed as expedited oral and written grievances, and CTM complaints	Clarified that this universe applies to reconsideration requests.	**Bullet 2**: Exclude all requests processed as expedited oral and written grievances, dismissals, and CTM complaints.
Attachment IV – Part C Organization Determinations, Appeals, and Grievances (ODAG) Audit Process and Data Request Table 11 – Column ID F Table 12 – Column ID F	**Description**: Indicate whether the grievance was submitted by a contract provider (CP), non-contract provider (NCP), beneficiary (B) or beneficiary's representative (BR).	Removed "CP" and "NCP" as valid responses.	**Description**: Indicate whether the grievance was submitted by a beneficiary (B) or a beneficiary's representative (BR).

Current Section in CMS-10191	Original Language	Clarification or Change	Revised Language
Attachment IV – Part C Organization Determinations, Appeals, and Grievances (ODAG) Audit Process and Data Request Table 11 – Column ID H Table 12 – Column ID I	**Field Length**: 40 **Description**: Describe how the grievance/complaint was received from the beneficiary or authorized representative (e.g., written letter, call to Customer Services, etc.).	Revised field length to account for spaces. Revised field description to provide valid responses rather than free text.	**Field Length**: 7 **Description**: Describe how the grievance/complaint was first received from the beneficiary or authorized representative. Valid values include: Oral or Written.
Attachment IV – Part C Organization Determinations, Appeals, and Grievances (ODAG) Audit Process and Data Request Table 11 – Column ID I	**Field Length**: 50	Revised field length to account for spaces.	**Field Length:** 54
Attachment IV – Part C Organization Determinations, Appeals, and Grievances (ODAG) Audit Process and Data Request Table 11 – Column ID J Table 12 – Column ID K	**Field Name**: Issue description **Field Length**: 300	Revised field name. Revised field length to account for spaces.	**Field Name**: Grievance/complaint description **Field Length**: 1800
Attachment IV – Part C Organization Determinations, Appeals, and Grievances (ODAG) Audit Process and Data Request Table 11 – New Field	None	A new field has been added as Column ID K in this universe.	**Field Name**: Was this a quality of care grievance? **Field Type**: CHAR Always Required **Field Length**: 1 **Description**: Yes (Y)/No (N) indicator of whether the grievance was a quality of care grievance.

Current Section in CMS-10191	Original Language	Clarification or Change	Revised Language
Attachment IV – Part C Organization Determinations, Appeals, and Grievances (ODAG) Audit Process and Data Request Table 11 Column ID	**Field Name and Column ID:** Was a timeframe extension taken? (Column ID K) If an extension was taken, did the sponsor notify the member of the reason(s) for the delay? (Column ID L) If the extension was taken because the sponsor needed more information, did the notice include how the delay was in the best interest of the enrollee? (Column ID M) Resolution Description (Column ID N) Date oral notification of resolution provided to enrollee (Column ID O) Date written notification of resolution provided to enrollee (Column ID P) AOR receipt date (Column ID Q) First Tier, Downstream, and Related Entity (Column ID R)	Changed column IDs	**Field Name and Column ID:** Was a timeframe extension taken? (Column ID L) If an extension was taken, did the sponsor notify the member of the reason(s) for the delay? (Column ID M) If the extension was taken because the sponsor needed more information, did the notice include how the delay was in the best interest of the enrollee? (Column ID N) Resolution Description (Column ID Q) Date oral notification of resolution provided to enrollee (Column ID O) Date written notification of resolution provided to enrollee (Column ID P) AOR receipt date (Column ID R) First Tier, Downstream, and Related Entity (Column ID S)
Attachment IV – Part C Organization Determinations, Appeals, and Grievances (ODAG) Audit Process and Data Request Table 12 Introductory Text	**Bullet 2**: Exclude all requests processed as standard oral and written grievances, and CTM complaints	Revised types of excluded cases.	**Bullet 2:** Exclude all requests processed as standard oral and written grievances, dismissals, and CTM complaints.
Attachment IV – Part C Organization Determinations, Appeals, and Grievances (ODAG) Audit Process and Data Request Table 12 – Column ID L	**Field Name**: Was a timeframe extension taken?	This field has been removed in its entirety.	None

Current Section in CMS-10191	Original Language	Clarification or Change	Revised Language
Attachment IV – Part C Organization Determinations, Appeals, and Grievances (ODAG) Audit Process and Data Request Table 12 – Column ID M	**Field Name**: If an extension was taken, did the sponsor notify the member of the reason(s) for the delay?	This field has been removed in its entirety.	None
Attachment IV – Part C Organization Determinations, Appeals, and Grievances (ODAG) Audit Process and Data Request Table 12 – Column ID N	**Field Name**: If the extension was taken because the sponsor needed more information, did the notice include how the delay was in the best interest of the enrollee?	This field has been removed in its entirety.	None
Attachment IV – Part C Organization Determinations, Appeals, and Grievances (ODAG) Audit Process and Data Request Table 12 – Column ID O	**Column ID O Field Name**: Resolution Description	This field has been moved from Column ID O to Column ID P.	**Column ID P Field Name**: Resolution Description
Attachment IV – Part C Organization Determinations, Appeals, and Grievances (ODAG) Audit Process and Data Request Table 12 Column ID	**Field Name and Column ID:** Date oral notification of resolution provided to enrollee (Column ID P) Time oral notification of resolution provided to enrollee (Column ID Q) Date written notification of resolution provided to enrollee (Column ID R) Time written notification of resolution provided to enrollee (Column ID S) AOR receipt date (Column ID T) AOR receipt time (Column ID U) First Tier, Downstream, and Related Entity (Column ID V)	Changed column IDs	**Field Name and Column ID:** Date oral notification of resolution provided to enrollee (Column ID L) Time oral notification of resolution provided to enrollee (Column ID M) Date written notification of resolution provided to enrollee (Column ID N) Time written notification of resolution provided to enrollee (Column ID O) AOR receipt date (Column ID Q) AOR receipt time (Column ID R) First Tier, Downstream, and Related Entity (Column ID S)

Current Section in CMS-10191	Original Language	Clarification or Change	Revised Language
Attachment IV – Part C Organization Determinations, Appeals, and Grievances (ODAG) Audit Process and Data Request Table 13 – Column ID G	**Field Name**: Person who made the request?	Revised field name	**Field Name**: Who made the request?
Attachment IV – Part C Organization Determinations, Appeals, and Grievances (ODAG) Audit Process and Data Request Table 13 – Column ID H	**Field Length**: 42	Revised field length to account for spaces.	**Field Length**: 45
Attachment IV – Part C Organization Determinations, Appeals, and Grievances (ODAG) Audit Process and Data Request Table 13 – Column ID K	**Field Name**: Time the request was received	This field has been removed in its entirety.	None
Attachment IV – Part C Organization Determinations, Appeals, and Grievances (ODAG) Audit Process and Data Request Table 13 – New Column	**None**	Added new field	**Field Name and Column ID**: Was a timeframe extension taken? (Column ID M) **Field Type**: CHAR Always Required **Field Length**: 1 **Field Description**: Yes (Y)/No (N) indicator of whether the sponsor extended the timeframe before dismissing the request.

Current Section in CMS-10191	Original Language	Clarification or Change	Revised Language
Attachment IV – Part C Organization Determinations, Appeals, and Grievances (ODAG) Audit Process and Data Request Table 13 – Column ID O	**Field Name**: Time the request was dismissed	This field has been removed in its entirety.	None
Attachment IV – Part C Organization Determinations, Appeals, and Grievances (ODAG) Audit Process and Data Request Table 13 – Column ID R	**Field Name**: Time written notification provided to enrollee/provider	This field has been removed in its entirety.	None
Attachment IV – Part C Organization Determinations, Appeals, and Grievances (ODAG) Audit Process and Data Request Table 13 Column ID	**Field Name and Column ID:** Description of the Issue (Column ID L) Is this an expedited or standard request? (Column ID M) Reason for Dismissal (Column ID P) Date written notification provided to enrollee/provider (Column ID Q) Appealed to IRE? (Column ID S) Date forwarded to IRE (Column ID T) First Tier, Downstream, and Related Entity (Column ID U)	Changed column IDs	**Field Name and Column ID:** Description of the Issue (Column ID K) Is this an expedited or standard request? (Column ID L) Reason for Dismissal (Column ID O) Date written notification provided to enrollee/provider (Column ID P) Appealed to IRE? (Column ID Q) Date forwarded to IRE (Column ID R) First Tier, Downstream, and Related Entity (Column ID S)

Current Section in CMS-10191	Original Language	Clarification or Change	Revised Language
Attachment IV – Part C Organization Determinations, Appeals, and Grievances (ODAG) Audit Process and Data Request Table 14 - Introductory Text	None	Added note to clarify call log universe layout expectations.	**NOTE:** Sponsors are not required to submit the information below in the format provided by the record layout as long as the information provided is sufficient for CMS review.
Attachment IV – Part C Organization Determinations, Appeals, and Grievances (ODAG) Audit Process and Data Request Table 14 – Column ID D	**Field Type**: CHAR Always Required	Field is now optional.	**Field Type**: CHAR Optional
Attachment IV – Part C Organization Determinations, Appeals, and Grievances (ODAG) Audit Process and Data Request Table 14 – Column ID E	**Field Type**: CHAR Always Required	Field is now optional.	**Field Type**: CHAR Optional
Attachment IV – Part C Organization Determinations, Appeals, and Grievances (ODAG) Audit Process and Data Request Table 14 – Column ID H	**Field Type**: CHAR Always Required	Field is now optional.	**Field Type**: CHAR Optional

Current Section in CMS-10191	Original Language	Clarification or Change	Revised Language
Attachment IV – Part C Organization Determinations, Appeals, and Grievances (ODAG) Audit Process and Data Request Table 14 – Column ID K	None	Added new field	**Field Name and Column ID**: First Tier, Downstream, and Related Entity **Field Type**: CHAR Always Required **Field Length**: 70 **Field Description**: Insert the name of the First Tier, Downstream, and Related Entity that processed the dismissal (e.g., Independent Physician Association, Physicians Medical Group or Third Party Administrator). Answer NA if not applicable.
Attachment V SNP-MOC Audit Process and Data Request Audit Purpose and General Guidelines Review Period	The review period for SNPs that have been operational for at least a year, will be the (13) thirteen month period preceding the date of the audit engagement letter (for example, for an engagement letter sent on January 25, 2016, the universe review period would be December 1, 2015 through January 25, 2017)	Revised example date to reflect 13 month period.	The review period for SNPs that have been operational for at least a year, will be the (13) thirteen month period preceding the date of the audit engagement letter (for example, for an engagement letter sent on January 25, 2017, the universe review period would be December 1, 2015 through January 25, 2017)
Attachment V SNP-MOC Audit Process and Data Request Universe Preparation & Submission Pull Universes and Submit Background Information	The universes collected for this program area tests the sponsor's performance in processing enrollments, care transitions, and plan performance monitoring and evaluation of the MOC. The sponsor will provide a universe consisting of all SNP beneficiaries who have been continuously enrolled for a period of at least 13 months as of the engagement letter date. The sponsor will also submit quality measurement and performance improvement metrics utilized by your organization to monitor and evaluate the effectiveness of the MOC. All applicable fields of the plan performance monitoring and evaluation record layout should be completed; a separate record layout should be submitted for each unique MOC.	Paragraph 1: revised language to be consistent with Chapter 5 of the Medicare Managed Care Manual. Paragraph 2: added clarification regarding continuous enrollment. Paragraph 3: added the option for sponsors to submit one workbook with a separate tab for each unique MOC.	The universes collected for this program area tests the sponsor's performance in processing enrollments, care coordination, and plan performance monitoring and evaluation of the MOC. The sponsor will provide a universe consisting of all SNP beneficiaries who have been enrolled in any of the sponsoring organization's SNPs, with no breaks in enrollment (i.e. continuously enrolled)for a period of at least 13 months as of the engagement letter date. Members may have switched from one SNP plan to another so long as they did not experience a break in enrollment. The sponsor will also submit quality measurement and performance improvement metrics utilized by your organization to monitor and evaluate the effectiveness of the MOC. All applicable fields of the plan performance monitoring and evaluation record layout should be completed; a separate record layout should be submitted for each unique MOC. Sponsors may opt to submit one workbook with a separate tab for each unique MOC.

Current Section in CMS-10191	Original Language	Clarification or Change	Revised Language
Attachment V SNP-MOC Audit Process and Data Request Sample Selection Select Sample Cases	CMS will select a sample of 30 beneficiaries from the sponsor-submitted universe as follows: • % selected = % of D-SNP beneficiaries • % selected = % of I-SNP beneficiaries • % selected = % of C-SNP beneficiaries • % selected = % of MMP beneficiaries CMS will sample proportionally with a minimum of 5 for each existing SNP type to obtain a total sample size of 30.	Removed MMP as MMP will have its own protocol in 2017. Added commas for emphasis that a minimum of 5 will be selected. Added clarification that the sample proportions will be based off each existing SNP type in the universe.	CMS will select a sample of 30 beneficiaries from the sponsor-submitted universe as follows: • % selected = % of D-SNP beneficiaries • % selected = % of I-SNP beneficiaries • % selected = % of C-SNP beneficiaries CMS will sample proportionally, with a minimum of 5, for each existing SNP type represented in the universe to obtain a total sample size of 30.
Attachment V SNP-MOC Audit Process and Data Request Audit Elements Population to be Served – Enrollment Verification For All Beneficiaries	• Documentation showing sponsor's verification of SNP eligibility prior to submission of the enrollment to CMS. • Documentation of the completed enrollment request. • Documentation showing sponsor's verification of SNP eligibility prior to submission of the enrollment to CMS.	Removed duplicate bullet	• Documentation showing sponsor's verification of SNP eligibility prior to submission of the enrollment to CMS. • Documentation of the completed enrollment request.
Attachment V SNP-MOC Audit Process and Data Request Audit Elements Care Coordination	2.2.2. Did the ICP include specific interventions designed to meet the needs identified in the HRA?	Revised compliance standard question to align with CMS regulations.	Did the sponsor develop a comprehensive ICP designed to address needs identified in the HRA, consistent with the MOC?
Attachment V SNP-MOC Audit Process and Data Request Table 1 - Column ID E	**Field Length**: 7	Revised field length to 5 to be consistent with other protocols	**Field Length**: 5
Attachment V SNP-MOC Audit Process and Data Request Table 1 - Column ID F	**Field Length**: 5	Revised field length to 3 to be consistent with other protocols	**Field Length**: 3

Current Section in CMS-10191	Original Language	Clarification or Change	Revised Language
Attachment V SNP-MOC Audit Process and Data Request Table 1 - Column ID H	**Description**: Enrollment mechanism for the beneficiary. Enter one of the following descriptions: Paper, Electronic, Telephonic or Seamless.	Revised to include passive enrollments.	**Description**: Enrollment mechanism for the beneficiary. Enter one of the following descriptions: Paper, Electronic, Telephonic, Passive or Seamless.
Attachment V SNP-MOC Audit Process and Data Request Table 1 - Column ID K	**Description**: Enter Yes if the beneficiary received an initial HRA within 90 days before or after his/her effective date of enrollment. Enter No if the beneficiary did not receive an initial HRA within 90 days before or after his/her effective date of enrollment.	Revised language to demonstrate the intent of the question is to determine whether or not an HRA was administered, completed or conducted within 90 days of enrollment.	**Description**: Enter Yes if sponsor completed an initial Enter Yes if the sponsor completed an initial HRA within 90 days before or after the member's effective date of enrollment. Enter No if the member did not have an initial HRA within 90 days before or after his/her effective date of enrollment.
Attachment V SNP-MOC Audit Process and Data Request Table 1 - Column ID L	**Description**: Date of the beneficiary's first HRA after enrolling. Submit in CCYY/MM/DD format (e.g., 20130101).	Added slashes to date example given in Description	**Description**: Date of the beneficiary's first HRA after enrolling. Submit in CCYY/MM/DD format (e.g., 2013/01/01).
Attachment V SNP-MOC Audit Process and Data Request Table 1 - Column ID M	**Description**: Enter Yes if the beneficiary received an HRA within the 13-month audit period. Enter No if the beneficiary did not receive an HRA within the audit period.	Revised language to demonstrate the intent of the question is to determine whether or not an HRA was administered, completed or conducted within the audit period.	**Description**: Enter Yes if the sponsor completed an HRA within the 13-month audit period. Enter No if the beneficiary did not have an HRA completed within the audit period.
Attachment V SNP-MOC Audit Process and Data Request Table 1 - Column ID N	**Description**: Submit in CCYY/MM/DD format (e.g., 2013/01/01). If HRA was not conducted during the current audit period, please enter the date of the most recently conducted HRA.	Revised description to include the option to enter NA if no HRA was conducted during the audit period.	**Description**: Submit in CCYY/MM/DD format (e.g., 2013/01/01). If no HRA was conducted during current audit period, please enter NA.
Attachment V SNP-MOC Audit Process and Data Request Table 1 - Column ID Q	**Description**: Enter the total dollar amount for all paid claims with dates of service during the audit review period (e.g., $430,265). If the arrangement with a provider group is capitated, sponsors should enter "N/A". This field is not to be populated with the number of claims.	Revised description to reflect that sponsors should include capitated payments in these totals. Added clarification regarding which claims should be excluded.	**Description**: Enter the total dollar amount for all paid claims with dates of service during the audit review period (e.g., $430,265). This field is not to be populated with the number of claims. Sponsors should exclude data related to the types of claims cited; duplicate claims and payment adjustments to claims, claims that are denied for invalid billing codes, billing errors, denied claims for bundled or not separately payable items, denied claims for beneficiaries who are not enrolled on the date of service and claims denied due to recoupment of payment.

Current Section in CMS-10191	Original Language	Clarification or Change	Revised Language
Attachment V SNP-MOC Audit Process and Data Request Table 1 - Column ID R	**Description**: Enter the total dollar amount for all denied claims with dates of service during the audit review period (e.g., $99,782). If the arrangement with a provider group is capitated, sponsors should enter "N/A". This field is not to be populated with the number of claims.	Revised description to reflect that sponsors should include capitated payments in these totals. Added clarification regarding which claims should be excluded.	**Description**: Enter the total dollar amount for all denied claims with dates of service during the audit review period (e.g., $99,782). This field is not to be populated with the number of claims. Sponsors should exclude data related to the types of claims cited; duplicate claims and payment adjustments to claims, claims that are denied for invalid billing codes, billing errors, denied claims for bundled or not separately payable items, denied claims for beneficiaries who are not enrolled on the date of service and claims denied due to recoupment of payment.
Attachment V SNP-MOC Audit Process and Data Request Table 1 - Column ID S	**Description**: Enter the number of all paid claims with dates of service during the audit review period (e.g., 10,000). This field is not to be populated with a dollar amount.	Added language to clarify which claims should be excluded.	**Description**: Enter the number of all paid claims with dates of service during the audit review period (e.g., 10,000). This field is not to be populated with a dollar amount. Sponsors should exclude data related to the types of claims cited; duplicate claims and payment adjustments to claims, claims that are denied for invalid billing codes, billing errors, denied claims for bundled or not separately payable items, denied claims for beneficiaries who are not enrolled on the date of service and claims denied due to recoupment of payment.
Attachment V SNP-MOC Audit Process and Data Request Table 1 - Column ID T	**Description**: Enter the number of all denied claims with dates of service during the audit review period (e.g., 2,000). This field is not to be populated with a dollar amount.	Added language to clarify which claims should be excluded.	**Description**: Enter the number of all denied claims with dates of service during the audit review period (e.g., 2,000). This field is not to be populated with a dollar amount. Sponsors should exclude data related to the types of claims cited; duplicate claims and payment adjustments to claims, claims that are denied for invalid billing codes, billing errors, denied claims for bundled or not separately payable items, denied claims for beneficiaries who are not enrolled on the date of service and claims denied due to recoupment of payment.
Attachment V SNP-MOC Audit Process and Data Request Table 2 - Column ID E	**Description**: Sponsors should enter the baseline result value (e.g., percentage 66.6%, ratio 33:50, etc.).	Revised description to allow the option to enter NA when no baseline information was collected/available.	**Description**: Sponsors should enter the baseline result value (e.g., percentage 66.6%, ratio 33:50, etc.). Enter NA if no baseline information was collected/available.
Attachment V SNP-MOC Audit Process and Data Request Table 2 - Column ID I	**Description**: Sponsor will report data for the 2 most recently conducted data measurement/ assessments. Enter the start date of the 1st measurement period. Submit in CCYY/MM/DD format (e.g., 20140331). Example: if the 1st of the 2 most recent measurement periods began on January 1, 2014, then enter 2014/01/01. If no measurement was conducted enter N/A	Added slashes to date example given in description	**Description**: Sponsor will report data for the 1 most recently conducted data measurement/ assessments. Enter the start date of the 1st measurement period. Submit in CCYY/MM/DD format (e.g., 2014/03/31). Example: if the 1st of the 2 most recent measurement periods began on January 1, 2014, then enter 2014/01/01. If no measurement was conducted enter NA.

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Attachment V SNP-MOC Audit Process and Data Request Table 2 - Column ID J	**Description**: Enter the end date of the 1st measurement period. Submit in CCYYMMDD format (e.g., 20140331). Example: if the 1st of the 2 most recent measurement periods ended on March 31, 2014, then enter 2014/03/31. If no measurement was conducted enter N/A.	Added slashes to date example given in	**Description**: Enter the end date of the 1st measurement period. Submit in CCYYMMDD format (e.g., 2014/03/31). Example: if the 1st of the 2 most recent measurement periods ended on March 31, 2014, then enter 2014/03/31. If no measurement was conducted enter NA.
Attachment V SNP-MOC Audit Process and Data Request Table 2 - Column ID L	**Field Name**: Goal Met/Not Met **Description**: Determination of whether the target value was met after the 2nd measurement period. (Yes/No) Enter Yes if the result for measurement period 2 is equal to or greater than the target percentage goal (e.g., target goal 90%, measurement period 2 results 95.5% ☐ goal Enter No if the result for measurement period 2 is less than the target percentage goal (e.g., target goal 90%, measurement period 2 results 45.5% ☐ goal not met, enter No	Removed "Not Met" from field name. Revised description to reflect that it relates to measurement period 1, simplified instructions to allow for multiple scenarios of the goal being met.	**Field Name**: Goal Met **Description**: Determination of whether the target value was met after the 1st measurement period. (Yes/No) Enter Yes if the goal is met. Enter No if the goal is not met. Enter NA if no information is available.
Attachment V SNP-MOC Audit Process and Data Request Table 2 - Column ID Q	**Field Name**: Goal Met/Not Met **Description**: Determination of whether the target value was met after the 2nd measurement period. (Yes/No) Enter Yes if the result for measurement period 2 is equal to or greater than the target percentage goal (e.g., target goal 90%, measurement period 2 results 95.5% ☐ goal Enter No if the result for measurement period 2 is less than the target percentage goal (e.g., target goal 90%, measurement period 2 results 45.5% ☐ goal not met, enter No	Removed "Not Met" from field name. Revised description to allow for multiple scenarios of the goal being met.	**Field Name**: Goal Met **Description**: Determination of whether the target value was met after the 2nd measurement period. (Yes/No) Enter Yes if the goal was met. Enter No if the goal was not met. Enter NA if no information was collected/available.
Attachment V SNP-MOC Audit Process and Data Request Table 1 & Table 2	N/A	Revised all instances where N/A abbreviation was used to NA	NA

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Attachment VI – Medication Therapy Management Program Area Pilot Audit Process and Data Request Audit Purpose and General Guidelines Review Period	**2.1 CY 2015 MTM Universe** • All beneficiaries who were enrolled in the sponsor's CY 2015 MTM program(s) as required under 42 CFR 423.153(d) (including members enrolled in employer plans and Medicare-Medicaid Plans (MMPs)). This includes all enrollees that were disenrolled from the MTM program during the 2015 contract year. Do not include beneficiaries that were offered MTM services, but do not meet the eligibility criteria under section 423.153(d). The audit review period for this universe covers January 1, 2015 through December 31, 2015.	Removed the CY 2015 MTM Universe, changed the names of the remaining two universes, and revised language to remove year specific references.	**2.1 MTM Universe** • All beneficiaries who were enrolled in the sponsor's MTM program(s) as required under 42 CFR 423.153(d) (including members enrolled in employer plans and Medicare-Medicaid Plans (MMPs)). This includes all enrollees that were disenrolled from the MTM program during the contract year. Do not include beneficiaries that were offered MTM services, but do not meet the eligibility criteria under section 423.153(d).
	2.2. CY 2016 MTM Universe • All beneficiaries who were enrolled in the sponsor's CY 2016 MTM program(s) as required under 42 CFR 423.153(d) (including members enrolled in employer plans and Medicare-Medicaid Plans (MMPs)). This includes all enrollees that were disenrolled from the MTM program during the 2016 contract year. Do not include beneficiaries that were offered MTM services, but do not meet the eligibility criteria under section 423.153(d). The audit review period for this universe covers January 1, 2016 through December 31, 2016. **CY 2016 Prescription Drug Event (PDE) Universe -** CMS will extract final action CY 2016 PDE data for audited sponsors from the Integrated Data Repository (IDR). The PDE universe will be used to identify enrollees who were potentially eligible for auto-enrollment in a CY 2016 MTM program, but were not enrolled at any time during CY 2016. Beneficiaries that were enrolled by the sponsor in a CY 2016 MTM program will be omitted from this universe.		The audit review period for this universe covers January 1st through December 31st of the contract year immediately prior to the audit year. For example, for audits conducted in 2017, sponsors should populate this universe using the MTM data for the 2016 contract year. 2.2 Prescription Drug Event (PDE) Universe - CMS will extract final action PDE data from the contract year immediately prior to the audit year for audited sponsors from the Integrated Data Repository (IDR). The PDE universe will be used to identify enrollees who were potentially eligible for auto-enrollment in a MTM program for the contract year of interest, but were not enrolled at any time during that year. Beneficiaries that were enrolled by the sponsor in an MTM program for the contract year of interest will be omitted from this universe.

Current Section in CMS-10191	Original Language	Clarification or Change	Revised Language
Attachment VI – Medication Therapy Management Program Area Pilot Audit Process and Data Request Audit Purpose and General Guidelines Calculation of Score	CMS will determine if each condition cited is an Observation (0 points), Corrective Action Required (CAR) (1 point), Immediate Corrective Action Required (ICAR) (2 points) or an Invalid Data Submission (IDS) (1 point). IDS conditions will be cited when a sponsor is not able to produce an accurate universe within 3 attempts.	Modified language to be consistent with other protocols.	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 Submission (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.
Attachment VI – Medication Therapy Management Program Area Pilot Audit Process and Data Request Universe Preparation and Submission Responding to Universe Requests	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.	Changed wording from "3rd" to "third".	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.
Attachment VI – Medication Therapy Management Program Area Pilot Audit Process and Data Request Universe Preparation and Submission Pull Universes	**Pull Universes:** The universes collected for this audit assist CMS in evaluating whether sponsors are 1) accurately identifying and appropriately enrolling targeted beneficiaries in MTM programs, 2) appropriately disenrolling beneficiaries enrolled in MTM programs, and 3) offering and providing required MTM services to the MTM program enrollees. The universes should be compiled using the appropriate record layout as described in Appendix A. These record layouts include: • CY 2015 Medication Therapy Management (MTM-2015) Universe • CY 2016 Medication Therapy Management (MTM-2016) Universe	Made text singular as applicable; revised text to make consistent with other program area protocols; removed CY 2015 Medication Therapy Management (MTM-2015) Universe; renamed the universe for CY 2016 as Medication Therapy Management Enrollee (MTME) Universe; removed the note related to the deleted universe; and revised language to remove year specific references.	**Pull Universe:** The universe collected for this program area tests whether sponsors are 1) accurately identifying and appropriately enrolling targeted beneficiaries in MTM programs, 2) appropriately disenrolling beneficiaries enrolled in MTM programs, and 3) offering and providing required MTM services to the MTM program enrollees. The universe should be compiled using the appropriate record layout as described in Appendix A. This record layout includes: • Medication Therapy Management Enrollee (MTME) Universe

Current Section in CMS-10191	Original Language	Clarification or Change	Revised Language
	NOTE: • For these universes, the sponsor should include all cases that match the description for that universe for all contracts in its organization as identified in the audit engagement letter (e.g., all beneficiaries for all contracts in your organization that were enrolled in each CY 2016 MTM program). • The CY 2015 MTM universe data from will be used in conjunction with elements I and II of the Pilot MTM protocol to assist with identifying members that were previously auto-enrolled in an MTM program and to establish a look back date for the annual CMR for continuing MTM program enrollees.		**NOTE:** • The sponsor should include all cases that match the description for this universe for all contracts in its organization as identified in the audit engagement letter (e.g., all beneficiaries, for all contracts in your organization, that were auto-enrolled in each MTM program for the contract year immediately prior to the audit year).
Attachment VI – Medication Therapy Management Program Area Pilot Audit Process and Data Request Universe Preparation & Submission Submit Universes to CMS	**Submit Universes to CMS:** Sponsors should submit each universe in the Microsoft Excel (.xlsx) or Comma Separated Values (.csv) 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 and 2). The sponsor should submit its universes in whole and not separately for each contract.	Made text and table references singular as a result of deleting one universe.	**Submit Universe to CMS:** Sponsors should submit the universe in the Microsoft Excel (.xlsx) or Comma Separated Values (.csv) file format with a header row (or Text (.txt) file format without a header row) following the record layout shown in Appendix A (Table 1). The sponsor should submit its universe in whole and not separately for each contract.
Attachment VI – Medication Therapy Management Program Area Pilot Audit Process and Data Request Audit Elements Enrollment/ Disenrollment Select Sample Cases	CMS will select a total of 20 cases from the CY 2016 PDE and MTM universes to test the appropriateness of the sponsor's enrollment of eligible beneficiaries into a CY 2016 MTM program as well as disenrollment from a CY 2016 MTM program. These 20 cases will consist of:	Revised language to remove year specific references.	CMS will select a total of 20 cases from the PDE and MTM universes to test the appropriateness of the sponsor's enrollment of eligible beneficiaries into a MTM program as well as disenrollment from a MTM program. These 20 cases will consist of:

Current Section in CMS-10191	Original Language	Clarification or Change	Revised Language
Attachment VI – Medication Therapy Management Program Area Pilot Audit Process and Data Request Audit Elements Enrollment/ Disenrollment Review Sample Case Documentation	The sponsor will need access to the following information during the live webinar and may be requested to produce screenshots. The screenshots must be provided to CMS via a Microsoft® Word or PDF document. The sponsor must provide a legend that directs CMS to the requested information on the screenshot. At a minimum, the first shot of each screen type must clearly indicate where the requested information resides on the screen. The sponsor may include additional documentation not requested, including but not limited to a narrative summary of the case, to provide additional detail or clarity.	Revised text to make consistent with other program area protocols.	The sponsor will need access to the following documents during the live audit webinar and may be requested to produce screenshots of any of the following:
Attachment VI – Medication Therapy Management Program Area Pilot Audit Process and Data Request Audit Elements Enrollment/ Disenrollment Review Sample Case Documentation	• Effective date of disenrollment/opt-out • Documentation of beneficiary's/authorized representative's request to disenroll from the MTM program	Replaced disenrollment with opt-out.	• Effective date of opt-out • Documentation of beneficiary's/authorized representative's request to opt-out from the MTM program
Attachment VI – Medication Therapy Management Program Area Pilot Audit Process and Data Request Audit Elements Comprehensive and Targeted Medication Review (CTMR)	Element II. Comprehensive Medication Review (CMR)	Elements II and III were combined into a single element. Element III was deleted.	Element II. Comprehensive and Targeted Medication Review (CTMR)

Current Section in CMS-10191	Original Language	Clarification or Change	Revised Language
Attachment VI – Medication Therapy Management Program Area Pilot Audit Process and Data Request Audit Elements Comprehensive and Targeted Medication Review (CTMR) Select Sample Cases	CMS will select a targeted sample of 15 cases from the CY 2016 MTM universe.	The number of total cases was reduced from 30 across 2 elements to 20 for the combined element. Also, dropped CY 2016 from the universe name.	CMS will select a targeted sample of 20 cases from the MTM universe.
Attachment VI – Medication Therapy Management Program Area Pilot Audit Process and Data Request Audit Elements Comprehensive and Targeted Medication Review (CTMR) Review Sample Case Documentation	CMS will review all sample case file documentation to determine if MTM program enrollees were offered and/or provided appropriate, complete and accurate CMRs, including interventions for beneficiaries and/or prescribers and written summaries in CMS' standardized format. During the live review portion of the audit CMS will also verify the accuracy of the dates provided in the universe submission. The sponsor will need access to the following documents during the live audit webinar and may be requested to produce screenshots of any of the following, where applicable:	Consolidated the case documentation section from the previous Elements II and III into one new Element II. Text was also revised to make it consistent with other program area protocols.	CMS will review all sample case file documentation to determine if MTM program enrollees were offered and/or provided appropriate, complete and accurate CMRs, including interventions for beneficiaries and/or prescribers, and written CMR summaries in CMS' standardized format. CMS will also review at least 10 cases to determine whether beneficiaries auto-enrolled in an MTM program received accurate, complete and at least quarterly TMRs with follow-up interventions when necessary. During the live review portion of the audit CMS will also verify the accuracy of the dates provided in the universe submission. The sponsor will need access to the following documents during the live audit webinar and may be requested to produce screenshots of any of the following, where applicable:

Current Section in CMS-10191	Original Language	Clarification or Change	Revised Language
Attachment VI – Medication Therapy Management Program Area Pilot Audit Process and Data Request Audit Elements Comprehensive and Targeted Medication Review (CTMR) Review Sample Case Documentation	• Effective date of eligibility determination • Documentation of targeted beneficiary's MTM program eligibility • Effective date of enrollment into the MTM program • Documentation regarding the cognitive impairment determination of the enrollee • Documentation regarding identification and outreach to authorized representative for cognitively impaired beneficiaries • Documentation regarding provider's inability to administer CMR • Documentation of CMR offer • Documentation of beneficiary's/authorized representative's declination of individual MTM services (including CMRs)	Consolidated the documentation sampled from the previous Elements II and III into one new Element II. Also made minor modifications to text for more clarity.	• Effective date of eligibility determination • Documentation of targeted beneficiary's MTM program eligibility • Effective date of enrollment into the MTM program • Documentation regarding the cognitive impairment determination of the enrollee • Documentation regarding identification and outreach to authorized representative for cognitively impaired beneficiaries • Documentation of comprehensive medication review (CMR) offer
Attachment VI – Medication Therapy Management Program Area Pilot Audit Process and Data Request Audit Elements Comprehensive and Targeted Medication Review (CTMR) Review Sample Case Documentation (cont'd)	• Documentation that a required CMR was administered to the beneficiary as a part of the MTM process • Date the comprehensive medication review was administered • Copy of the comprehensive medication review report • Documentation of personnel involved in the comprehensive medication review • Documentation of notification to beneficiary regarding the comprehensive medication review • Copy of the written summary of the comprehensive medication review • Effective date of disenrollment/opt-out • Documentation of beneficiary's/authorized representative's request to disenroll from the MTM program		• Documentation of beneficiary's/authorized representative's declination of individual MTM services (including CMRs) • Documentation including date that a required CMR was administered to the beneficiary as a part of the MTM process (e.g., copy of the comprehensive medication review report) • Documentation regarding provider's inability to administer CMR • Documentation of personnel involved in the comprehensive medication review • Copy of written summary of the comprehensive medication review or alternative documentation of the CMR • Documentation including date that a targeted medication review was performed (e.g., copy of the targeted medication review report) • Documentation of personnel involved in the targeted medication review • Documentation of any interventions taken as a result of the targeted review (or documentation that interventions were not necessary) • Effective date of opt-out • Documentation of beneficiary's/authorized representative's request to opt-out from the MTM program

Current Section in CMS-10191	Original Language	Clarification or Change	Revised Language
Attachment VI – Medication Therapy Management Program Area Pilot Audit Process and Data Request Audit Elements Comprehensive and Targeted Medication Review (CTMR) Apply Compliance Standard	**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 MTM requirements not being met. • Was a CMR offered at least annually? For newly targeted beneficiaries, was a CMR offered within 60 days of enrollment? • For cognitively impaired members, did the sponsor perform appropriate outreach to the beneficiary's authorized representative to offer a CMR? • Did the sponsor perform an annual comprehensive medication review in accordance with CMS' professional service definition? • Did the sponsor provide the beneficiary or their authorized representative with a written summary of the comprehensive medication review? i. Was the written summary provided in the standardized format? ii. Was the written summary provided within 14 days of the completed CMR? • Did the sponsor utilize the appropriate qualified staff when performing the CMR? • Were the required CMR services offered and provided consistent with the approved MTM description?	Consolidated the compliance standards from previous Elements II and III into one new Element II.	**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 MTM requirements not being met. • Was a CMR offered at least annually? For newly targeted beneficiaries, was a CMR offered within 60 days of enrollment? • For cognitively impaired members, did the sponsor perform appropriate outreach to the beneficiary's authorized representative to offer a CMR? • Did the sponsor perform an annual comprehensive medication review in accordance with CMS' professional service definition? • Did the sponsor provide the beneficiary or their authorized representative with a written summary of the comprehensive medication review? i. Was the written summary provided in the standardized format? ii. Was the written summary provided within 14 days of the completed CMR? • Did the sponsor utilize the appropriate qualified staff when performing the CMR? • Were the required CMR services offered and provided consistent with the approved MTM description? • Did the sponsor provide TMRs at least quarterly or according to the timeframe as described in the CMS approved MTM description? • Were the TMRs performed consistent with the approved MTM description? • Did the sponsor implement beneficiary and/or prescriber interventions resulting from TMRs when necessary and/or as described in the CMS approved MTM description?

Current Section in CMS-10191	Original Language	Clarification or Change	Revised Language
Attachment VI – Medication Therapy Management Program Area Pilot Audit Process and Data Request Audit Elements Comprehensive and Targeted Medication Review (CTMR) Sample Case Results	CMS will test each of the 15 cases.	Modified the total cases to 20 to account for merging Elements II and III into one new Element II.	CMS will test each of the 20 cases.
Attachment VI – Medication Therapy Management Program Area Pilot Audit Process and Data Request Audit Elements Targeted Medication Review (TMR)	**Select Sample Cases:** CMS will select 15 targeted cases from the CY 2016 MTM universe who received a targeted medication review (TMR). **Review Sample Case Documentation:** CMS will review all sample case file documentation to determine if beneficiaries auto-enrolled in an MTM program received accurate, complete and at least quarterly TMRs with follow-up interventions when necessary. During the live review portion of the audit, CMS will also verify the accuracy of the dates provided in the universe submission. The sponsor will need access to the following documents during the live audit webinar and may be requested to produce screenshots of any of the following, where applicable: • Effective date of eligibility determination • Documentation of targeted beneficiary's MTM program eligibility • Effective date of enrollment into the MTM program • Date the targeted medication reviews were performed • Documentation that a targeted medication review was performed • Copy of the targeted medication review report • Documentation of personnel involved in the targeted medication review	Removed Element III and combined into a new Element II (Comprehensive and Targeted Medication Review (CTMR)).	None.

Current Section in CMS-10191	Original Language	Clarification or Change	Revised Language
Attachment VI – Medication Therapy Management Program Area Pilot Audit Process and Data Request Audit Elements Targeted Medication Review (TMR) (cont'd)	• Documentation of any interventions taken as a result of the targeted review (or documentation that interventions were not necessary) • Documentation of beneficiary's/authorized representative's declination of individual MTM services • Effective date of disenrollment/opt-out • Documentation of beneficiary's/authorized representative's request to disenroll from the MTM program		
Attachment VI – Medication Therapy Management Program Area Pilot Audit Process and Data Request Audit Elements Targeted Medication Review (TMR) (cont'd)	**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 MTM requirements not being met. **3.1** Did the sponsor provide TMRs at least quarterly or according to the timeframe as described in the CMS approved MTM description? Were the TMRs performed consistent with the approved MTM description? **3.2** Did the sponsor implement beneficiary and/or prescriber interventions resulting from TMRs when necessary and/or as described in the CMS approved MTM description? **Sample Case Results**: CMS will test each of the 15 cases.		
Attachment VI – Medication Therapy Management Program Area Pilot Audit Process and Data Request Record Layout Instructions	The universes for the Medication Therapy Management program area must be submitted as a Microsoft Excel (.xlsx) or Comma Separated Values (.csv) file with a header row reflecting the field names (or Text (.txt) file without a header row).	Modified language from record layouts to record layout and from universes to universe.	The universe for the Medication Therapy Management program area must be submitted as a Microsoft Excel (.xlsx) or Comma Separated Values (.csv) file with a header row reflecting the field names (or Text (.txt) file without a header row).

Current Section in CMS-10191	Original Language	Clarification or Change	Revised Language
Attachment VI – Medication Therapy Management Program Area Pilot Audit Process and Data Request Table 1	Table 1. CY 2015 Medication Therapy Management Program (MTM-2015) Record Layout	Deleted existing table 1 and renamed remaining table.	Table 1. Medication Therapy Management Enrollee (MTME) Record Layout
Attachment VI – Medication Therapy Management Program Area Pilot Audit Process and Data Request Table 1 - Introductory Text	**Bullet 1**: Include all beneficiaries auto-enrolled in the sponsor's CY 2016 MTM program as required under 42 CFR § 423.153(d) and the CMS approved MTM Description. If a beneficiary was auto-enrolled more than once in an MTM program during CY 2016, include information related to the first effective enrollment in a 2016 MTM program. This would include MTM information from the first contract enrollment date through the end of the year or through disenrollment from the MTM program (if applicable) – whichever comes first.	Revised language to remove year specific references.	**Bullet 1**: Include all beneficiaries auto-enrolled in the sponsor's MTM program as required under 42 CFR § 423.153(d) and the CMS approved MTM Description. If a beneficiary was auto-enrolled more than once in an MTM program during the contract year, include information related to the first effective enrollment in a MTM program during that year. This would include MTM information from the date of the first contract enrollment that offered an MTM program through the end of the year or through disenrollment from the MTM program (if applicable) – whichever comes first. o When populating this universe, sponsors should use data from the contract year immediately prior to the audit year. For example, for audits conducted in 2017, sponsors should populate this universe using the MTM data from contract year 2016.

Current Section in CMS-10191	Original Language	Clarification or Change	Revised Language
Attachment VI – Medication Therapy Management Program Area Pilot Audit Process and Data Request Table 1 – Column ID J Column ID M Column ID T Column ID AJ Column ID AM Column ID AN	**Field Name**: Beneficiary MTM Enrollment Type **Field Name**: MTM Disenrollment Date **Field Name**: Number of CMR offers declined **Field Name**: TMR Intervention Description(s) **Field Name**: TMR Intervention Delivery Method(s) **Field Name**: TMR Intervention Resolution(s)	Removed fields from the remaining record layout.	None
Attachment VI – Medication Therapy Management Program Area Pilot Audit Process and Data Request Table 1 - Column ID B	**Field Length**: 100	Changed field length	**Field Length**: 50
Attachment VI – Medication Therapy Management Program Area Pilot Audit Process and Data Request Table 1 - Column ID C	**Field Length**: 100	Changed field length	**Field Length**: 50
Attachment VI – Medication Therapy Management Program Area Pilot Audit Process and Data Request Table 1 - Column ID E	**Description**: Effective date of enrollment for the beneficiary into a CY 2016 contract. If the beneficiary was enrolled in multiple contracts in CY 2016, enter the contract enrollment effective date for the first CY 2016 contract ID that offered an MTM program.	Revised language to remove year specific references.	**Description**: Effective date of enrollment for the beneficiary into a contract. If the beneficiary was enrolled in multiple contracts during the year, enter the contract enrollment effective date for the first contract ID that offered an MTM program.

Current Section in CMS-10191	Original Language	Clarification or Change	Revised Language
Attachment VI – Medication Therapy Management Program Area Pilot Audit Process and Data Request Table 1 - Column ID G	**Description**: If the beneficiary was enrolled in multiple contracts in CY 2016, enter the first CY 2016 contract ID that offered an MTM program.	Revised language to remove year specific references.	**Description**: If the beneficiary was enrolled in multiple contracts during the year, enter the first contract ID that offered an MTM program.
Attachment VI – Medication Therapy Management Program Area Pilot Audit Process and Data Request Table 1 - Column ID H	**Description**: Date sponsor determined the beneficiary's eligibility for the CY 2016 MTM program. If the beneficiary was enrolled in multiple contracts in CY 2016, enter the MTM program eligibility determination date for the first CY 2016 contract ID that offered an MTM program.	Revised language to remove year specific references.	**Description**: Date sponsor determined the beneficiary's eligibility for the MTM program. If the beneficiary was enrolled in multiple contracts during the year, enter the MTM program eligibility determination date for the first contract ID that offered an MTM program.
Attachment VI – Medication Therapy Management Program Area Pilot Audit Process and Data Request Table 1 - Column ID I	**Description**: First effective date of auto-enrollment for the beneficiary into the CY 2016 MTM program. For continuing members from CY 2015, this would be the date the member was re-enrolled in the same contract's MTM program for all of CY 2016. For new members (i.e., never enrolled in an MTM program or enrolled in a different contract's MTM program in CY 2015 as compared to CY 2016), this would be the date the beneficiary was newly auto-enrolled in the CY 2016 MTM program.	Revised language to remove year specific references and removed text regarding specification of continuing and new members.	**Description**: First effective date of auto-enrollment for the beneficiary into the MTM program.
Attachment VI – Medication Therapy Management Program Area Pilot Audit Process and Data Request Table 1 - Column ID J	**Column ID K Field Name:** Did beneficiary Opt-out of the MTM Program? **Description**: Yes (Y) or No (N) indicator of whether the beneficiary opted-out of the first auto-enrollment in a CY 2016 MTM program. Opt-out does not include a request to decline individual MTM services.	Column ID K in the previous version is now Column J, provided clarification for populating field such as giving an example of individual MTM services, and revised language to remove year specific references.	**Column ID J Field Name**: Did beneficiary Opt-out of the MTM Program? **Description**: Yes (Y) or No (N) indicator of whether the beneficiary opted-out of the first auto-enrollment in the MTM program. Opt-out does not include a request to decline individual MTM services, such as CMRs.

Current Section in CMS-10191	Original Language	Clarification or Change	Revised Language
Attachment VI – Medication Therapy Management Program Area Pilot Audit Process and Data Request Table 1 - Column ID K	**Column ID L Field Name**: MTM Opt-out Date **Description**: Date beneficiary or authorized representative opted-out of the first CY 2016 MTM program. Submit in CCYY/MM/DD format (e.g., 2016/03/01).	Column ID L in the previous version is now Column ID K, added clarification for populating field when the opt-out was due to death and revised language to remove year specific references.	**Column ID K Field Name**: MTM Opt-out Date **Description**: Date beneficiary or authorized representative opted-out of the first MTM program. If the opt-out was due to death, please include the date the sponsor was made aware of the beneficiary's death if the actual date of death is not available. Submit in CCYY/MM/DD format (e.g., 2016/03/01). Answer NA if the beneficiary did not opt-out of the MTM program.
Attachment VI – Medication Therapy Management Program Area Pilot Audit Process and Data Request Table 1 - Column ID L	**Column ID N Field Name**: MTM Disenrollment Reason **Description**: Reason for disenrollment by the organization from the first CY 2016 MTM program. Valid values are: 01 = Death 02 = Beneficiary disenrolled from contract 03 = Beneficiary/authorized representative requested disenrollment 04 = Other Enter NA if the beneficiary was not disenrolled by the organization from the first CY 2016 MTM program.	Column ID N in the previous version is now Column ID L, replaced the term "disenrolled /disenrollment" with "opt-out," clarified options 3 and 4, and revised language to remove year specific references.	**Column ID L Field Name**: MTM Opt-out Reason **Description**: Reason for opt-out of the first MTM program. Valid values are: 01 = Death 02 = Beneficiary disenrolled from contract 03 = Beneficiary requested opt-out 04 = Other (e.g., authorized representative requested opt-out) Enter NA if the beneficiary did not opt-out of the first MTM program into which they were auto-enrolled.
Attachment VI – Medication Therapy Management Program Area Pilot Audit Process and Data Request Table 1 - Column ID M	**Column ID O Field Name**: MTM Disenrollment Explanation of Reason **Description**: If "03 (Requested Disenrollment)" or "04 (Other)" was selected for the CY 2016 MTM program disenrollment reason, explain why the beneficiary was disenrolled by the organization from the MTM program. Answer "no reason provided" if the beneficiary or authorized representative did not provide an explanation for their request to opt-out of the MTM program. Answer NA if the disenrollment type was "01 (Death)," "02 (Disenrolled from contract)," or the beneficiary was not disenrolled by the organization from the first CY 2016 MTM program.	Column ID O in the previous version is now Column ID M, modified field name, reordered description paragraphs, replaced the "disenrollment/ disenrolled/" with "opt-out" as applicable, and revised language to remove year specific references.	**Column ID M Field Name**: MTM Opt-out Reason Explanation **Description**: Answer NA if the opt-out type was "01 (Death)," "02 (Disenrolled from contract)," or the beneficiary was not disenrolled by the organization from the first MTM program. If "03 (Beneficiary requested opt-out)" was selected for the MTM program opt-out reason, explain why the beneficiary requested to opt-out of the MTM program. Answer "no reason provided" if the beneficiary did not provide an explanation for their request to opt-out of the MTM program. If "04 (Other)" was selected, please further define this option and explain the reason it led to an opt-out.

Current Section in CMS-10191	Original Language	Clarification or Change	Revised Language
Attachment VI – Medication Therapy Management Program Area Pilot Audit Process and Data Request Table 1 - Column ID N	**Column ID P Field Name**: Was the beneficiary residing in a long term care facility? (Column ID P) **Description**: Indicate whether the beneficiary was identified as being in long term care facility either at the time the first CY 2016 CMR was offered or administered. Answer NA if no CMRs were offered or administered in CY 2016.	Column ID P in the previous version is now Column ID N, added guidance about determining beneficiary residence status, and revised language to remove year specific references.	**Column ID Field Name N**: Was the beneficiary residing in a long term care facility? **Description**: Indicate whether the beneficiary was identified as being in long term care facility either at the time the first CMR was offered or administered during the year. Sponsors should use all available information to determine LTC status at the time the MTM services are offered and administered, such as the patient residence code on drug claims data and the Long Term Institutionalized (LTI) resident report. Answer NA if no CMRs were offered or administered during the year.
Attachment VI – Medication Therapy Management Program Area Pilot Audit Process and Data Request Table 1 - Column ID O	**Column ID Q Field Name**: Cognitively Impaired **Description**: Indicate whether the beneficiary was identified as being cognitively impaired either at the time the first CY 2016 CMR was offered or administered? Answer NA if no CMRs were offered or administered in CY 2016.	Column ID Q in the previous version is now Column ID O, revised language to remove year specific references.	**Column ID O Field Name:** Cognitively Impaired **Description**: Indicate whether the beneficiary was identified as being cognitively impaired either at the time the first CMR was offered or administered? Answer NA if no CMRs were offered or administered during the year.
Attachment VI – Medication Therapy Management Program Area Pilot Audit Process and Data Request Table 1 - Column ID P	**Column ID R Field Name**: Authorized Representative **Description**: Indicate whether the beneficiary had an authorized representative (e.g., prescriber, caregiver, health care proxy or legal guardian) either at the time the first CY 2016 CMR was offered or administered? Answer NA if no CMRs were offered or administered in CY 2016.	Column ID R in the previous version is now Column ID P, revised language to remove year specific references.	**Column ID P Field Name**: Authorized Representative **Description**: Indicate whether the beneficiary had an authorized representative (e.g., prescriber, caregiver, health care proxy or legal guardian) either at the time the first CMR was offered or administered during the year? Answer NA if no CMRs were offered or administered during the year.
Attachment VI – Medication Therapy Management Program Area Pilot Audit Process and Data Request Table 1 - Column ID Q	**Column ID S Field Name**: Number of CMRs offered **Description**: Total number of distinct CMRs in CY 2016 for which offers were delivered to the beneficiary, regardless of the number and type of delivery methods attempted for the CMR offer. Answer NA if no CMRs were offered in CY 2016.	Column ID S in the previous version is now Column ID Q, replaced NA with a zero option, and revised language to remove year specific references.	**Column ID Q Field Name**: Number of CMRs offered **Description**: Total number of distinct CMRs for which offers were delivered to the beneficiary, regardless of the number and type of delivery methods attempted for the CMR offer. Answer "0" (zero) if no CMRs were offered during the year.

Current Section in CMS-10191	Original Language	Clarification or Change	Revised Language
Attachment VI – Medication Therapy Management Program Area Pilot Audit Process and Data Request Table 1 - Column ID R	**Column ID U Field Name**: Number of CMRs administered **Description**: Total number of CMRs administered in CY 2016. Answer NA if no CMRs were administered in CY 2016.	Column ID U in the previous version is now Column ID R, replaced NA with a zero option, and revised language to remove year specific references.	**Column ID R Field Name**: Number of CMRs administered **Description**: Total number of CMRs administered during the year. Answer "0" (zero) if no CMRs were administered during the year.
Attachment VI – Medication Therapy Management Program Area Pilot Audit Process and Data Request Table 1 - Column ID S	**Column ID V Field Name**: Number of written CMR summaries **Description**: Total number of written CMR summaries provided in CY 2016. Answer NA if no CMRs were administered in CY 2016 or no written CMR summaries were provided in CY 2016.	Column ID V in the previous version is now Column ID S, replaced NA with a zero option, and revised language to remove year specific references.	**Column ID S Field Name**: Number of written CMR summaries **Description**: Total number of written CMR summaries provided during the year. Answer "0" (zero) if no CMRs were administered or no written CMR summaries were provided during the year.
Attachment VI – Medication Therapy Management Program Area Pilot Audit Process and Data Request Table 1 - Column ID T	**Column ID W Field Name**: Date of 1st CMR offer in 2016 **Description**: Date the first CMR was offered in CY 2016. Answer NA if no CMRs were offered in CY 2016.	Column ID W in the previous version is now Column ID T, revised language to remove year specific references.	**Column ID T Field Name**: Date of 1st CMR offer **Description**: Date the first CMR was offered. Answer NA if no CMRs were offered in during the year.
Attachment VI – Medication Therapy Management Program Area Pilot Audit Process and Data Request Table 1 - Column ID U	**Column ID X Field Name**: 1st CMR offer declined? **Description**: Yes (Y) or No (N) indicator of whether the first CY 2016 CMR offered was declined. Answer NA if no CMRs were offered in CY 2016.	Column ID X in the previous version is now Column ID U revised language to remove year specific references.	**Column ID U Field Name**: 1st CMR offer declined? **Description**: Yes (Y) or No (N) indicator of whether the first CMR offered was declined. Answer NA if no CMRs were offered during the year.
Attachment VI – Medication Therapy Management Program Area Pilot Audit Process and Data Request Table 1 - Column ID V	**Column ID Y Field Name**: Who declined 1st CMR offer? **Description**: Indicate who declined the first CY 2016 CMR offer. Answer NA if no CMRs were offered in CY 2016 or the first CY 2016 CMR offer was not declined.	Column ID Y in the previous version is now Column ID V, revised language to remove year specific references.	**Column ID V Field Name**: Who declined 1st CMR offer? **Description**: Indicate who declined the first CMR offer. Answer NA if no CMRs were offered during the year or the first CMR offer was not declined.

Current Section in CMS-10191	Original Language	Clarification or Change	Revised Language
Attachment VI – Medication Therapy Management Program Area Pilot Audit Process and Data Request Table 1 - Column ID W	**Column ID Z Field Name**: Date 1st CMR administered **Description**: Date the first CMR was administered in CY 2016. Submit in CCYY/MM/DD format (e.g., 2016/03/01). Answer NA if no CMRs were administered in CY 2016.	Column ID Z in the previous version is now Column ID W, revised language to remove year specific references.	**Column ID W Field Name**: Date 1st CMR administered **Description**: Date the first CMR was administered. Submit in CCYY/MM/DD format (e.g., 2016/03/01). Answer NA if no CMRs were administered during the year.
Attachment VI – Medication Therapy Management Program Area Pilot Audit Process and Data Request Table 1 - Column ID X	**Column ID AA Field Name**: 1st CMR Delivery Method **Description**: Indicate the delivery method for the first CMR administered in CY 2015. Answer NA if no CMRs were administered in CY 2016 or the beneficiary/authorized representative declined CY 2016 CMR services.	Column ID AA in the previous version is now Column X, revised language to remove year specific references.	**Column ID X Field Name**: 1st CMR Delivery Method **Description**: Indicate the delivery method for the first CMR administered. Answer NA if no CMRs were administered during the year or the beneficiary/authorized representative declined CMR services.
Attachment VI – Medication Therapy Management Program Area Pilot Audit Process and Data Request Table 1 - Column ID Y	**Column ID AB Field Name**: Qualified Provider of 1st CMR **Description**: Indicate the type of qualified provider that administered the first CY 2016 CMR. Answer NA if no CMRs were administered or the beneficiary/authorized representative declined CY 2016 CMR services.	Column ID AB in the previous version is now Column Y, revised language to remove year specific references.	**Column ID Y Field Name**: Qualified Provider of 1st CMR **Description**: Indicate the type of qualified provider that administered the first CMR. Answer NA if no CMRs were administered during the year or the beneficiary/authorized representative declined CMR services.
Attachment VI – Medication Therapy Management Program Area Pilot Audit Process and Data Request Table 1 - Column ID Z	**Column ID AC Field Name**: 1st CMR Recipient **Description**: Indicate who received the first CY 2016 CMR. Answer NA if no CY 2016 CMRs were offered or the beneficiary/authorized representative declined CY 2016 CMR services.	Column ID AC in the previous version is now Column Z, revised language to remove year specific references.	**Column ID Z Field Name**:1st CMR Recipient **Description**: Indicate who received the first CMR. Answer NA if no CMRs were offered during the year or the beneficiary/authorized representative declined CMR services.
Attachment VI – Medication Therapy Management Program Area Pilot Audit Process and Data Request Table 1 - Column ID AA	**Column ID AD Field Name**: Date 1st Written CMR Summary Provided **Description**: Date the first written CMR summary was provided in CY 2016. Submit in CCYY/MM/DD format (e.g., 2015/03/15). Answer NA if no written CMR summaries were provided in CY 2016.	Column ID AD in the previous version is now Column AA, revised example date and revised language to remove year specific references.	**Column ID AA Field Name**: Date 1st Written CMR Summary Provided **Description**: Date the first written CMR summary was provided in. Submit in CCYY/MM/DD format (e.g., 2016/03/15). Answer NA if no written CMR summaries were provided during the year.

Current Section in CMS-10191	Original Language	Clarification or Change	Revised Language
Attachment VI – Medication Therapy Management Program Area Pilot Audit Process and Data Request Table 1 - Column ID AB	**Column ID AE Field Name**: Number of TMRs performed **Description**: Total number of TMRs performed during CY 2016. Answer NA if no TMRs were performed in CY 2016.	Column ID AE in the previous version is now Column AB, replaced NA with a "0" option, and revised language to remove year specific references	**Column ID AB Field Name**: Number of TMRs performed **Description**: Total number of TMRs performed during the year. Answer "0" (zero) if no TMRs were performed.
Attachment VI – Medication Therapy Management Program Area Pilot Audit Process and Data Request Table 1 - Column ID AC	**Column ID AF Field Name**: Date of 1st TMR performed **Description**: Date of the first TMR performed in CY 2016. Answer NA if no TMRs were performed in CY 2016.	Column ID AF in the previous version is now Column AC, revised language to remove year specific references.	**Column ID AC Field Name**: Date of 1st TMR performed **Description**: Date of the first TMR performed during the year. Answer NA if no TMRs were performed.
Attachment VI – Medication Therapy Management Program Area Pilot Audit Process and Data Request Table 1 - Column ID AD	**Column ID AG Field Name**: Were interventions necessary for any TMRs? **Description**: Yes (Y) or No (N) indicator of whether follow-up interventions were deemed necessary based on the results of any TMRs conducted in CY 2016. Answer NA if no TMRs were performed in CY 2016.	Column ID AG in the previous version is now Column AD, revised language to remove year specific references.	**Column ID AD Field Name**: Were interventions necessary for any TMRs? **Description**: Yes (Y) or No (N) indicator of whether follow-up interventions were deemed necessary based on the results of any TMRs conducted during the year. Answer NA if no TMRs were performed.
Attachment VI – Medication Therapy Management Program Area Pilot Audit Process and Data Request Table 1 - Column ID AE	**Column ID AH Field Name**: Date of 1st TMR requiring intervention(s) **Description**: Date of the first CY 2016 TMR requiring follow-up intervention(s). This may be different than the date of the first CY 2016 TMR performed as some TMRs may not result in the need for an intervention. Answer NA if no TMRs were performed in CY 2016 or interventions were not necessary for any CY 2016 TMRs.	Column ID AH in the previous version is now Column AE, revised language to remove year specific references.	**Column ID AE Field Name**: Date of 1st TMR requiring intervention(s) **Description**: Date of the first TMR requiring follow-up intervention(s). This may be different than the date of the first TMR performed as some TMRs may not result in the need for an intervention. Answer NA if no TMRs were performed during the year or interventions were not necessary for any TMRs.
Attachment VI – Medication Therapy Management Program Area Pilot Audit Process and Data Request Table 1 - Column ID AF	**Column ID AI Field Name**: TMR Intervention Recipient(s) **Description**: Indicate who was targeted to receive the first CY 2016 TMR follow-up intervention(s). Answer NA if no TMRs were performed in CY 2016 or interventions were not necessary for any CY 2016 TMRs.	Column ID AI in the previous version is now Column AF, revised language to remove year specific references.	**Column ID AF Field Name**: TMR Intervention Recipient(s) **Description**: Indicate who was targeted to receive the first TMR follow-up intervention(s). Answer NA if no TMRs were performed during the year or interventions were not necessary for any TMRs.

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Attachment VI – Medication Therapy Management Program Area Pilot Audit Process and Data Request Table 1 - Column ID AG	**Column ID AK Field Name**: TMR Intervention(s) Delivered? **Field Length**: 200 **Description**: Yes (Y) or No (N) indicator of whether the first CY 2016 TMR intervention(s) were delivered. A "No" response would be appropriate when no attempt was made to deliver an intervention or an attempt was unsuccessful (e.g., returned mail or wrong number). Answer "Y" if every previously described intervention was delivered. Answer "N" if none of the previously described interventions were delivered. If some but not all of the first CY 2016 TMR interventions were delivered, specify which interventions were and were not delivered and separate by a number as needed. Use a forward slash (/) to separate the intervention from the delivery status (e.g., 1. Dosage too high/N, 2. Adherence/Y, 3. Needs additional drug therapy/Y). Answer NA if no TMRs were performed in CY 2016 or interventions were not necessary for any CY 2016 TMRs.	Column ID AK in the previous version is now Column AG, reduced field length, added clarification for populating this field, and revised language to remove year specific references.	**Column ID AG Field Name**: TMR Intervention(s) Delivered? **Field Length**: 2 **Description**: Yes (Y), No (N), or Some (S) indicator of whether the first TMR drug therapy problem (DTP) recommendation intervention(s) were delivered. Answer "Y" if every DTP intervention was delivered. Answer "N" when no attempt was made to deliver an intervention or an attempt was unsuccessful (e.g., returned mail or wrong number). Answer "S" if some, but not all of the first TMR DTP interventions were delivered. Answer NA if no TMR interventions were delivered, no TMRs were performed during the year, or interventions were not necessary for any TMRs.
Attachment VI – Medication Therapy Management Program Area Pilot Audit Process and Data Request Table 1 - Column ID AH	**Column ID AL Field Name**: TMR Intervention(s) Delivery Date **Field Length**: 60 **Description**: Date(s) the first CY 2016 TMR intervention(s) were delivered to the targeted recipient(s). Submit in CCYY/MM/DD and separate by a number as needed for multiple dates (e.g., 1. 2016/03/05, 2. 2016/03/05, 3. 2016/03/09). Answer NA if no CY 2016 TMR interventions were delivered, no TMRs were performed in CY 2016, or interventions were not necessary for any CY 2016 TMRs.	Column ID AL in the previous version is now Column AH, reduced field length, added clarification for populating this field, and revised language to remove year specific references.	**Column ID AH Field Name**: TMR Intervention(s) Delivery Date **Field Length**: 10 **Description**: Date the first TMR DTP recommendation intervention was delivered to the targeted recipient. When there are multiple DTP recommendation interventions for the TMR, submit the date that the last one was delivered. Submit in CCYY/MM/DD. Answer NA if no TMR interventions were delivered, no TMRs were performed during the year, or interventions were not necessary for any TMRs.

Current Section in CMS-10191	Original Language	Clarification or Change	Revised Language
Attachment VI – Medication Therapy Management Program Area Pilot Audit Process and Data Request Medication Therapy Management Impact Analysis Template	MTM Program disenrollment date (N/A if not applicable) MTM Program disenrollment reason (N/A if not applicable) MTM Program disenrollment method Date 2015 CMR offered Date 2014 CMR offered – for continuing members Date 2015 CMR declined Method 2015 CMR declined Provider type(s) administering 2015 CMR TMR intervention description(s) (N/A if not applicable) TMR intervention(s) delivery method(s) (N/A if not applicable) TMR interventions declined (NA if not applicable) Date TMR intervention(s) declined (MM/DD/YY) (NA if not applicable) Method TMR declined (Phone/Fax/Mail/Email/Text/Other) (N/A if not applicable)	Removed or changed wording of impact analysis fields	Removed Removed MTM Program opt-out method Date CMR offered Removed Date CMR declined Method CMR declined Provider type(s) administering CMR Removed Removed Removed Removed Removed
Pre-Audit Issue Summary NEW Column B	N/A	Added a column asking for the program area the disclosed issue impacted.	Program Area Impacted (CPE, FA, CDAG, ODAG, SNP-MOC, MTM)
Pre-Audit Issue Summary Column F	Was the issue previously disclosed to CMS (Y/N)	Deleted this column as CMS will only be collecting disclosed issues in 2017.	N/A
Pre-Audit Issue Summary Column H	Date Issue Disclosed (if applicable MM/DD/YYYY)	CMS will only be requesting disclosed issues so we are deleting the “if applicable” and clarifying this field.	Date Issue Previously Disclosed to CMS (MM/DD/YYYY)

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CMS-10191_Supporting Statement A Background	Currently CMS utilizes the following 7 protocols to audit sponsor performance: Formulary Administration (FA), Coverage Determinations, Appeals & Grievances (CDAG), Organization Determination, Appeals and Grievances (ODAG), Special Needs Model of Care (SNPMOC) (only administered on organizations who operate SNPs), Compliance Program Effectiveness (CPE), Medication Therapy Management (MTM) and Provider Network Accuracy (PNA).	Deleted reference to the 7th protocol (PNA).	Currently CMS utilizes the following 6 protocols to audit sponsor performance: Formulary Administration (FA), Coverage Determinations, Appeals & Grievances (CDAG), Organization Determination, Appeals and Grievances (ODAG), Special Needs Model of Care (SNPMOC) (only administered on organizations who operate SNPs), Compliance Program Effectiveness (CPE), and Medication Therapy Management (MTM).
CMS-10191_Supporting Statement A Background	None	Added language about the PNA pilot in response to comments.	Additionally, CMS will continue to pilot the Provider Network Accuracy (PNA) validation in 2017 as described in the HPMS memo released on March 16, 2016 (CY 2016 Pilot Audit Protocol Release and Updates: Medication Therapy Management (MTM) and Provider Network Accuracy (PNA)). There is no protocol for the PNA pilot, as we are simply validating that previously identified errors in a sponsor's online provider directory have been corrected.
CMS-10191_Supporting Statement A Background	Finally, to assist in improving the audit process, CMS sends sponsors a link to a survey (Appendix D) at the end of each audit to complete in order to obtain the sponsors' feedback. The sponsor is not required to complete the survey.	Deleted reference to Appendix D since this survey is not included in PRA and also added a clarifying sentence to explain that the survey is not included in PRA although the time associated with the survey is.	Finally, to assist in improving the audit process, CMS sends sponsors a link to a survey at the end of each audit to complete in order to obtain the sponsors' feedback. The sponsor is not required to complete the survey, and the actual survey is not included in this package, although we accounted for the time associated with taking the survey in our burden estimate.
CMS-10191_Supporting Statement A Background	None	Added a new paragraph relating to a new monitoring effort using the CDAG and ODAG protocols for timeliness.	We have changed the number of respondents for one portion of our audits. For a number of years now, as a result of audit findings, CMS has determined that several sponsors' Part C and Part D appeals data are inaccurate for the calculation of Star Ratings. In these scenarios, CMS lowered the Star Rating for the relevant appeals measures to one star. Sponsors raised concerns with this practice, claiming it unduly harmed sponsors selected for audit in a given year. Based on these concerns and wanting the best data for the Star Ratings, CMS will now request all MA and Part D sponsors to submit universes annually for their coverage/organization determinations and appeals.

Current Section in CMS-10191	Original Language	Clarification or Change	Revised Language
CMS-10191_Supporting Statement A Background (cont'd)			This will allow a more comprehensive review of the accuracy of Part C and D appeals data to calculate Star Ratings. Additionally, since sponsors continue to have deficiencies in these two program areas the collection of this data will support increased oversight of sponsors. The burden estimate now reflects the new number of respondents who will be submitting this audit data.
CMS-10191_Supporting Statement A Use of Information Technology	Sponsoring organizations are able to produce approximately 70% of requested information from their internal systems. CMS is able to obtain the remaining 30% via our internal systems.	Reduced sponsor produced data from 70% to 60% and added a sentence about 10% of data being manual.	Sponsoring organizations are able to produce approximately 60% of requested information from their internal systems. CMS is able to obtain the remaining 30% via our internal systems. The remaining 10% of data is manually entered by the sponsoring organization in response to questionnaires or other audit requests.
CMS-10191_Supporting Statement A Federal Register/Outside Consultation Federal Register	The 2013 protocols were made available to the public for review/comment during the 30-day Federal Register notice on July 18, 2013 (78 FR 42957). The 2017 protocols, provided in this package will be published for a 60-day comment period and subsequent 30-day Federal Register comment period. This package can be updated with specific dates when publication dates are known.	Updated with the dates this package was published for the 60 day comment period. Also updated this section to account for the new timeliness monitoring effort being conducted by CMS.	The 2013 protocols were made available to the public for review/comment during the 30-day Federal Register notice on July 18, 2013 (78 FR 42957). The 2017 protocols, provided in this package were published for a 60-day comment period on June 13, 2016. Following the 60- day comment period, as indicated in the background section above, CMS added an industry- wide timeliness monitoring effort to this package. This monitoring effort will test timeliness of all Part C organization determinations, Part D coverage determinations and Part C and D appeals for each of the 201 sponsoring organizations in the MA and Part D programs to better evaluate sponsors' performance in the respective appeals Star Rating measures and increase monitoring and oversight of sponsor performance overall in these two program areas. This package will be published for a subsequent 30-day Federal Register comment period, and can be updated with specific dates when publication dates are known.
CMS-10191_Supporting Statement A Burden Estimates and Hourly Wages Burden Estimates	Burden Estimates	Changed title for the burden	Burden Estimates for Routine Audits

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CMS-10191_Supporting Statement A Burden Estimates and Hourly Wages Burden Estimates for Routine Audits	Program Director $143 Compliance Officer $70 Management Analyst $84 Quality Assurance Spec. $72 Computers & Information Systems Manager $134 (2) Admin Assistants $38/assistant Claims Analyst $60 Total Salary/hour: $639 $639/ 8 positions= $79.86	Originally estimated 8 staff as the sponsor burden for program audits. Increased our estimate to 30 staff based on comments received.	(2) Program Director $143 Compliance Officer $70 (6) Management Analyst $84 (6) Quality Assurance Spec. $72 (5) Computers & Information Systems Manager $134 (6) Admin Assistants $38/assistant (4) Claims Analyst $60 Total Salary/hour: $2,430 $2,430/ 8 positions= $81.00
CMS-10191_Supporting Statement A Burden Estimates and Hourly Wages Burden Estimates for Industry- Wide Monitoring	None	Created a burden estimate for the new industry- wide monitoring initiative.	We also created a burden estimate for the industry- wide monitoring effort using the same table above. 2 Computer & Information Systems Manager $134/manager 2 Administrative Assistants $38/assistant 2 Claims Analyst $60/analyst Total Salary/hour: $464.00 $2,430/6 positions= $77.33 Taking the average of the above rates, we estimate an average hourly rate of $77.33.
CMS-10191_Supporting Statement A Burden Estimates and Hourly Wages Burden Estimates Routine Audits	Based on our audit strategy, routine audits are defined as the audits scheduled throughout the year. For each sponsoring organization we estimate an average of 80 hours for administrative and systemic work to assemble the requested information, 40 hours to review the information for completeness, 30 minutes to submit the information to CMS, 80 hours for the actual administration of the audit, 20 hours to review and respond to the draft audit report and 30 minutes to complete the post audit survey. We believe an additional 120 hours is spend on validation and audit close out activities. This is a total of approximately 341 hours for each sponsoring organization. The average number of parent organizations that will receive a routine audit annually is 40.	Due to comments received, increased the burden estimate from 341 hours for a program audit to 701. Also added costs of hiring an independent auditing firm into the burden, assuming approximately 65% of sponsors will incur these costs, and assuming the average cost is approximately 250,000 dollars.	Based on our audit strategy, routine audits are defined as the audits scheduled throughout the year. For each sponsoring organization we estimate an average of 200 hours for administrative and systemic work to assemble the requested information, 60 hours to review the information for completeness, 30 minutes to submit the information to CMS, 160 hours for the actual administration of the audit, 40 hours to respond to audit documentation requests, 40 hours to review and respond to the draft audit report and 30 minutes to complete the post audit survey.

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CMS-10191_Supporting Statement A Burden Estimates and Hourly Wages Burden Estimates Routine Audits (cont'd)			We believe an additional 200 hours is spend on validation and audit close out activities. This is a total of approximately 701 hours for each sponsoring organization. The average number of parent organizations that will receive a routine audit annually is 40. However, while this estimate accounts for sponsor time spent before, during and after the audit, for many sponsors there is an additional cost of hiring an Independent Auditing Firm for validation. We are estimating that 65% of sponsors (26 sponsors) will need to hire an Independent Auditing Firm, and while costs for that will vary, we estimate the average cost is $250,000. We will add this cost to the total audit estimate.
CMS-10191_Supporting Statement A Burden Estimates and Hourly Wages Burden Estimates Yearly Industry- Wide Timeliness Monitoring	None	Added an explanation of the burden for the new industry-wide monitoring effort.	**Yearly Industry- Wide Timeliness Monitoring** For the industry- wide monitoring effort, for each sponsoring organization we estimate an average of 80 hours for administrative and systemic work to assemble the requested information, 24 hours to review the information for completeness, 30 minutes to submit the information to CMS, and 16 hours to conduct validation webinars to ensure accurate information. This is a total of approximately 120.5 hours for each sponsoring organization. This monitoring effort will be done on each of the 201 sponsoring organizations each year.
CMS-10191_Supporting Statement A Burden Estimates and Hourly Wages Burden Estimates Attachments CDAG and ODAG Program Area Audit Process and Data Request attachments	We audit approx. 1/6 to ¼ of MA and Part D Plan Sponsors annually.	Added monitoring effort to the attachments.	We audit approx. 1/6 to ¼ of MA and Part D Plan Sponsors annually. Additionally we will monitor timeliness on all sponsors annually.

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CMS-10191_Supporting Statement A Burden Estimates and Hourly Wages Burden Estimates Attachments All IA templates	Only used if a deficiency is cited during the audit. Response time can vary based on the size of the impact. It is usually 24-48 hours.	For all IA templates included in the package, we changed the response timeframe to 10 business days.	Only used if a deficiency is cited during the audit. Response time can vary based on the size of the impact, but should not exceed 10 business days.
CMS-10191_Supporting Statement A Burden Estimates and Hourly Wages Burden Estimates Burden Summary	Total Audit hours (40 x 341)= 13,640 Average hourly wage = 79.86 per hour Total Cost of Collection Effort= $1,089,290	Due to our increased staffing and increased hours (above), as well as the increased burden of the annual monitoring effort, we increased the total cost of collection.	Total audit hours (40 x 701)= 28,040 Average hourly wage = $81.00 per hour Independent Auditing (26 x 250,000) = $6,500,000 Total Cost of Auditing= $8,771,240 Total monitoring hours (201 x 120.5)= 24,220.5 Average hourly wage= $77.33 Total Cost of Monitoring= $1,872,971 Total Cost of the Collection Effort (Total Cost of Auditing + Total Cost of Monitoring) = $10,644,211
CMS-10191_Supporting Statement A Burden Estimates and Hourly Wages Burden Estimates Costs to the Federal Government Contractor Costs	None.	Added costs to contractors for the annual monitoring effort.	For the timeliness monitoring effort, the duties from the contractor include receiving, analyzing and ensuring the completeness of all of the data collected from each of the 201 sponsors. Additionally, contractors will run validation webinars with the sponsors to ensure that the data in each universe contain accurate information. Finally, the contractor will conduct timeliness tests on the universes and report out on the results. We estimate that the cost to the contractors will be 1.7 million dollars for this monitoring effort per year. Therefore we estimate the total contractor costs of this package to be: $7,200,000 + $1,700,000 = $8,900,000

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CMS-10191_Supporting Statement A Burden Estimates and Hourly Wages Burden Estimates Costs to the Federal Government	Staff Cost: $1,620,557 Travel Cost: $132,000 Contractor Costs: $7,200,000 Total Cost: $8,952,557	Added contractor costs for the monitoring effort.	Staff Cost: $1,620,557 Travel Cost: $132,000 Contractor Costs: $8,900,000 Total Cost: $10,652,557
CMS-10191_Supporting Statement A Burden Estimates and Hourly Wages Burden Estimates Changes to the Burden	Under Routine Audits, the total hour burden has been adjusted from 121 hours to 341 hours to more accurately reflect the entirety of the audit process. Additionally, PACE organizations have been removed from this collection request and will be submitted under a different PRA package, as the collection instruments and burden estimates for this collection and a PACE audit differ greatly. Additionally, ad hoc audits have been removed from the burden estimate because ad hoc audits have not exceeded 3 per year in the last 5 years and routine audits have not exceeded 30 in the last 3 years. Therefore, we believe the total number of 40 routine audits more accurately reflects the burden associated with this collection. Consequently, the total burden has been adjusted from 23,595 hours to 13,640 hours.	Increased the Changes to the Burden section in order to account for other changes to the burden (increased hours). We also added the changes to the burden as a result of the new monitoring effort.	Under Routine Audits, the total hour burden has been adjusted from 121 hours to 701 hours to more accurately reflect the entirety of the audit process. Additionally, PACE organizations have been removed from this collection request and will be submitted under a different PRA package, as the collection instruments and burden estimates for this collection and a PACE audit differ greatly. Additionally, ad hoc audits have been removed from the burden estimate because ad hoc audits have not exceeded 3 per year in the last 5 years and routine audits have not exceeded 30 in the last 3 years. Therefore, we believe the total number of 40 routine audits more accurately reflects the burden associated with this collection. Consequently, the total burden has been adjusted from 23,595 hours to 28,040 hours. Additionally, we increased the number of respondents who will submit coverage determinations, organization determinations and appeals universes, as we will be conducting industry-wide monitoring of timeliness to be used for Star Rating purposes. The changes to the burden are reflected and discussed in this document. We have also prepared a detailed crosswalk of all the changes to the burden, as well as crosswalks detailing all changes to documents from the 60-day to the 30-day comment period. Please see the crosswalks for changes.
CMS-10191_Supporting Statement A Collections of Information Employing Statistical Methods	CMS has included 3 questionnaires send during the conduct of the audit, however, no statistical methods are applied to any of our audit information collected.	Updated to reflect all CPE questionnaires, as well as CDAG and ODAG.	CMS has included 6 questionnaires collected during the audit; however, no statistical methods are applied to any of our audit information collected.