Document in CMS-10717 (version 05/2020)	Original Language	Clarification or Change	Revised Language
CPE Protocol Document Title	Compliance Program Effectiveness (CPE)	Technical Clarification	Medicare Part C and Part D Compliance Program Effectiveness (CPE)
CPE Protocol Program Audit Protocol Purpose	To evaluate performance in the areas outlined in this Program Audit Protocol and Data Request related to Compliance Program Effectiveness (CPE). The Centers for Medicare and Medicaid Services (CMS) performs its program audit activities in accordance with the CPE Program Audit Data Request and applying the compliance standards outlined in this Program Audit Protocol and the Program Audit Process Overview document.	Technical Clarification	To evaluate performance in the areas outlined in this Program Audit Protocol and Data Request related to Compliance Program Effectiveness (CPE). The Centers for Medicare and Medicaid Services (CMS) performs its program audit activities in accordance with the CPE Program Audit Data Request and applying the compliance standards outlined in this Program Audit Protocol and the Program Audit Process Overview document. At a minimum, CMS will evaluate cases against the criteria listed below. CMS may review factors not specifically addressed below if it is determined that there are other related CPE requirements not being met.
CPE Protocol Compliance Standard Integrity Testing	Supplemental Documentation: • Compliance Officer Questionnaire • Customized Organizational Structure and Governance PowerPoint Presentation • First-Tier, Downstream, and Related Entities (FDR) Operations Oversight Questionnaire • Standards of Conduct/Code of Conduct document (in effect at any time during the audit review period) • Corporate Compliance/Medicare Compliance/FWA Plan (or similar document in effect at any time during the audit review period) • Risk Assessments and Compliance Performance Mechanisms that show the extent to which Medicare Parts C and/or D operational areas, FDRs, and FWA risks were identified and compliance goals were monitored at any time during the audit review period • Audit and Monitoring Work Plans (for both internal operations and FDRs) in effect at any time during the audit review period • Listing of employees who have involvement in the administration or delivery of Medicare Advantage (Part C) and/or Prescription Drug (Part D) benefits who were hired during the 26-week period preceding and including the date of the audit engagement letter, including the date of hire Universe Table 1: Compliance Oversight Activities (COA)	Technical Clarification	Supplemental Documentation: • Compliance Officer Questionnaire • Customized Organizational Structure and Governance PowerPoint Presentation • First Tier, Downstream, and Related Entities (FDR) Operations Oversight Questionnaire • Standards of Conduct/Code of Conduct document (in effect at any time during the audit review period) • Risk Assessments and Compliance Performance Mechanisms that show the extent to which Medicare Parts C and/or D operational areas, FDRs, and FWA risks were identified and compliance goals were monitored at any time during the audit review period • Audit and Monitoring Work Plans (for both internal operations and FDRs) in effect at any time during the audit review period Universe Table 1: Compliance Oversight Activities (COA)

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CPE Protocol Compliance Standard 1.1	Supplemental Documentation: • Compliance Officer Questionnaire • Standards of Conduct/Code of Conduct document (in effect at any time during the audit review period) [Method of Evaluation] • Articulate the organization/Part D plan sponsor's commitment to comply with all applicable Federal and State standards; • Describe how potential compliance issues are investigated and resolved by the organization/Part D plan sponsor; and	Technical Clarification	Supplemental Documentation: • Compliance Officer Questionnaire • Standards of Conduct/Code of Conduct document (in effect at any time during the audit review period) • Customized Organizational Structure and Governance PowerPoint Presentation Universe Table 1: Compliance Oversight Activities (COA) [Method of Evaluation] • Articulate the Sponsoring organization's commitment to comply with all applicable Federal and State standards; • Describe how potential compliance issues are investigated and resolved by the Sponsoring organization; and Select targeted samples of 20 audit participants and 2 First Tier Entities (FTEs) from attendance logs and impacted individuals and entities from tracers, supporting documentation and/or supplemental documentation. Sample selections will be provided to the Sponsoring organization on the first day of the onsite audit. Evaluate the 20 samples and 2 FTEs via live presentation by Sponsoring organization or review of evidence (e.g., accessibility of compliance policies and procedures and Standards of Conduct via the intranet, FTE attestation).

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CPE Protocol Compliance Standard 1.2	Supplemental Documentation: • Compliance Officer Questionnaire • Customized Organizational Structure and Governance PowerPoint Presentation • Listing of employees who have involvement in the administration or delivery of Medicare Advantage (Part C) and/or Prescription Drug (Part D) benefits who were hired during the 26-week period preceding and including the date of the audit engagement letter, including the date of hire. Supporting Documentation: • Evidence of training [Method of Evaluation] Conduct review of supplemental and supporting documentation via interviews with compliance officer and individuals responsible for SIU/FWA and FDR oversight, as applicable. Assess whether compliance training was provided to: • New employees and new appointment to a chief executive, manager, or governing body member as part of orientation • All employees at least annually Note: Select 20 samples of audit participants from sign in sheets and impacted individuals and entities from tracers, supporting documentation and/or supplemental documentation. Employee attestation of receipt of compliance policies and procedures and Standards of Conduct is an acceptable evidence of compliance training. Sample selections will be provided to the Sponsoring organization one day in advance.	Technical Clarification	Supplemental Documentation: • Compliance Officer Questionnaire • Customized Organizational Structure and Governance PowerPoint Presentation Supporting Documentation: • Employee and governing body members training records [Method of Evaluation] Conduct review of supplemental and supporting documentation via interviews with compliance officer and individuals responsible for SIU/FWA and FDR oversight, as applicable. Assess whether compliance training was provided annually to the compliance officer and organization employees, the Sponsoring organization's chief executive and other senior administrators, managers and governing body members. Use the same 20 samples of audit participants from attendance logs and impacted individuals from tracers, supporting documentation and/or supplemental documentation. Sample selections will be provided to the Sponsoring organization on the first day of the onsite audit. Evaluate the 20 samples via live presentation by Sponsoring organization or review of evidence (e.g., training attendance log, training certificate, employee attestation of receipt of compliance policies and procedures and Standards of Conduct).
CPE Protocol Compliance Standard 2.1	Supplemental Documentation: • Compliance Officer Questionnaire • Customized Organizational Structure and Governance PowerPoint Presentation • Standards of Conduct/Code of Conduct document (in effect at any time during the audit review period)	Technical Clarification	Supplemental Documentation: • Compliance Officer Questionnaire • Standards of Conduct/Code of Conduct document (in effect at any time during the audit review period)

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CPE Protocol Compliance Standard 4.1	[Method of Evaluation] Select 6 tracer cases by targeting those that represent compliance risk to Sponsoring organization's operations and enrollees with the likelihood of touching multiple elements of a compliance program, including intelligence obtained from documentation received with the universe, such as oversight of: • Pharmacy benefit management* • Appeals and grievances, including call routing • First-tier entity* performing function other than below* • Quality improvement program, if applicable* Tracer case selections will be provided to the Sponsoring organization two weeks prior to the Entrance Conference. *Always required	Technical Clarification	[Method of Evaluation] Select 6 tracer case samples by targeting those that represent compliance risk to Sponsoring organization's operations and enrollees with the likelihood of touching multiple elements of a compliance program, including intelligence obtained from documentation received with the universe. When available, choose: • Pharmacy benefit management • Appeals and grievances, including oversight of call routing process • FTE performing a delegated function • Quality improvement program, if applicable Tracer case sample selections will be provided to the Sponsoring organization two weeks prior to the Entrance Conference.
CPE Protocol Compliance Standard 4.2	[Data Request] Universe Table 1: Compliance Oversight Activities (COA) Supporting Documentation: • Evidence of communication to the affected or involved business areas regarding compliance issues • Meeting minutes/agendas, letters/correspondence, etc. to support statements within the tracer case summaries [Method of Evaluation] Ask compliance officer via interview to provide insight on types, including examples, of oral communication.	Technical Clarification	[Data Request Universe Table 1: COA removed] Supporting Documentation: • Evidence of communication to the affected or involved business areas regarding compliance issues • Evidence of oversight activities that occurred as a result of the detected issue(s) • Description of the enrollee and/or Sponsoring organization impact as a result of the detected compliance issues • Meeting minutes/agendas, letters/correspondence, etc. to support statements within the tracer case summaries [Method of Evaluation] Language removed

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CPE Protocol Compliance Standard 4.3	[Data Request] Universe Table 1: Compliance Oversight Activities (COA) Supplemental Documentation: • Corporate Compliance/Medicare Compliance/FWA Plan (or similar document in effect at any time during the audit review period) Supporting Documentation: • Meeting minutes/agendas, letters/correspondence, etc. to support statements within the tracer case summaries [Method of Evaluation] Evaluate 6 tracer case summaries via live presentation by Sponsoring organization, including interviews with compliance officer and individuals responsible for SIU/FWA and FDR oversight, as applicable. Assess whether Sponsoring organization established and implemented: •An effective system for routine monitoring and identification of compliance risks including internal monitoring and audits of its internal operations and FTEs to evaluate compliance with CMS requirements and the overall effectiveness of the compliance program.	Technical Clarification	[Data Request] Universe Table 1: COA removed Supplemental Documentation language removed Supporting Documentation: • Evidence of oversight activities that occurred as a result of the detected issue(s) • Description of the enrollee and/or Sponsoring organization impact as a result of the detected compliance issues • Meeting minutes/agendas, letters/correspondence, etc. to support statements within the tracer case summaries [Method of Evaluation] Evaluate the 6 tracer case summaries via live presentation by Sponsoring organization, including interviews with compliance officer and individuals responsible for SIU/FWA and FDR oversight, as applicable. Assess whether Sponsoring organization established and implemented an effective system for routine monitoring and identification of compliance risks including internal monitoring and audits of its internal operations and FTEs to evaluate compliance with CMS requirements and the overall effectiveness of the compliance program.
CPE Protocol Compliance Standard 4.4	[Data Request] Universe Table 1: Compliance Oversight Activities (COA) Supporting Documentation: • Policies and procedures reviewed and revised in response to detecting and correcting compliance issues • Training provided in response to identifying and correcting compliance issues • Evidence of accountability and oversight by the Sponsoring organization when issues are detected at the FDR level, including response and correction procedures, communication, educational requirements and engagement with the compliance department, operational areas and oversight entities • Meeting minutes/agendas, letters/correspondence, etc. to support statements within the tracer case summaries	Technical Clarification	[Data Request] Universe Table 1: COA removed Supporting Documentation: • Policies and procedures reviewed and revised in response to detecting and correcting compliance issues • Training provided in response to identifying and correcting compliance issues • Evidence of oversight activities that occurred as a result of the detected issue(s) • Evidence of accountability and oversight by the Sponsoring organization when issues are detected at the FDR level, including response and correction procedures, communication, educational requirements and engagement with the compliance department, operational areas and oversight entities • Description of the enrollee and/or Sponsoring organization impact as a result of the detected compliance issues • Meeting minutes/agendas, letters/correspondence, etc. to support statements within the tracer case summaries

Document in CMS-10717 (version 05/2020)	Original Language	Clarification or Change	Revised Language
CPE Protocol Program Audit Data Request Audit Engagement and Universe Submission Phase Universe Submissions	Sponsoring organizations must submit each universe, comprehensive of all contracts and Plan Benefit Packages (PBP) identified in the audit engagement letter, in either Microsoft Excel (.xlsx) file format with a header row or Text (.txt) file format without a header row.	Technical Clarification	Sponsoring organizations must submit the universe, comprehensive of all contracts and Plan Benefit Packages (PBP) identified in the audit engagement letter, in either Microsoft Excel (.xlsx) file format with a header row or Text (.txt) file format without a header row.
CPE Protocol Table 1: COA Table Instructions	•Include all auditing, monitoring, and investigation activities (including compliance and fraud, waste and abuse (FWA) activities) that were initiated, performed, re-opened or closed, related to the Sponsoring organization's Medicare Advantage (Part C) and/or Prescription Drug (Part D) business during the universe request period. Include the activity if the Activity Start Date (Column ID G) or Activity Completion Date (Column ID H) falls within the universe request period. •Use consistent naming conventions throughout the submitted universe. For instance, when the name of the Sponsoring organization's component (e.g., department, operational area, business unit) is requested, a consistent response (e.g., Agent Broker vs. Agent/ Broker vs. vs. A/B) must be used.	Technical Clarification	• Include all auditing, monitoring, and investigation activities (including compliance and fraud, waste and abuse (FWA) activities) that were initiated, performed, or closed, related to the Sponsoring organization's Medicare Advantage (Part C) and/or Prescription Drug (Part D) business during the universe request period. Include the activity if the Activity Start Date (Column ID G) or Activity Completion Date (Column ID H) falls within the universe request period, or if the activity is still in progress but the start and completion dates fall outside the universe period. • Daily activities should be rolled up into an aggregate time period of one month and included in the universe each time the aggregate time period into which they were rolled occurred. • Use consistent naming conventions throughout the submitted universe. For instance, when the name of the Sponsoring organization's component (e.g., department, operational area, business unit) is requested, a consistent response (e.g., Agent Broker vs. Agent/ Broker vs. AB vs. A/B) must be used. • Ensure that all fields are populated; do not leave any fields blank (e.g. if there are no deficiencies enter "0" for Number of Deficiencies in Column ID I, and Column ID J (Description of Deficiencies) would be "NA ".

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CPE Protocol Component Table 1: Column ID A	[Description] Enter the name of the Sponsoring organization's department, operational area, or FTE conducting the oversight activity (e.g., PBM Claims Department, SIU, etc.).	Technical Clarification	[Description] Enter the name of the Sponsoring organization's department, operational area, or First Tier Entity that is the focus of the oversight activity.
CPE Protocol Activity Type Table 1: Column ID B	[Description] Enter the activity type as: • auditing • monitoring • investigating non-compliance • investigating FWA	Technical Clarification	[Description] Enter the activity type as: • Auditing • Monitoring • Investigations
CPE Protocol Compliance or FWA? Table 1: Column ID C	[Description] Enter whether the activity was: • compliance • FWA • Both	Technical Clarification	[Description] Enter whether the activity was: • Compliance • FWA • Both
CPE Protocol Activity Frequency Table 1: Column ID D	[Description] Enter the frequency of the oversight activity as: • daily • weekly • monthly • quarterly • annually • ad-hoc Field Length: 10	Technical Clarification	[Description] Enter the frequency of the oversight activity. Valid values include but are not limited to: • Daily • Weekly • Bi-monthly • Monthly • Quarterly • Semi-annually • Annually • Ad-hoc Field Length: 30
CPE Protocol Activity Description Table 1: Column ID F	[Description] Enter who is the subject of the oversight activity. Then enter a description of the activity (e.g., operational area, training requirements, timeliness, accuracy of organization determinations and notifications, messaging errors, contractual agreements, unannounced or onsite audits, spot checks, compliance monitoring, targeted or stratified sampling, audit protocols).	Technical Clarification	[Description] Provide a description of the activity (e.g., operational area, training requirements, timeliness, accuracy of organization determinations and notifications, messaging errors, contractual agreements, unannounced or onsite audits, spot checks, compliance monitoring, targeted or stratified sampling, audit protocols).

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CPE Protocol Activity Start Date Table 1: Column ID G	[Description] Enter the date that the specific activity was initiated or reopened. For example, if the Sponsoring organization started an audit of the appeals process/ function within the Sponsoring organization on January 1, 2020, that is the date that would be used for the date the activity started.	Technical Clarification	[Description] Enter the date that the specific activity was initiated. For example, if the Sponsoring organization started an audit of the appeals process/ function within the Sponsoring organization on January 1, 2020, that is the date that would be used for the date the activity started.
CPE Protocol Description of Deficiencies Table 1: Column ID J	N/A	Technical Clarification - Added field & relettered remaining Column IDs within the table.	Field Type: CHAR Always Required Field Length: 1000 Description: Provide a summary of all deficiencies, findings or issues identified during the oversight activity. If the oversight activity is identified in the pre-audit issue summary submitted to CMS, please include the issue number. Enter TBD if deficiencies have yet to be identified for an ongoing activity.
CPE Protocol Supplemental Documentation Requests	1. Compliance Officer Questionnaire 2. Customized Organizational Structure and Governance PowerPoint Presentation 3. First-Tier, Downstream, and Related Entities (FDR) Operations Oversight Questionnaire 4. Standards of Conduct/Code of Conduct document (in effect at any time during the audit review period) 5. Corporate Compliance/Medicare Compliance/FWA Plan (or similar document in effect at any time during the audit review period) 6. Risk Assessments and Compliance Performance Mechanisms that show the extent to which Medicare Parts C and/or D operational areas, FDRs, and FWA risks were identified and compliance goals were monitored at any time during the audit review period. Compliance performance mechanisms could include (but are not limited to) monthly compliance dashboards that track the goals and statuses of the identified risk/issue, self-assessments, surveys, or any other tools or mechanisms (outside the risk assessment) that are used to identify potential compliance risks. 7. Audit and Monitoring Work Plans (for both internal operations and FDRs) in effect at any time during the audit review period 8. Listing of employees who have involvement in the administration or delivery of Medicare Advantage (Part C) and/or Prescription Drug (Part D) benefits who were hired during the 26-week period preceding and including the date of the audit engagement letter, including the date of hire	Technical Clarification	1. Compliance Officer Questionnaire 2. Customized Organizational Structure and Governance PowerPoint Presentation 3. First Tier, Downstream, and Related Entities (FDR) Operations Oversight Questionnaire 4. Standards of Conduct/Code of Conduct document (in effect at any time during the audit review period) 5. Risk Assessments and Compliance Performance Mechanisms that show the extent to which Medicare Parts C and/or D operational areas, FDRs, and FWA risks were identified and compliance goals were monitored at any time during the audit review period. Compliance performance mechanisms could include (but are not limited to) monthly compliance dashboards that track the goals and statuses of the identified risk/issue, self-assessments, surveys, or any other tools or mechanisms (outside the risk assessment) that are used to identify potential compliance risks. 6. Audit and Monitoring Work Plans (for both internal operations and FDRs) in effect at any time during the audit review period

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CPE Protocol Tracer Case Summary Submissions	i. All communications within the Sponsoring organization and with its FDRs regarding the issue.	Technical Clarification	i. All relevant communications within the Sponsoring organization and with its FDRs regarding the issue.
CPE Protocol Supporting Documentation Submissions	During audit field work, CMS will review 6 tracer case summaries in addition to 20 employee samples of audit participants selected from sign in sheets, tracers, supplemental documentation and/or supporting documentation to determine whether the Sponsoring organization is compliant with its Part C and/or Part D contract requirements.	Technical Clarification	During audit field work, CMS will review 6 tracer case summaries in addition to 20 employee samples of audit participants and 2 FTEs selected from attendance logs, tracers, supplemental documentation and/or supporting documentation to determine whether the Sponsoring organization is compliant with its Part C and/or Part D contract requirements.
CPE Compliance Officer Questionnaire (CO-Q)	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.	Technical Clarification	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.
CPE Compliance Officer Questionnaire (CO-Q)	Please specifically note the following when completing the questionnaire: • "FDRs" refer to the organization's first tier, downstream, and related entities contracted to perform an administrative or healthcare service to enrollees on behalf of the organization.	Technical Clarification	Please specifically note the following when completing the questionnaire: [Removed FDRs language] [Added language below] • "First Tier Entity" refers to any party that enters into a written agreement, acceptable to CMS, with an organization to provide administrative services or health care services to a Medicare eligible individual under the Part C and/or Part D program. • "Downstream Entity" refers to any party that enters into a written agreement, acceptable to CMS, with persons or entities involved with the Medicare Part C and/or Part D benefits below the level of the arrangement between an organization and a first tier entity. These written agreements continue down to the level of the ultimate provider of both health and administrative services. • "Related Entity" refers to any entity that is related to an organization by common ownership or control, and o performs some of an organization's management functions under contract or delegation, o furnishes services to Medicare enrollees under an oral or written agreement, or o Leases real property or sells materials to the organization at a cost of more than $2,500 during a contract period.

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CPE Compliance Officer Questionnaire (CO-Q)	1. How long have you been employed with the sponsoring organization and served as the Medicare Compliance Officer?	Technical Clarification	1. How long have you been employed with the Sponsoring organization and served as the Medicare Compliance Officer?
CPE Compliance Officer Questionnaire (CO-Q)	3. Do you have any other responsibilities in addition to being the Compliance Officer for this sponsoring organization? If yes, please describe those positions and responsibilities.	Technical Clarification	3. Do you have any other responsibilities in addition to being the Compliance Officer for this Sponsoring organization? If yes, please describe those positions and responsibilities.
CPE Compliance Officer Questionnaire (CO-Q)	4. What resources do you use to keep current on CMS requirements, and, compliance, audit, and enforcement information and activities? How is this information shared throughout your organization & FDRs?	Technical Clarification	4. What resources do you use to keep current on CMS requirements, and, compliance, audit, and enforcement information and activities? How is this information shared throughout your organization and First Tier, Downstream, and Related Entities?
CPE Compliance Officer Questionnaire (CO-Q)	6. How is the compliance department informed and kept up-to-date on tasks and assignments that have been delegated to internal operations and FDRs?	Technical Clarification	6. How is the compliance department informed and kept up-to-date on tasks and assignments that have been delegated to internal operations and First Tier, Downstream, and Related Entities?
CPE Compliance Officer Questionnaire (CO-Q)	7. Briefly explain how you would handle a compliance issue that involves a Medicare operational area and/or a FDR that impacts enrollees' timely access to their health or drug benefits? Provide an example if you have one.	Technical Clarification	7. Briefly explain how you would handle a compliance issue that involves a Medicare operational area and/or a First Tier, Downstream, and Related Entity that impacts enrollees' timely access to their health or drug benefits? Provide an example if you have one.
CPE Compliance Officer Questionnaire (CO-Q)	8. Describe how you handle, or would handle poor compliance performance of Medicare operations within your sponsoring organization.	Technical Clarification	8. Describe how you handle, or would handle poor compliance performance of Medicare operations within your Sponsoring organization.
CPE Compliance Officer Questionnaire (CO-Q)	12. How do you measure employee, governing body member, and FDR awareness and understanding of the compliance program?	Technical Clarification	12. How do you measure employee, governing body member, and First Tier, Downstream, and Related Entity awareness and understanding of the compliance program?
CPE Compliance Officer Questionnaire (CO-Q)	14. What is your process to ensure written policies and procedures and standards of conduct are available within your sponsoring organization?	Technical Clarification	14. What is your process to ensure written policies and procedures and standards of conduct are available within your Sponsoring organization?
CPE Compliance Officer Questionnaire (CO-Q)	N/A	Technical Clarification - Added question & renumbered remaining questions	17. Since CMS no longer collects call logs for program audit purposes, what has your organization done to ensure that incoming requests are handled properly?

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CPE First Tier Downstream and Related Entities Operations Oversight Questionnaire (FDR-Q)	Please specifically note the following when completing the questionnaire: • "FDRs" refer to the organization's first tier, downstream, and related entities contracted to perform an administrative or healthcare service to enrollees on behalf of the organization. • "Related Entity" refers to any entity that is related to an organization by common ownership or control, and o performs some of the an organization's management functions under contract or delegation	Technical Clarification	Please specifically note the following when completing the questionnaire: [Removed FDRs language] • "Related Entity" refers to any entity that is related to an organization by common ownership or control, and o performs some of an organization's management functions under contract or delegation
CPE First Tier Downstream and Related Entities Operations Oversight Questionnaire (FDR-Q)	2. How long has the individual identified in Question 1 been employed with the organization and been involved with overseeing FDRs?	Technical Clarification	2. How long has the individual identified in Question 1 been employed with the organization and been involved with overseeing First Tier, Downstream, and/or Related Entities?
CPE First Tier Downstream and Related Entities Operations Oversight Questionnaire (FDR-Q)	3. Briefly describe your process for determining if a potential FDR is capable of complying with contractual, and regulatory obligations. Who or which business operations are responsible for this process.	Technical Clarification	3. Briefly describe your process for determining if a potential First Tier, Downstream, and/or Related Entity is capable of complying with contractual, and regulatory obligations. Who or which business operations are responsible for this process.
CPE First Tier Downstream and Related Entities Operations Oversight Questionnaire (FDR-Q)	5. Please describe your criteria/process for determining which delegated entities are identified as FDRs subject to Medicare compliance requirements.	Technical Clarification	5. Please describe your criteria/process for determining which delegated entities are identified as First Tier, Downstream, and/or Related Entities subject to Medicare compliance requirements.
CPE First Tier Downstream and Related Entities Operations Oversight Questionnaire (FDR-Q)	7. Describe the communications process between the Compliance Department and FDR Oversight for Medicare requirements, policy updates, performance concerns, or issues with FDRs. At minimum, please include the process for communications about, or for, first tier entities such as your PBM, appeals and grievances, enrollment/membership functions, coverage or claims adjudication, network management, etc.	Technical Clarification	7. Describe the communications process between the Compliance Department and First Tier, Downstream, and/or Related Entity Oversight for Medicare requirements, policy updates, performance concerns, or issues with First Tier, Downstream, and/or Related Entities. At minimum, please include the process for communications about, or for, first tier entities such as your PBM, appeals and grievances, enrollment/membership functions, coverage or claims adjudication, network management, etc.

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CPE First Tier Downstream and Related Entities Operations Oversight Questionnaire (FDR-Q)	8. How do you ensure compliance issues involving a FDR is communicated to upper management (e.g., compliance committee, senior managers, Board of Directors, CEO)? Please provide a recent example/scenario.	Technical Clarification	8. How do you ensure compliance issues involving a First Tier, Downstream, and/or Related Entity is communicated to upper management (e.g., compliance committee, senior managers, Board of Directors, CEO)? Please provide a recent example/scenario.
CPE First Tier Downstream and Related Entities Operations Oversight Questionnaire (FDR-Q)	9. How do you share information with FDRs on your organization's culture, compliance and productivity expectations, CMS regulations, and policy for the Medicare function performed on the organization's behalf?	Technical Clarification	9. How do you share information with First Tier, Downstream, and/or Related Entities on your organization's culture, compliance and productivity expectations, CMS regulations, and policy for the Medicare function performed on the organization's behalf?
CPE First Tier Downstream and Related Entities Operations Oversight Questionnaire (FDR-Q)	10. What types of monitoring reports do you receive from FDRs, and how often?	Technical Clarification	10. What types of monitoring reports do you receive from First Tier, Downstream, and/or Related Entities, and how often?
CPE First Tier Downstream and Related Entities Operations Oversight Questionnaire (FDR-Q)	12. What happens or is the consequence if a FDR fails to satisfactorily implement a corrective action plan or commits a serious act of non-compliance with a Medicare requirement that affects enrollees from receiving their health care or drug benefit appropriately or timely?	Technical Clarification	12. What happens or is the consequence if a First Tier, Downstream, and/or Related Entity fails to satisfactorily implement a corrective action plan or commits a serious act of noncompliance with a Medicare requirement that affects enrollees from receiving their health care or drug benefit appropriately or timely?
FA Protocol Program Audit Protocol Purpose	To evaluate performance in the areas outlined in this Program Audit Protocol and Data Request related to Part D Formulary and Benefit Administration (FA). The Centers for Medicare and Medicaid Services (CMS) performs its program audit activities in accordance with the FA Program Audit Data Request and applying the compliance standards outlined in this Program Audit Protocol and the Program Audit Process Overview document.	Technical Clarification	To evaluate performance in the areas outlined in this Program Audit Protocol and Data Request related to Part D Formulary and Benefit Administration (FA). The Centers for Medicare and Medicaid Services (CMS) performs its program audit activities in accordance with the FA Program Audit Data Request and applying the compliance standards outlined in this Program Audit Protocol and the Program Audit Process Overview document. At a minimum, CMS will evaluate cases against the criteria listed below. CMS may review factors not specifically addressed below if it is determined that there are other related FA requirements not being met.

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FA Protocol Method of Evaluation column of the protocol	[Font Sizes 8, 9 and 10]	Technical Clarification	[Font Size 10]
FA Protocol Compliance Standard Universe Integrity Testing	[Data Request] Universe Table 1: Rejected Claims Formulary Administration (RCFA) Universe Table 2: Rejected Claims Transition- New Contract Year (RCT-N) Universe Table 3: Rejected Claims Transition- Previous Contract Year (RCT-P) [Method of Evaluation] Select 5 cases from each universe, Tables 1 through 3, for a total of 15 cases. Prior to field work, CMS will schedule a webinar with the Sponsoring organization to verify accuracy of data within each rejected claims universe submission for each of the sampled cases. Sample selections will be provided to the Sponsoring organization approximately one hour prior to the scheduled webinar.	Technical Clarification	[Data Request] Universe Table 1: Rejected Claims Formulary Administration (RCFA) Universe Table 2: Rejected Claims Transition (RCT) [Method of Evaluation] Select 5 cases from each universe, Tables 1 and 2, for a total of 10 cases. Prior to field work, CMS will schedule a webinar with the Sponsoring organization to verify accuracy of data within each rejected claims universe submission for each of the sampled cases. Sample selections will be provided to the Sponsoring organization approximately one hour prior to the scheduled webinar.
FA Protocol Compliance Standard 1.1 Compliance Standard 1.2	[Criteria Effective 01/01/2021] Contract with Part D Sponsors	Technical Clarification	[Criteria Effective 01/01/2021] Part D Contract with CMS
FA Protocol Compliance Standard 1.5	[Data Request] Universe Table 1: Rejected Claims Formulary Administration (RCFA) Universe Table 2: Rejected Claims Transition- New Contract Year (RCT-N) Universe Table 4: Prescription Drug Event (PDE) Data	Technical Clarification	[Data Request] Universe Table 1: Rejected Claims Formulary Administration (RCFA) Universe Table 2: Rejected Claims Transition (RCT) Universe Table 3: Prescription Drug Event (PDE) Data

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FA Protocol Compliance Standard 2.1	[Data Request] Universe Table 2: Rejected Claims Transition- New Contract Year (RCT-N) Universe Table 3: Rejected Claims Transition- Previous Contract Year (RCT-P) Table 4: Prescription Drug Event (PDE) Data Universe Table 5: New Enrollee (NE) [Method of Evaluation] Select a targeted sample of up to 15 claims from Universe Tables 2 and 3 for continuing enrollees as follows: 7 claims for non-protected class drugs and 8 claims for protected class drugs. If the target number of claims are not available for one group (e.g. protected class drugs), consider supplementing with claims from the other group (e.g., non-protected class drugs). Select a targeted sample of up to 15 claims from Universe Tables 2 and 3 for new enrollees as follows: 7 claims for non-protected class drugs and 8 claims for protected class drugs. If the target number of claims are not available for one group (e.g. protected class drugs), consider supplementing with claims from the other group (e.g., non-protected class drugs). • New and continuing members eligible for a transition fill are afforded the full transition benefit consistent with the submitted enrollment and disenrollment date. • For continuing members that have prior history of the drug determine the type of change that occurred between contract years for that drug. • Enrollees with a November or December effective enrollment date are afforded a full new enrollee transition benefit as well as a full continuing enrollee transition benefit, if applicable	Technical Clarification	[Data Request] Universe Table 1: Rejected Claims Formulary Administration (RCFA) Universe Table 2: Rejected Claims Transition (RCT) Universe Table 3: Prescription Drug Event (PDE) Data Universe Table 4: New Enrollee (NE) [Method of Evaluation] Select a targeted sample of up to 15 claims from Universe Table 2 for continuing enrollees. Select a targeted sample of up to 15 claims from Universe Table 2 for new enrollees. • New and continuing enrollees eligible for a transition fill are afforded the full transition benefit consistent with the submitted enrollment and disenrollment date. • For continuing enrollees that have prior history of the drug determine the type of change that occurred between contract years for that drug. • Enrollees with a November or December effective enrollment date are afforded a full continuing enrollee transition benefit, if applicable.

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FA Protocol Compliance Standard 2.2	[Data Request] Universe Table 2: Rejected Claims Transition- New Contract Year (RCT-N) Universe Table 3: Rejected Claims Transition- Previous Contract Year (RCT-P) Universe Table 4: Prescription Drug Event (PDE) Data Universe Table 5: New Enrollee (NE)	Technical Clarification	[Data Request] Universe Table 1: Rejected Claims Formulary Administration (RCFA) Universe Table 2: Rejected Claims Transition (RCT) Universe Table 3: Prescription Drug Event (PDE) Data Universe Table 4: New Enrollee (NE)
FA Protocol Audit Engagement and Universe Submission Phase Universe Requests	Universe Requests 1. Universe Table 1: Rejected Claims Formulary Administration (RCFA) Record Layout 2. Universe Table 2: Rejected Claims Transition – New Contract Year (RCT-N) Record Layout 3. Universe Table 3: Rejected Claims Transition – Previous Contract Year (RCT-P) Record Layout 4. Universe Table 4: Prescription Drug Event (PDE) Data Record Layout 5. Universe Table 5: New Enrollee (NE) Record Layout	Technical Clarification	Universe Requests 1. Universe Table 1: Rejected Claims Formulary Administration (RCFA) Record Layout 2. Universe Table 2: Rejected Claims Transition (RCT) Record Layout 3. Universe Table 3: Prescription Drug Event (PDE) Data Record Layout 4. Universe Table 4: New Enrollee (NE) Record Layout
FA Protocol Universe Record Layout/ Scope of Universe Request	Table 3: Submit all rejected claims with dates of service for November and December of the contract year immediately prior to the audit year for all enrollees with effective enrollment dates of November or December of the contract year immediately prior to the audit year. Table 4: Submit all final action PDEs accepted by CMS with dates of service September – December of the contract year immediately prior to the audit year for all enrollees in Tables 2 and 3. Table 5: Sponsoring organizations with – • < 100,000 enrollees: submit all enrollees with effective enrollment dates 11/1/previous audit year (i.e., 2018) through 2/1/current audit year (i.e., 2019). • ≥ 100,000 enrollees: submit all enrollees with effective enrollment dates 11/1/previous audit year (i.e., 2018) through 1/1/current audit year (i.e., 2019).	Technical Clarification	Table 3: Submit all final action PDEs accepted by CMS with dates of service September – December of the contract year immediately prior to the audit year for all enrollees in Table 2 and enrollees with effective enrollment dates of November and December of the contract year immediately prior to the audit year. Table 4: Sponsoring organizations with – • < 100,000 enrollees: submit all enrollees with effective enrollment dates 11/1/previous audit year through 2/1/current audit year. • ≥ 100,000 enrollees: submit all enrollees with effective enrollment dates 11/1/previous audit year through 1/1/current audit year.

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FA Protocol Universe Requests	1. Universe Table 1: Rejected Claims Formulary Administration (RCFA) Record Layout 2. Universe Table 2: Rejected Claims Transition – New Contract Year (RCT-N) Record Layout 3. Universe Table 3: Rejected Claims Transition – Previous Contract Year (RCT-P) Record Layout	Technical Clarification	Please use the guidance below for the following record layouts: Universe Table 1: Rejected Claims Formulary Administration (RCFA) Record Layout Universe Table 2: Rejected Claims Transition – New Contract Year (RCT-N) Record Layout
FA Protocol Contract ID Tables 1-2: Column ID H Table 3: Column ID F Table 2IA: Column ID B Table 4: Column ID H	[Table 1, Table 2, Table 3 & Table 2IA Description] Enter the contract number (e.g., H1234) of the organization. [Table 4 Description] Enter the contract number (e.g., H1234, S1234) of the organization.	Technical Clarification	[Table 1, Table 2, Table 3 & Table 2IA Description] Enter the contract number (e.g., H1234) of the Sponsoring organization. [Table 4 Description] Enter the contract number (e.g., H1234, S1234) of the Sponsoring organization.
FA Protocol NDC Table 1-2: Column ID J Table 3: Column ID H Table 2IA: Column ID I Related Drug NDC Table 2IA: Column ID V	[Description] Enter the 11-Digit National Drug Code using the NDC 11 format. Remove special characters separating the labeler, product, and trade package size. When less than 11 characters or a blank field is submitted by the pharmacy or delegate, populate the field as submitted. If the pharmacy submits a value greater than 11 characters, enter "valueXeeded" in the field. For multi-ingredient compound claims populate the field with the NDC of the most expensive drug (or as submitted on the associated PDE). When compound claims do not include any Part D drug products, populate the field with "00000000000" consistent with the NDC 11 format.	Technical Clarification	[Description] Enter the 11-Digit National Drug Code using the NDC 11 format. Remove special characters separating the labeler, product, and trade package size. When less than 11 characters or a blank field is submitted by the pharmacy or delegate, populate the field as submitted. If the pharmacy submits a value greater than 11 characters, enter "valueXeeded" in the field. For multi-ingredient compound claims populate the field with the NDC as submitted on the associated PDE.
FA Protocol Universe Table 3: Prescription Drug Event (PDE) Data Record Layout	[Table Name] Universe Table 4: Prescription Drug Event (PDE) Data Record Layout	Technical Clarification	[Table Name] Universe Table 3: Prescription Drug Event (PDE) Data Record Layout

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FA Protocol Table 3: PDE Table Instructions	o Include PDEs only for the period requested for enrollees from the rejected claims transition universes Tables 2 and 3 (including enrollees enrolled in employer plans and Medicare-Medicaid Plans (MMPs)).	Technical Clarification	o Include PDEs only for the period requested for enrollees from the rejected claims transition universe Table 2 (including enrollees enrolled in employer plans and Medicare-Medicaid Plans (MMPs)).
FA Protocol Universe Table 4: New Enrollee (NE) Record Layout	[Table Name] Universe Table 5: New Enrollee (NE) Record Layout	Technical Clarification	[Table Name] Universe Table 4: New Enrollee (NE) Record Layout
FA Protocol Audit Field Work Phase Supporting Documentation Submissions	During audit field work, CMS will review 30 samples selected from Table 1 and up to 30 samples from Tables 2 and 3 to determine whether the Sponsoring organization is compliant with its Part D contract requirements.	Technical Clarification	During audit field work, CMS will review 30 samples selected from Table 1 and up to 30 samples from Table 2 to determine whether the Sponsoring organization is compliant with its Part D contract requirements.
FA Protocol Table 1IA: IAS Table Instructions	• Include all medications and enrollees impacted by the issue of non-compliance. This should include medications affected by rejected claims in addition to non-compliant authorization records that may not have an associated rejected claim.	Technical Clarification	• Include all medications impacted by the issue, including those that may not have an associated rejected claim.
FA Protocol Methodology for Identifying Impact of Noncompliance List of Medications Affected Table 1IA: Column IDs A & B	N/A	Technical Clarification-Added Fields & relettered remaining Column IDs in the table	Field Type: CHAR Always Required Field Length: 4,000 Description: Describe the process undertaken to determine the medications and enrollees impacted by the issue of noncompliance. Description: Provide the list of medications at the RXCUI level (by drug name, strength, and dosage form) affected by the issue in vertical list format.
FA Protocol Table 2IA: ENR-IA Table Instructions	• Include all enrollees impacted by the issue of non-compliance. • Include enrollees affected by rejected claims in addition to non-compliant authorization records that may not be associated with a claim. For enrollees that have an inappropriate authorization record with no associated rejected claim, Sponsoring organizations should only complete the following fields: Cardholder ID, Contract ID, Plan ID, Effective Date of Enrollment, Is enrollee currently enrolled, and Drug Name and Strength.	Technical Clarification	• Include the following data for impacted enrollees: • Rejected claims affected by the issue of noncompliance; • Inaccurate records (i.e. authorization, enrollment records) that may not be associated with a rejected claim. In this scenario, Sponsoring organizations should only complete the following fields: Enrollee ID, Contract ID, Plan Benefit Package (PBP), Enrollment Effective Date, Is enrollee currently enrolled, and Drug Name and Strength (if applicable).

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FA Protocol Process Date of Subsequent Paid Claim Table 2IA: Column ID R	[Description] Enter the date of the paid claim subsequent to the rejected claim having the same RXCUI. Submit in (CCYY/MM/DD) format (e.g., 2020/01/01). Enter NA if never received.	Technical Clarification	[Description] Enter the date of the paid claim subsequent to the rejected claim for the medication utilizing the same RXCUI, GPI, GCN, or HICL. Submit in CCYY/MM/DD format. (e.g., 2020/01/01). Enter NA if never received.
FA Protocol Number of Hours Enrollee Went Without Medication (Target or Related) Table 2IA: Column ID AA	[Description] If the value in the field "Number of Days Enrollee Went Without Medication" is 0 or 1. Enter the difference between the date and time of the rejected and paid claim. A whole number is acceptable in this field.	Technical Clarification-removed field & relettered remaining Column IDs in the table	N/A
FA Supplemental Questionnaire	1. If yes, do not include these enrollees in Table 5: New Enrollee Universe. If no, include these enrollees in Table 5: New Enrollee Universe.	Technical Clarification	1. If yes, do not include these enrollees in Table 4: New Record Layout. If no, include these enrollees in Table 4: New Enrollee Record Layout.
CDAG Protocol Program Audit Protocol Purpose	To evaluate performance in the areas outlined in this Program Audit Protocol and Data Request related to Part D Coverage Determinations, Appeals and Grievances (CDAG). The Centers for Medicare and Medicaid Services (CMS) performs its program audit activities in accordance with the CDAG Program Audit Data Request and applying the compliance standards outlined in this Program Audit Protocol and the Program Audit Process Overview document.	Technical Clarification	To evaluate performance in the areas outlined in this Program Audit Protocol and Data Request related to Part D Coverage Determinations, Appeals and Grievances (CDAG). The Centers for Medicare and Medicaid Services (CMS) performs its program audit activities in accordance with the CDAG Program Audit Data Request and applying the compliance standards outlined in this Program Audit Protocol and the Program Audit Process Overview document. At a minimum, CMS will evaluate cases against the criteria listed below. CMS may review factors not specifically addressed below if it is determined that there are other related CDAG requirements not being met.
CDAG Protocol Compliance Standard 2.6	Universe Table 3: Payment Coverage Determination and Redeterminations Universe Table 4: Standard and Expedited Redeterminations	Technical Clarification	Universe Table 3: Payment Coverage Determination and Redeterminations (PYMT_D) Universe Table 4: Standard and Expedited Redeterminations (RD)

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CDAG Protocol Compliance Standard 3.1	[Data Request] Universe Table 1: Standard and Expedited Coverage Determination (CD) Universe Table 2: Standard and Expedited Coverage Determination Exception Requests (CDER) Universe Table 3: Payment Coverage Determinations and Redeterminations (PYMT_D) Universe Table 4: Standard and Expedited Redeterminations (RD) Universe Table 6: Part D Standard and Expedited Grievances [Method of Evaluation] Select up to 10 dismissed cases from Tables 1-4 and 6.	Technical Clarification	[Data Request] Universe Table 1: Standard and Expedited Coverage Determination (CD) Universe Table 2: Standard and Expedited Coverage Determination Exception Requests (CDER) Universe Table 3: Payment Coverage Determinations and Redeterminations (PYMT_D) Universe Table 4: Standard and Expedited Redeterminations (RD) [Method of Evaluation] Select up to 10 dismissed cases from Tables 1-4.
CDAG Protocol Compliance Standard 3.2	Universe Table 6: Part D Standard and Expedited Grievances	Technical Clarification	Universe Table 6: Part D Standard and Expedited Grievances (GRV_D)
CDAG Protocol Compliance Standards 4.1, 4.2 & 4.3	Also review case file documentation to ensure Sponsoring organization made an effort to provide the beneficiary's prescriber(s) of frequently abused drugs with a copy of the notice.	Technical Clarification	Also review case file documentation to ensure Sponsoring organization made reasonable efforts to provide the beneficiary's prescriber(s) of frequently abused drugs with a copy of the notice.
CDAG Protocol Table 1: CD Table Instructions	Each coverage determination request must be listed as its own line item in the submitted universe (i.e., if multiple requests are made at the same time but processed as separate cases, enter each case in a separate row, if a coverage determination request contains multiple distinct disputes (i.e., multiple drugs), enter each drug in a separate row).	Technical Clarification	Each coverage determination request must be listed as its own line item in the submitted universe. If a request for multiple drugs is made at the same time, enter each drug in a separate row. Requests for a single drug involving multiple UM criteria (e.g. step therapy and a prior authorization) must be entered as a single line item.
CDAG Protocol Table 2: CDER Table Instructions	Each exception request must be listed as its own line item in the submitted universe (i.e., if multiple requests are made at the same time but processed as separate cases, enter each case in a separate row). Requests involving multiple UM criteria that were processed as one case must be entered as a single line item. If an exception request contains multiple distinct disputes (i.e., multiple drugs), enter each drug in a separate row.	Technical Clarification	Each exception request must be listed as its own line item in the submitted universe. If a request for multiple drugs is made at the same time, enter each drug in a separate row. Requests for a single drug involving multiple exception types (e.g., tiering exception, prior authorization exception, quantity limit exception, and step therapy exception) must be entered as a single line item.

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CDAG Protocol Table 3: PYMT_D Table Instructions	The date of the Sponsoring organization's determination (Column ID S) must fall within the universe request period. Each request must be listed as its own line item in the submitted universe (i.e., if multiple requests are made at the same time but processed as separate cases, enter each case in a separate row. If a request contains multiple distinct disputes (i.e., multiple drugs), enter each drug in a separate row). Exclude all requests processed as coverage determinations and any requests for coverage that were withdrawn.	Technical Clarification	The date of the Sponsoring organization's determination (Column ID T) must fall within the universe request period. Each payment request must be listed as its own line item in the submitted universe. If a request for multiple drugs is made at the same time, enter each drug in a separate row. Requests for a single drug must be entered as a single line item. Exclude requests for coverage that were withdrawn.
CDAG Protocol Table 4: RD Table Instructions	Each redetermination request must be listed as its own line item in the submitted universe (i.e., if multiple requests are made at the same time but processed as separate cases, enter each case in a separate row. If a redetermination request contains multiple disputes (i.e., multiple drugs), enter each drug in a separate row). Exclude all requests processed as payment redeterminations, withdraws, and direct member reimbursement requests.	Technical Clarification	Each redetermination request must be listed as its own line item in the submitted universe. If a request for multiple drugs is made at the same time, enter each drug in a separate row. Requests for a single drug involving multiple UM criteria (e.g. step therapy and prior authorization) must be entered as a single line item. Exclude all requests processed as payment redeterminations and withdrawn cases.
CDAG Protocol Table 5: EFF_D Table Instructions	If a case contains multiple distinct disputes (i.e., multiple drugs), enter each drug in a separate row. Exclude any cases that were re-opened or that were dismissed or upheld by the IRE, ALJ, or MAC.	Technical Clarification	If a case contains multiple drugs, enter each drug in a separate row. Exclude any cases that were re-opened by the Sponsoring organization or that were dismissed or upheld by the IRE, ALJ, or MAC.
CDAG Protocol Table 6: GRV_D Table Instructions	Include all grievances the Sponsoring organization responded to during the universe request period. The date of the Sponsoring organization's response (Column ID P or R) must fall within the universe request period. Exclude all grievances that were withdrawn during the universe request period.	Technical Clarification	Include all grievances the Sponsoring organization responded to during the universe request period. The date of the Sponsoring organization's notification (Column ID P or R) must fall within the universe request period. Exclude all grievances that were withdrawn and dismissed during the universe request period.

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CDAG Protocol NDC Tables 1-5: Column ID G	[Tables 1, 2 & 3 Description] For multi-ingredient compound claims populate the field with the NDC of the most expensive drug (or as submitted on the associated PDE). When compound claims do not include any Part D drug products, populate the field with "00000000000" consistent with the NDC 11 format. [Tables 4 & 5 Description] When less than 11 characters or a blank field is submitted by the pharmacy or delegate, populate the field as submitted. For multi-ingredient compound claims populate the field with the NDC of the most expensive drug (or as submitted on the associated PDE). When compound claims do not include any Part D drug products, populate the field with "00000000000" consistent with the NDC 11 format.	Technical Clarification	[Tables 1, 2 & 3 Description] For multi-ingredient compound claims populate the field with the NDC as submitted on the associated PDE. [Tables 4 & 5 Description] When less than 11 characters or a blank field is submitted by the pharmacy or delegate, or NDC is not applicable (e.g., for at-risk redeterminations), populate the field as submitted. For multi-ingredient compound claims populate the field with the NDC as submitted on the associated PDE.
CDAG Protocol Authorization or Claim Number Tables 1-5: Column ID I	[Description] Enter the associated authorization number for this request. If an authorization number is not available, provide the internal tracking or case number. Enter None if there is no authorization or other tracking number available.	Technical Clarification	[Description] Enter the associated authorization or claim number for this request. If an authorization or claim number is not available, provide the internal tracking or case number. Enter None if there is no authorization, claim or other tracking number available.
CDAG Protocol AOR/Equivalent notice Receipt Date Tables 1, 2 & 4: Column ID L Table 3: Column ID K Table 6: Column ID H	[Tables 1, 2, 3, 4 & 6 Description] Enter None if no AOR or equivalent written notice was received. Enter NA if no AOR or equivalent written notice was required.	Technical Clarification	[Tables 1, 2, 3 & 4 Description] Enter None for dismissed cases or if no AOR or equivalent written notice was received or required. [Table 6 Description] Enter None if no AOR or equivalent written notice was received or required.

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CDAG Protocol AOR/Equivalent notice Receipt Time Tables 1, 2 & 4: Column ID M Table 6: Column ID I	[Tables 1, 2, 4 & 6 Description] Enter None if no AOR or equivalent written notice was received. Enter NA if no AOR or equivalent written notice was required. Enter NA for dismissed cases.	Technical Clarification	[Tables 1 & 2 Description] Enter None for dismissed cases or if no AOR or equivalent written notice was received or required. [Table 4 Description] Enter None for standard cases, dismissed cases or if no AOR or equivalent written notice was received or required. [Table 6 Description] Enter None for standard cases or if no AOR or equivalent written notice was received or required.
CDAG Protocol Request Determination Tables 1, 2 & 4: Column ID N Table 3: Column ID M	[Description] Enter: • Approved • Denied • IRE auto-forward • Re-opened Approved • Re-opened Denied • Dismissed	Technical Clarification-moved field up in order within the record layout for consistency with ODAG & relettered remaining Column IDs in the tables.	[Description] Enter: • Approved • Denied • IRE auto-forward • Re-opened Approved • Re-opened Denied • Dismissed
CDAG Protocol Was the original request made under the standard timeframe and later requested to be expedited? Tables 1, 2 & 4: Column ID P	[Description] Enter: • Y for Yes • N for No • NA if the request was made under the expedited timeframe. Field Length: 2	Technical Clarification	[Description] Enter: • Y for Yes • N for No • None if the request was made under the expedited timeframe. Field Length: 4

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CDAG Protocol Date request was upgraded to expedited Tables 1, 2 & 4: Column ID Q Time the request was upgraded to expedited Tables 1, 2 & 4: Column ID R	[Description] Enter NA if the initial request was made under the expedited timeframe or if the Sponsoring organization chose not to expedite the request.	Technical Clarification	[Description] Enter None if the initial request was made under the expedited timeframe, if the Sponsoring organization chose not to expedite the request, or if the request was received and processed under the standard timeframe.
CDAG Protocol Issue Description Tables 1, 2 & 4: Column ID S Table 3: Column ID O	[Description] Enter a description of the issue and, if applicable, why the request was denied.	Technical Clarification	[Description] Enter a description of the issue and, if applicable, why the request was denied. For dismissed cases, provide the reason for dismissal.
CDAG Protocol Formulary UM Type Table 1: Column ID T	[Description] Enter the formulary UM criteria the enrollee satisfied or was attempting to satisfy. Enter: • PA for Prior Authorization • ST for Step Therapy • QL for Quantity Limit If the case was a safety edit enter: • SE for Safety Edit Enter NA if the request was not an attempt to satisfy formulary UM criteria or was not a safety edit. If multiple formulary UM criteria apply, enter the criteria applicable based on the approval or denial reason.	Technical Clarification	[Description] Enter the formulary UM criteria the enrollee satisfied or was attempting to satisfy. Enter: • PA for Prior Authorization • ST for Step Therapy If multiple formulary UM criteria apply, enter the criteria applicable based on the approval or denial reason.

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CDAG Protocol Date of Determination Table 1: Column ID U Table 2: Column ID X Table 3: Column ID T Table 4: Column ID W	[Tables 1, 2 & 3 Description] Enter the date of the determination. Submit in CCYY/MM/DD format (e.g., 2020/01/01). [Table 4 Description] Enter the date of the Sponsoring organization's determination. Submit in CCYY/MM/DD format (e.g., 2020/01/01).	Technical Clarification	[Description] Enter the date of the determination. Submit in CCYY/MM/DD format (e.g., 2020/01/01). For dismissed cases, enter the date the sponsoring organization dismissed the request.
CDAG Protocol Time of Determination Table 1: Column ID V Table 2: Column ID Y Table 4: Column ID X	[Tables 1 & 2 Description] Enter the time of the determination. Submit in HH:MM:SS military time format (e.g., 23:59:59). [Table 4 Description] Enter the time of the Sponsoring organization’s determination. Submit in HH:MM:SS military time format (e.g., 23:59:59. For standard cases entering NA is an acceptable response.	Technical Clarification	[Tables 1 & 2 Description] Enter the time of the determination. Submit in HH:MM:SS military time format (e.g., 23:59:59). Enter None for dismissed cases. [Table 4 Description] Enter the time of the determination. Submit in HH:MM:SS military time format (e.g., 23:59:59). Enter None for standard cases and dismissed cases.
CDAG Protocol Date effectuated in the system Table 1: Column ID W Table 2: Column ID Z Table 3: Column ID U Table 4: Column ID Y Time effectuated in the system Table 1: Column ID X Table 2: Column ID AA Table 4: Column ID Z	[Table 1 Description] Enter NA for requests that were not approved. [Table 2 Description] Enter NA if the exception was not approved. [Table 3 Description] Enter NA if the payment request was not approved. [Table 4, Column ID Y Description] Enter NA for requests that were not approved. [Table 4, Column ID Z Description] Enter NA for requests that were not approved. For standard cases entering NA is also an acceptable response.	Technical Clarification	[Table 1 Description] Enter None for requests that were not approved. [Table 2 Description] Enter None if the exception was not approved. [Table 3 Description] Enter None if the payment request was not approved. [Table 4, Column ID Y Description] Enter None for requests that were not approved. [Table 4, Column ID Z Description] Enter None for standard cases and requests that were not approved.

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CDAG Protocol Date oral notification provided to enrollee Table 1: Column ID Y Table 2: Column ID AC Table 4: Column ID AB Time oral notification provided to enrollee Table 1: Column ID Z Table 2: Column ID AD Table 4: Column ID AC	[Table 1 Description] Enter None if no oral notification was provided. [Table 2 Description] Enter None if no oral notification was attempted or provided. [Table 4, Column ID AB Description] Enter None if no oral notification was attempted or provided. [Table 4, Column ID AC Description] Enter None if no oral notification was attempted or provided. For standard cases, entering NA is an acceptable response.	Technical Clarification	[Table 1 Description] Enter None for dismissed cases or if no oral notification was provided. [Table 2 Description] Enter None for dismissed cases or if no oral notification was provided. [Table 4, Column ID AB Description] Enter None for standard cases, dismissed cases or if no oral notification was provided. [Table 4, Column ID AC Description] Enter None for standard cases, dismissed cases or if no oral notification was provided.
CDAG Protocol Date written notification provided to enrollee Table 1: Column ID AA Table 2: Column ID AE Table 3: Column ID W Table 4: Column ID AD	[Tables 1, 3 & 4 Description] Enter the date written notification of determination was provided (i.e. delivered) to enrollee. Do not enter the date a letter is generated or printed. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None for if no written notification was provided. [Table 2 Description] Enter the date written notification was of determination provided (i.e. delivered) to enrollee. Do not enter the date a letter is generated or printed. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None if no written notification was provided.	Technical Clarification	[Tables 1, 2, 3 & 4 Description] Enter the date written notification of determination was provided to enrollee. Do not enter the date a letter is generated or printed. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None if no written notification was provided.

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CDAG Protocol Time written notification provided to enrollee Table 1: Column ID AB Table 2: Column ID AF Table 4: Column ID AE	[Tables 1 & 2 Description] Enter the time written notification of determination was provided (i.e. delivered) to the enrollee. Do not enter the time a letter is generated or printed. Submit in HH:MM:SS military time format (e.g., 23:59:59). Enter None if no written notification was provided. Enter NA for dismissed cases. [Table 4 Description] Enter the time written notification of determination was provided (i.e. delivered) to the enrollee. Do not enter the time a letter is generated or printed. Submit in HH:MM:SS military time format (e.g., 23:59:59). Enter None if no written notification was provided. Enter NA for standard and dismissed cases.	Technical Clarification	[Tables 1 & 2 Description] Enter the time written notification of determination was provided to the enrollee. Do not enter the time a letter is generated or printed. Submit in HH:MM:SS military time format (e.g., 23:59:59). Enter None for dismissed cases or if no written notification was provided. [Table 4 Description] Enter the time written notification of determination was provided to the enrollee. Do not enter the time a letter is generated or printed. Submit in HH:MM:SS military time format (e.g., 23:59:59). Enter None for standard cases, dismissed cases or if no written notification was provided.
CDAG Protocol Who made the request? Table 1: Column ID AC Table 2: Column ID AG Table 3: Column ID X Table 4: Column ID AF	N/A	Technical Clarification-Added Field	Field Type: CHAR Always Required Field Length: 2 Field Description: Enter who made the request: • E for enrollee • ER for enrollee's representative • P for prescribing physician or other prescriber

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CDAG Protocol Date forwarded to IRE Table 1: Column ID AD Table 2: Column ID AH Table 3: Column ID Z Table 4: Column ID AG Time forwarded to IRE Table 1: Column ID AE Table 2: Column ID AI Table 4: Column ID AH	[Description] Enter NF if the request was not forwarded to the IRE.	Technical Clarification	[Description] Enter None if the request was not forwarded to the IRE.
CDAG Protocol Formulary UM Exception Type Tables 2 and 4: Column ID U Table 3: Column ID Q	[Description] Enter NA if the request was not a formulary UM exception or safety edit exception. Field Length: 2	Technical Clarification	[Description] Enter None if the request was not a formulary UM exception or safety edit exception. Field Length: 4
CDAG Protocol Date prescriber supporting statement received Table 2: Column ID V Table 3: Column ID R Time prescriber supporting statement received Table 2: Column ID W	[Description] Enter NA if no prescriber supporting statement was received.	Technical Clarification	[Description] Enter None if no prescriber supporting statement was received.

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CDAG Protocol Expiration date of the approval Table 2: Column ID AB Table 3: Column ID V Table 4: Column ID AA Table 5: Column ID P	[Table 2 Description] Enter NA if the exception was not approved. [Tables 3 & 4 Description] Enter NA if the exception was not approved or if the request was not an exception request. [Table 5 Description] Enter NA if it was not an exception request.	Technical Clarification	[Table 2 Description] Enter None if the exception was not approved. [Tables 3 & 4 Description] Enter None if the exception was not approved or if the request was not an exception request. [Table 5 Description] Enter None if it was not an exception request.
CDAG Protocol Type of Request Table 3: Column ID L	N/A	Technical Clarification-Added Field	Field Type: CHAR Always Required Field Length: 30 Field Description: Enter: • payment coverage determination • payment redetermination
CDAG Protocol Exception Type Table 3: Column ID P Table 4: Column ID T	[Description] Enter NA if the request was not an exception request.	Technical Clarification	[Description] Enter None if the request was not an exception request.
CDAG Protocol Was the coverage determination request denied for lack of medical necessity? Table 3: Column ID S Table 4: Column ID V	[Table 3 Description] NA if the request was not denied (i.e., approved, auto-forwarded, dismissed). [Table 4 Description] Enter: • Y for Yes • N for No Field Length: 2	Technical Clarification	[Table 3 Description] None if the request was not denied (i.e., approved, auto-forwarded, dismissed). [Table 4 Description] Enter: • Y for Yes • N for No • None if the request was auto-forwarded Field Length: 4
CDAG Protocol Date reimbursement provided Table 3: Column ID Y Table 5: Column ID O	[Table 3 Description] Enter NA if the request was not approved. [Table 5 Description] Enter the date the check or reimbursement was provided (i.e. delivered) to the enrollee. Submit in CCYY/MM/DD format (e.g., 2020/01/01).	Technical Clarification	[Table 3 Description] Enter None if the request was not approved. [Table 5 Description] Enter the date the check or reimbursement was provided to the enrollee. Submit in CCYY/MM/DD format (e.g., 2020/01/01).

Document in CMS-10717 (version 05/2020)	Original Language	Clarification or Change	Revised Language
CDAG Protocol Drug Name, Strength, and Dosage Form Table 4: Column ID F	Enter NA if not applicable.	Technical Clarification	Enter None if not applicable.
CDAG Protocol Is this a protected class drug? Tables 4-5: Column ID H	[Table 4 Description] Y for Yes N for No NA if not applicable [Table 5 Description] Y for Yes N for No Field Length: 1	Technical Clarification	[Table 4 Description] Y for Yes N for No [Table 5 Description] Y for Yes N for No None if not applicable Field Length: 4
CDAG Protocol Time the request was received Table 4: Column ID K	[Description] If a reconsideration request became valid based on the establishment of good cause, enter the time the Sponsoring organization received the information establishing good cause. For standard cases entering NA is also an acceptable response.	Technical Clarification	[Description] If the Sponsoring organization obtained information establishing good cause after the 60-day filing timeframe, enter the time the Sponsoring organization received the information establishing good cause. Enter None for standard cases.
CDAG Protocol Plan Benefit Package (PBP) Table 5: Column ID E	[Field Name] Plan Benefit Package	Technical Clarification	[Field Name] Plan Benefit Package (PBP)

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CDAG Protocol Date the overturn decision was effectuated in the system Table 5: Column ID M Time the overturn decision was effectuated in the system Table 5: Column ID N	[Description] Enter the date the benefit was provided, payment was made or the change to the at risk determination was implemented. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter NE if the overturn decision was not effectuated or if no effectuation was required. Enter the time the benefit was provided, payment was made or the change to the at risk determination was implemented. Submit in HH:MM:SS military time format (e.g., 23:59:59). Enter NE if the overturn decision was not effectuated or if no effectuation was required.	Technical Clarification	[Description] Enter the date the benefit was provided, payment was authorized or the change to the at-risk determination was implemented. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None if the overturn decision was not effectuated or if no effectuation was required. Enter the time the benefit was provided, payment was authorized or the change to the at-risk determination was implemented. Submit in HH:MM:SS military time format (e.g., 23:59:59). Enter None if the overturn decision was not effectuated or if no effectuation was required.
CDAG Protocol Time the grievance was received Table 6: Column ID G	[Description] For standard cases entering NA is an acceptable response.	Technical Clarification	[Description] Enter None for standard cases.
CDAG Protocol Grievance Description Table 6: Column ID M	[Description] Enter the description of the complaint.	Technical Clarification	[Description] Enter the description of the grievance.
CDAG Protocol Date oral notification provided to enrollee Table 6: Column ID P	[Field Name] Date oral response provided to enrollee [Description] Enter None if no oral notification was attempted or provided.	Technical Clarification	[Field Name] Date oral notification provided to enrollee [Description] Enter None if no oral notification was provided.
CDAG Protocol Time oral notification provided to enrollee Table 6: Column ID Q	[Field Name] Time oral response provided to enrollee [Description] Enter None if no oral notification was attempted or provided. For standard cases entering NA is an acceptable response.	Technical Clarification	[Field Name] Time oral notification provided to enrollee [Description] Enter None for standard cases or if no oral notification was provided.
CDAG Protocol Date written notification provided to enrollee Table 6: Column ID R	[Field Name] Date written response provided to enrollee [Description] Enter the date written response was provided (i.e. delivered) to enrollee.	Technical Clarification	[Field Name] Date written notification provided to enrollee [Description] Enter the date written notification was provided to enrollee.

Document in CMS-10717 (version 05/2020)	Original Language	Clarification or Change	Revised Language
CDAG Protocol Time written notification provided to enrollee Table 6: Column ID S	[Field Name] Time written response provided to enrollee [Description] Enter the time written response was provided (i.e. delivered) to enrollee. Submit in HH:MM:SS military time format (e.g., 23:59:59). Enter NA for standard cases or if no written notification was provided.	Technical Clarification	[Field Name] Time written notification provided to enrollee [Description] Enter the time written notification was provided to enrollee. Submit in HH:MM:SS military time format (e.g., 23:59:59). Enter None for standard cases or if no written notification was provided.
CDAG Protocol Drug Name, Strength, and Dosage Form Table 7: Column ID F	[Description] Enter NA if this is related to an at risk determination and not specific to a single drug.	Technical Clarification	[Description] Enter None if not related to a specific drug (e.g. pharmacy lock-in, prescriber lock-in) or if the at-risk determination is drug related, but is not specific to a single drug (e.g. beneficiary level edit blocking all opioid access, beneficiary level edit allowing a defined cumulative MME dosage).
CDAG Protocol Date the Initial Written Notification of potential at-risk status was provided to enrollee Table 7: Column ID G	[Description] Enter the date the initial notification was provided (i.e. delivered) to the enrollee that identified them as potentially at risk.	Technical Clarification	[Description] Enter the date the initial notification was provided to the enrollee that identified them as potentially at-risk
CDAG Protocol Date Second Written Notification of At-Risk Determination Provided to Enrollee Table 7: Column ID H	[Description] Enter the date the second written notification or alternate second written notification was provided (i.e. delivered) to enrollee that identified them as being at risk. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None if no written notification was sent.	Technical Clarification	[Description] Enter the date the second written notification or alternate second written notification was provided to enrollee. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None if no written notification was provided.
CDAG Protocol Request Determination Table 7: Column ID J	[Description] Enter the final status of the at risk determination:	Technical Clarification	[Description] Enter the determination:
CDAG Protocol Type of At-Risk Limitation Table 7: Column ID K	Field Length: 50	Technical Clarification	Field Length: 54

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CDAG Protocol Confirmation of Agreement to Place Limitation upon Enrollee Table 7: Column ID L	[Description] Enter NA if no confirmation of agreement was received. Field Length: 3	Technical Clarification	[Description] Enter None if no confirmation of agreement was received. Field Length: 4
CDAG Protocol If an enrollee edit was used, date the edit was effectuated in the system Table 7: Column ID M	[Description] Enter NA if no limitations were entered into the system.	Technical Clarification	[Description] Enter None if no limitations were entered into the system.
CDAG Protocol Expiration date of the at risk restriction/lock-in Table 7: Column ID N	[Description] Enter NA if there was not a restriction/lock-in placed on enrollee.	Technical Clarification	[Description] Enter None if there was not a restriction/lock-in placed on enrollee.
CDAG Protocol Audit Field Work Phase Supporting Documentation Submissions	• Copies of any case notes as to why the case was withdrawn or dismissed. • Any notification regarding the dismissal or withdrawal.	Technical Clarification	• Copies of any case notes as to why the case was dismissed. • Any notification regarding the dismissal.
ODAG Protocol Header	Program Audit Protocol an Data Request Part C Organization Determinations, Appeals, and Grievances (ODAG)	Technical Clarification	Program Audit Protocol and Data Request Part C Organization Determinations, Appeals, and Grievances (ODAG)

Document in CMS-10717 (version 05/2020)	Original Language	Clarification or Change	Revised Language
ODAG Protocol Table of Contents	Universe Requests Universe Table 1: Standard and Expedited Pre-service Organization Determinations (OD) Record Layout Universe Table 2: Standard and Expedited Pre-service Reconsiderations (RECON) Record Layout Universe Table 3: Payment Organization Determinations and Reconsiderations (PYMT_C) Record Layout Universe Table 4: Part C Effectuations of Overturned Decisions by IRE, ALJ, or MAC (EFF_C) Record Layout Universe Table 5: Part C Standard and Expedited Grievances (GRV_C) Record Layout Universe Table 6: Standard and Expedited Pre-Service Part B Drug Organization Determinations and Reconsiderations (Part B Drugs) Record Layout Universe Table 7: Dual Special Needs Plan – Applicable Integrated Plan Reconsiderations (AIP)	Updated Table of Contents to remove Table Standard and Expedited Pre-Service Part B Drug Organization Determinations and Reconsiderations (Part B Drugs) Record Layout. The DSNP Applicable Integrated Plan table was renamed and is now Table 6: Dual Special Needs Plan – Applicable Integrated Plan Reductions, Suspensions, and Terminations (AIP) Record Layout	Universe Requests Universe Table 1: Standard and Expedited Pre-service Organization Determinations (OD) Record Layout Universe Table 2: Standard and Expedited Pre-service Reconsiderations (RECON) Record Layout Universe Table 3: Payment Organization Determinations and Reconsiderations (PYMT_C) Record Layout Universe Table 4: Part C Effectuations of Overturned Decisions by IRE, ALJ, or MAC (EFF_C) Record Layout Universe Table 5: Part C Standard and Expedited Grievances (GRV_C) Record Layout Universe Table 6: Dual Special Needs Plan – Applicable Integrated Plan Reductions, Suspensions, and Terminations (AIP) Record Layout
ODAG Protocol Program Audit Protocol Purpose	To evaluate performance in the areas outlined in this Program Audit Protocol and Data Request related to Part C Organization Determinations, Appeals and Grievances (ODAG). The Centers for Medicare and Medicaid Services (CMS) performs its program audit activities in accordance with the ODAG Program Audit Data Request and applying the compliance standards outlined in this Program Audit Protocol and the Program Audit Process Overview document.	Technical Clarification	To evaluate performance in the areas outlined in this Program Audit Protocol and Data Request related to Part C Organization Determinations, Appeals and Grievances (ODAG). The Centers for Medicare and Medicaid Services (CMS) performs its program audit activities in accordance with the ODAG Program Audit Data Request and applying the compliance standards outlined in this Program Audit Protocol and the Program Audit Process Overview document. At a minimum, CMS will evaluate cases against the criteria listed below. CMS may review factors not specifically addressed below if it is determined that there are other related ODAG requirements not being met.

Document in CMS-10717 (version 05/2020)	Original Language	Clarification or Change	Revised Language
ODAG Protocol Compliance Standard Universe Integrity Testing	[Data Request] Universe Table 1: Standard and expedited Pre-Service Organization Determinations (OD) Universe Table 2: Standard and Expedited Pre-service Reconsiderations (RECON) Universe Table 3: Payment Organization Determinations and Reconsiderations (PYMT_C) Universe Table 4: Part C Effectuations of Overturned Decisions by IRE, ALJ, or MAC (EFF_C) Universe Table 5: Part C Standard and Expedited Grievances (GRV_C) Universe Table 6: Standard and Expedited Pre-Service Part B Drug Organization Determinations and Reconsiderations (Part B Drugs) Universe Table 7: Dual Special Needs Plan – Applicable Integrated Plan Reconsiderations (AIP). [Method of Evaluation] Select 10 cases from each universe, Tables 1 through 7, for a total of 70 cases.	Technical Clarification	[Data Request] Universe Table 1: Standard and expedited Pre-Service Organization Determinations (OD) Universe Table 2: Standard and Expedited Pre-service Reconsiderations (RECON) Universe Table 3: Payment Organization Determinations and Reconsiderations (PYMT_C) Universe Table 4: Part C Effectuations of Overturned Decisions by IRE, ALJ, or MAC (EFF_C) Universe Table 5: Part C Standard and Expedited Grievances (GRV_C) Universe Table 6: Dual Special Needs Plan – Applicable Integrated Plan Reductions, Suspension, and Terminations (AIP) [Method of Evaluation] Select 10 cases from each universe, Tables 1 through 6, for a total of 60 cases.
ODAG Protocol Compliance Standard 1.5	[Method of Evaluation] For DSNP-AIPs, the timeliness assessment will ensure written notification of the upheld reconsideration decision was provided to the enrollee in addition to being forwarded to the IRE no later than 30 calendar days after receipt of the request.	Technical Clarification	[Method of Evaluation] For DSNP-AIPs, the timeliness assessment will ensure written notification of the upheld reconsideration decision was provided to the enrollee in addition to being forwarded to the IRE no later than 30 calendar days or 44 days with extension after receipt of the request.
ODAG Protocol Compliance Standard 1.2 Compliance Standard 1.4	Universe Table 6: Standard and Expedited Part B Drug Organization Determinations and Reconsiderations (Part B Drugs)	Technical Clarification	Universe Table 1: Standard and expedited Pre-Service Organization Determinations (OD)
ODAG Protocol Compliance Standard 1.6 Compliance Standard 1.8	Universe Table 6: Standard and Expedited Part B Drug Organization Determinations and Reconsiderations (Part B Drugs)	Technical Clarification	Universe Table 2: Standard and Expedited Pre-service Reconsiderations (RECON)
ODAG Protocol Compliance Standard 1.20 Compliance Standard 1.21 Compliance Standard 1.22	Universe Table 7: Dual Special Needs Plan – Applicable Integrated Plan Reconsiderations (AIP).	Technical Clarification	Universe Table 6: Dual Special Needs Plan – Applicable Integrated Plan Reductions, Suspensions, and Terminations (AIP).

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ODAG Protocol Compliance Standard 2.1	[Data Request] Universe Table 1: Standard and Expedited Pre-service Organization Determinations (OD) Record Layout Universe Table 2: Standard and Expedited Pre-service Reconsiderations (RECON) Record Layout Universe Table 3: Payment Organization Determinations and Reconsiderations (PYMT_C) Record Layout Universe Table 6: Standard and Expedited Pre-Service Part B Drug Organization Determinations and Reconsiderations (Part B Drugs) Record Layout Universe Table 7: Dual Special Needs Plan – Applicable Integrated Plan Reconsiderations (AIP) [Method of Evaluation] Select 30 denial cases from tables 1-3 and 6. Additionally, select 5 denial cases from Table 7.	Technical Clarification	[Data Request] Universe Table 1: Standard and Expedited Pre-service Organization Determinations (OD) Record Layout Universe Table 2: Standard and Expedited Pre-service Reconsiderations (RECON) Record Layout Universe Table 3: Payment Organization Determinations and Reconsiderations (PYMT_C) Record Layout Universe Table 6: Dual Special Needs Plan – Applicable Integrated Plan Reductions, Suspensions, and Terminations (AIP) [Method of Evaluation] Select 30 denied requests from tables 1-3. The number of cases per record layout will vary. Additionally, select 5 denial cases from Table 6.
ODAG Protocol Compliance Standard 2.2	[Data Request] Universe Table 1: Standard and Expedited Pre-service Organization Determinations (OD) Record Layout Universe Table 2: Standard and Expedited Pre-service Reconsiderations (RECON) Record Layout Universe Table 3: Payment Organization Determinations and Reconsiderations (PYMT_C) Record Layout Universe Table 6: Standard and Expedited Pre-Service Part B Drug Organization Determinations and Reconsiderations (Part B Drugs) Record Layout Universe Table 7: Dual Special Needs Plan – Applicable Integrated Plan Reconsiderations (AIP)	Technical Clarification	[Data Request] Universe Table 1: Standard and Expedited Pre-service Organization Determinations (OD) Record Layout Universe Table 2: Standard and Expedited Pre-service Reconsiderations (RECON) Record Layout Universe Table 3: Payment Organization Determinations and Reconsiderations (PYMT_C) Record Layout Universe Table 6: Dual Special Needs Plan – Applicable Integrated Plan Reductions, Suspensions, and Terminations (AIP)
ODAG Protocol Compliance Standard 2.3	[Data Request] Universe Table 1: Standard and Expedited Pre-service Organization Determinations (OD) Record Layout Universe Table 2: Standard and Expedited Pre-service Reconsiderations (RECON) Record Layout Universe Table 3: Payment Organization Determinations and Reconsiderations (PYMT_C) Record Layout Universe Table 6: Standard and Expedited Pre-Service Part B Drug Organization Determinations and Reconsiderations (Part B Drugs) Record Layout	Technical Clarification	[Data Request] Universe Table 1: Standard and Expedited Pre-service Organization Determinations (OD) Record Layout Universe Table 2: Standard and Expedited Pre-service Reconsiderations (RECON) Record Layout Universe Table 3: Payment Organization Determinations and Reconsiderations (PYMT_C) Record Layout

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ODAG Protocol Compliance Standard 2.4	[Data Request] Universe Table 1: Standard and Expedited Pre-service Organization Determinations (OD) Record Layout Universe Table 2: Standard and Expedited Pre-service Reconsiderations (RECON) Record Layout Universe Table 7: Dual Special Needs Plan – Applicable Integrated Plan Reconsiderations (AIP)	Technical Clarification	[Data Request] Universe Table 1: Standard and Expedited Pre-service Organization Determinations (OD) Record Layout Universe Table 2: Standard and Expedited Pre-service Reconsiderations (RECON) Record Layout Universe Table 6: Dual Special Needs Plan – Applicable Integrated Plan Reductions, Suspensions, and Terminations (AIP)
ODAG Protocol Compliance Standard 2.5	[Data Request] Universe Table 1: Standard and Expedited Pre-service Organization Determinations (OD) Record Layout Universe Table 2: Standard and Expedited Pre-service Reconsiderations (RECON) Record Layout Universe Table 6: Standard and Expedited Pre-Service Part B Drug Organization Determinations and Reconsiderations (Part B Drugs) Record Layout Universe Table 7: Dual Special Needs Plan – Applicable Integrated Plan Reconsiderations (AIP)	Technical Clarification	[Data Request] Universe Table 1: Standard and Expedited Pre-service Organization Determinations (OD) Record Layout Universe Table 2: Standard and Expedited Pre-service Reconsiderations (RECON) Record Layout Universe Table 6: Dual Special Needs Plan – Applicable Integrated Plan Reductions, Suspensions, and Terminations (AIP)
Compliance Standard 2.6	[Data Request] Universe Table 6: Standard and Expedited Pre-Service Part B Drug Organization Determinations and Reconsiderations (Part B Drugs) Record Layout	Technical Clarification	[Data Request] Universe Table 1: Standard and Expedited Pre-service Organization Determinations (OD) Record Layout Universe Table 2: Standard and Expedited Pre-service Reconsiderations (RECON) Record Layout
Compliance Standard 2.7	[Data Request] Universe Table 7: Dual Special Needs Plan – Applicable Integrated Plan Reconsiderations (AIP)	Technical Clarification	[Data Request] Universe Table 6: Dual Special Needs Plan – Applicable Integrated Plan Reductions, Suspensions, and Terminations (AIP)

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ODAG Protocol Compliance Standard 3.1	[Data Request] Universe Table 1: Standard and expedited Pre-Service Organization Determinations (OD) Universe Table 2: Standard and Expedited Pre-service Reconsiderations (RECON) Universe Table 3: Payment Organization Determinations and Reconsiderations (PYMT_C) Universe Table 4: Part C Effectuations of Overturned Decisions by IRE, ALJ, or MAC (EFF_C) Universe Table 5: Part C Standard and Expedited Grievances (GRV_C) Universe Table 6: Standard and Expedited Pre-Service Part B Drug Organization Determinations and Reconsiderations (Part B Drugs) Universe Table 7: Dual Special Needs Plan – Applicable Integrated Plan Reconsiderations (AIP). [Method of Evaluation] Select up to 15 dismissals from Tables 1-3, 5 - 7.	Technical Clarification	[Data Request] Universe Table 1: Standard and expedited Pre-Service Organization Determinations (OD) Universe Table 2: Standard and Expedited Pre-service Reconsiderations (RECON) Universe Table 3: Payment Organization Determinations and Reconsiderations (PYMT_C) [Method of Evaluation] Select 10 dismissed requests from Tables 1-3.
ODAG Protocol Program Audit Data Request Audit Engagement and Universe Submission Phase Universe Submissions	Sponsoring organizations must submit universe tables 1 - 6, comprehensive of all contracts and Plan Benefit Packages (PBP), identified in the audit engagement letter, in either Microsoft Excel (.xlsx) file format with a header row or Text (.txt) file format without a header row. Sponsoring organizations determined to be an Applicable Integrated Plan (AIP) must submit universe table 7 comprehensive of all contracts and/or PBPs offered as Dual Eligible Special Needs Plans only. Descriptions and clarifications of what must be included in each submission and data field are outlined in the individual universe record layouts below. Characters are required in all requested fields, unless otherwise specified, and data must be limited to the request specified in each record layout. Sponsoring organizations must provide accurate and timely universe submissions within 15 business days of the audit engagement letter date. Submissions that do not strictly adhere to the record layout specifications will be rejected.	Technical Clarification	Sponsoring organizations must submit universe tables 1 - 5, comprehensive of all contracts and Plan Benefit Packages (PBP), identified in the audit engagement letter, in either Microsoft Excel (.xlsx) file format with a header row or Text (.txt) file format without a header row. Sponsoring organizations determined to be an Applicable Integrated Plan (AIP) must submit universe table 6 comprehensive of all contracts and/or PBPs offered as Dual Eligible Special Needs Plans only. Descriptions and clarifications of what must be included in each submission and data field are outlined in the individual universe record layouts below. Characters are required in all requested fields, unless otherwise specified, and data must be limited to the request specified in each record layout. Sponsoring organizations must provide accurate and timely universe submissions within 15 business days of the audit engagement letter date. Submissions that do not strictly adhere to the record layout specifications will be rejected.

Document in CMS-10717 (version 05/2020)	Original Language	Clarification or Change	Revised Language
ODAG Protocol Program Audit Data Request Audit Engagement and Universe Submission Phase Universe Requests	1. Universe Table 1: Standard and Expedited Pre-service Organization Determinations (OD) Record Layout 2. Universe Table 2: Standard and Expedited Pre-service Reconsiderations (RECON) Record Layout 3. Universe Table 3: Payment Organization Determinations and Reconsiderations (PYMT_C) Record Layout 4. Universe Table 4: Part C Effectuations of Overturned Decisions by IRE, ALJ, or MAC (EFF_C) Record Layout 5. Universe Table 5: Part C Standard and Expedited Grievances (GRV_C) Record Layout 6. Universe Table 6: Standard and Expedited Part B Drug Organization Determinations and Reconsiderations (Part B Drugs) Record Layout Universe 7. Universe Table 7: Dual Eligible Special Needs Plan – Applicable Integrated Plan Reconsiderations (AIP).	Technical Clarification	1. Universe Table 1: Standard and Expedited Pre-service Organization Determinations (OD) Record Layout 2. Universe Table 2: Standard and Expedited Pre-service Reconsiderations (RECON) Record Layout 3. Universe Table 3: Payment Organization Determinations and Reconsiderations (PYMT_C) Record Layout 4. Universe Table 4: Part C Effectuations of Overturned Decisions by IRE, ALJ, or MAC (EFF_C) Record Layout 5. Universe Table 5: Part C Standard and Expedited Grievances (GRV_C) Record Layout 6. Universe Table 6: Dual Eligible Special Needs Plan – Applicable Integrated Plan Reductions, Suspensions, and Terminations (AIP).
ODAG Protocol Program Audit Data Request Audit Engagement and Universe Submission Phase Universe Requests	[Universe Record Layout] Table 1 Table 2 Table 3 Table 4 Table 5 Table 6 Table 7	Technical Clarification	[Universe Record Layout] Table 1 Table 2 Table 3 Table 4 Table 5 Table 6

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ODAG Protocol Table 1: OD Table Instructions	• Include all pre-service organization determination requests the Sponsoring organization approved, denied or dismissed during the universe request period. The date of the Sponsoring organization's determination (Column ID O) must fall within the universe request period. Include all pre-service requests for supplemental services that meet the criteria defined in Chapter 4, Section 30.1. • Include all pre-service requests for supplemental services that meet the criteria defined in Chapter 4, Section 30.1. • If a pre-service organization determination includes more than one service, include all of the request's line items in a single row and enter the multiple line items as a single organization determination request. o Enter any request denied in whole or in part as denied. • Enter all fields for a single request in the same time zone. For example, if the Sponsoring organization has systems in EST and CST, all data in a single line item must be in the same time zone. • Exclude all requests processed as reconsiderations, payments, reopenings, withdrawals, and Part B drug requests. o Exclude all concurrent reviews for inpatient hospital services and inpatient SNF services, and notifications of admissions. o Exclude all requests for Value Added Items and Services.	Technical Clarification	• Include all pre-service organization determination requests the Sponsoring organization approved, denied or dismissed during the universe request period. The date of the Sponsoring organization's determination (Column ID P) must fall within the universe request period. • Include all pre-service requests for supplemental services that meet the criteria defined in 42 CFR § 422.100(c)(2). • Include all pre-service organization determination requests for Part B drugs. • If a pre-service organization determination includes more than one service, include all of the request's line items in a single row and enter the multiple line items as a single organization determination request. o Enter any request denied in whole or in part as denied. • Enter all fields for a single request in the same time zone. For example, if the Sponsoring organization has systems in EST and CST, all data in a single line item must be in the same time zone. • Exclude all requests processed as reconsiderations, payments, reopenings, and withdrawals. o Exclude all concurrent reviews for inpatient hospital services and inpatient SNF services, and notifications of admissions. o Exclude all requests for Value Added Items and Services.
ODAG Protocol First Tier, Downstream, and Related Entity Tables 1-5: Column ID F	[Tables 1-4 Description] Enter the name of the First Tier, Downstream, and Related Entity (which is any party that enters into a written arrangement, acceptable to CMS, with the Sponsoring organization to provide administrative or health care services to an enrollee under the Part C or D program) that processed the request. Enter NA if the Sponsoring organization processed the request. [Table 5 Description] Enter the name of the First Tier, Downstream, and Related Entity (which is any party that enters into a written arrangement, acceptable to CMS, with the Sponsoring organization to provide administrative or health care services to an enrollee under the Part C or D program) which processed the grievance. Enter NA if the grievance was processed by the Sponsoring organization.	Technical Clarification	[Tables 1-4 Description] Enter the name of the First Tier, Downstream, and Related Entity (which is any party that enters into a written arrangement, acceptable to CMS, with the Sponsoring organization to provide administrative or health care services to an enrollee under the Part C or D program) that processed the request. Enter None if the Sponsoring organization processed the request. [Table 5 Description] Enter the name of the First Tier, Downstream, and Related Entity (which is any party that enters into a written arrangement, acceptable to CMS, with the Sponsoring organization to provide administrative or health care services to an enrollee under the Part C or D program) that processed the grievance. Enter None if the Sponsoring organization processed the grievance.

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ODAG Protocol Authorization or Claim Number Tables 1-4 and 6: Column ID G	[Table 1 and Table 3 Description] Enter the associated authorization number for this request. If an authorization number is not available, provide the internal tracking or case number. Enter None if an authorization or other tracking number is unavailable. [Table 2 Description] Enter the associated authorization number for this request. If an authorization number is not available, enter the internal tracking or case number. Enter None if there is no authorization or other tracking number available. [Table 4 Description] Enter the associated authorization number for this request. If an authorization number is not available, provide the internal tracking or case number. Enter None if there is no authorization or other tracking number available. [Table 6 Column ID F] The associated authorization number assigned by the DSNP-AIP for this request. If an authorization number is not available, please provide your internal tracking or case number. Answer NA if there is no authorization or other tracking number available.	Technical Clarification	[Tables 1-4 & 6 Description [Column ID G] Enter the associated authorization or claim number for this request. If an authorization or claim number is not available, enter the internal tracking or case number. Enter None if there is no authorization, claim or other tracking number available.

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ODAG Protocol Time the request was received Tables 1-2: Column ID I	[Table 1 Description] Enter the time the request was received. Submit in HH:MM:SS military time format (e.g., 23:59:59). If a standard request was upgraded to expedited, enter the date the request was upgraded. Enter NA for standard and dismissed requests. [Table 2 Description] Enter the time the reconsideration request was received. If a standard request was upgraded to expedited, enter the date the request was upgraded. If the Sponsoring organization obtained information establishing good cause after the 60-day filing timeframe, enter the time the Sponsoring organization received the information establishing good cause. Submit in HH:MM:SS military time format (e.g., 23:59:59). Enter NA for standard and dismissed requests.	Technical Clarification	[Table 1 Description] For all expedited requests and standard Part B drug requests, enter the time the request was received. Submit in HH:MM:SS military time format (e.g., 23:59:59). If a standard request was upgraded to expedited, enter the time the request was upgraded. Enter None for standard and dismissed requests. [Table 2 Description] For all expedited requests, enter the time the reconsideration request was received. If a standard request was upgraded to expedited, enter the time the request was upgraded. If the Sponsoring organization obtained information establishing good cause after the 60-day filing timeframe, enter the time the Sponsoring organization received the information establishing good cause. Submit in HH:MM:SS military time format (e.g., 23:59:59). Enter None for standard and dismissed requests.
ODAG Protocol Part B Drug Request? Table 1-2: Column ID J	N/A	Technical Clarification - Added field and relettered remaining Column IDs in the table	[Column ID] J [Field Name] Part B Drug Request? [Field Type] CHAR Always Required [Field Length] 1 [Description] Enter: • Y for Yes • N for No Sponsors must indicate ‘Y’ for any pre-service request that includes a Part B drug (primary or ancillary) or Part D drug that is part of a Sponsor’s step therapy requirement for a Part B drug.

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ODAG Protocol AOR/Equivalent notice Receipt Date Tables 1-2: Column ID K Table 3: Column ID I	[Table 1 Column ID J Description] Enter the date the Appointment of Representative (AOR) form or equivalent written notice was received by the Sponsoring organization. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None if no AOR or equivalent written notice was received. Enter NA for dismissed requests and if no AOR or equivalent written notice was required. [Table 2 Column ID J Description] Enter the date the Appointment of Representative (AOR) form or equivalent written notice was received by the Sponsoring organization. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None if an AOR or equivalent written notice was not received. Enter NA if an AOR or equivalent written notice was not required. [Table 3 Column ID I Description] Enter the date the Appointment of Representative (AOR) form or equivalent written notice was received by the Sponsoring organization. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None if no AOR or equivalent written notice was received. Enter NA if no AOR or equivalent written notice was required.	Technical Clarification	[Table 1 Column ID K Description] Enter the date the Appointment of Representative (AOR) form or equivalent written notice was received by the Sponsoring organization. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None for dismissed requests or if no AOR or equivalent written notice was received or required. [Table 2 Column ID K and Table 3 Column ID I Description] Enter the date the Appointment of Representative (AOR) form or equivalent written notice was received by the Sponsoring organization. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None for dismissed requests or if no AOR or equivalent written notice was received or required.
ODAG Protocol AOR Equivalent notice Receipt Date Table 5: Column ID I Table 6: Column ID M	[Table 5 Column ID I Description] Enter the date the Appointment of Representative (AOR) form or equivalent written notice was received by the Sponsoring organization. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None if an AOR or equivalent written notice was not received. Enter NA if an AOR or equivalent written notice was not required. [Table 7 Column ID Y Description] Enter the date the Appointment of Representative (AOR) form or equivalent written notice was received by the Sponsoring organization. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None if no AOR or equivalent written notice was received. Enter NA if no AOR or equivalent written notice was required.	Technical Clarification	[Table 5 Column ID I Description] Enter the date the Appointment of Representative (AOR) form or equivalent written notice was received by the Sponsoring organization. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None if no AOR or equivalent written notice was received or required. [Table 6 Column ID M Description] Enter the date the Appointment of Representative (AOR) form or equivalent written notice was received by the Sponsoring organization. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None for dismissed requests, if no AOR or equivalent written notice was received or required, or if the decision was not appealed as indicated by N in column ID J.

Document in CMS-10717 (version 05/2020)	Original Language	Clarification or Change	Revised Language
ODAG Protocol AOR/Equivalent notice Receipt Time Tables 1-2: Column ID L	[Table 1 Column ID K Description] Enter the time the Appointment of Representative (AOR) form or equivalent written notice was received by the Sponsoring organization. Submit in HH:MM:SS format (e.g., 23:59:59). Enter None if no AOR or equivalent written notice was received. Enter NA for standard and dismissed cases or if an AOR or equivalent written notice was not required. [Table 2 Column ID K Description] Enter the time the Appointment of Representative (AOR) form or equivalent written notice was received by the Sponsoring organization. Submit in HH:MM:SS format (e.g., 23:59:59). Enter None if an AOR or equivalent written notice was not received. Enter NA if an AOR or equivalent written notice was not required. Enter NA for standard and dismissed requests.	Technical Clarification	[Table 1 Column ID L Description] For all expedited requests and standard Part B drug requests, enter the time the Appointment of Representative (AOR) form or equivalent written notice was received by the Sponsoring organization. Submit in HH:MM:SS format (e.g., 23:59:59). Enter None for standard requests, dismissed requests or if no AOR or equivalent written notice was received or required. [Table 2 Column ID L Description] For all expedited requests, enter the time the Appointment of Representative (AOR) form or equivalent written notice was received by the Sponsoring organization. Submit in HH:MM:SS format (e.g., 23:59:59). Enter None for dismissed requests or if no AOR or equivalent written notice was received or required.
ODAG Protocol AOR/Equivalent notice Receipt Time Table 5: Column ID J	[Table 5 Column ID J Description] Enter the time the Appointment of Representative (AOR) form or equivalent written notice was received by the Sponsoring organization. Submit in HH:MM:SS format (e.g., 23:59:59). Enter None if an AOR or equivalent written notice was not received. Enter NA if no AOR or equivalent written notice was required. Enter NA for standard and dismissed cases.	Technical Clarification	[Table 5: Column ID J Description] For expedited grievances, enter the time the Appointment of Representative (AOR) form or equivalent written notice was received by the Sponsoring organization. Submit in HH:MM:SS format (e.g., 23:59:59). Enter None for standard grievances, dismissed grievances, or if an AOR or equivalent written notice was not received or required.
ODAG Protocol Request Determination Tables 1-2: Column ID M	[Column ID] N [Table 2 Field Length] 21	Technical Clarification - moved field up in order within the record layout & relettered remaining Column IDs in the tables.	[Column ID] M [Table 2 Field Length] 9

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ODAG Protocol Date of Determination Tables 1-2: Column ID P Table 3: Column ID N	Table 1 and Table 2 [Column ID] O [Description] Enter the date of the determination. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Table 3 Column ID N [Description] Enter the date of the determination. Submit in CCYY/MM/DD format (e.g., 2020/01/01). This is the date the determination was entered in the system and may be the same as the date claim was paid.	Technical Clarification	Table 1 and Table 2 [Column ID] P [Description] Enter the date of the determination. Submit in CCYY/MM/DD format (e.g., 2020/01/01). For dismissed requests, enter the date the Sponsor dismissed the request. Table 3 Column ID N [Description] Enter the date of the determination. Submit in CCYY/MM/DD format (e.g., 2020/01/01). This is the date the determination was entered in the system and may be the same as the date claim was paid. For dismissed requests, enter the date the Sponsor dismissed the request.
ODAG Protocol Time of Determination Tables 1-2: Column ID Q	[Column ID] P [Description] Enter the time of the determination. Submit in HH:MM:SS military time format (e.g., 23:59:59). Enter NA for standard and dismissed requests.	Technical Clarification	[Column ID] Q [Table 1 Description] For all expedited requests and standard Part B drug requests, enter the time of the determination. Submit in HH:MM:SS military time format (e.g., 23:59:59). Enter None for standard and dismissed requests. [Table 2 Description] For all expedited requests, enter the time of the determination. Submit in HH:MM:SS military time format (e.g., 23:59:59). Enter None for standard and dismissed requests.
ODAG Protocol Date oral notification provided to enrollee Table 2: Column ID R	[Column ID] Q [Table 2 Description] Enter the date oral notification was provided to enrollee. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None if no oral notification was attempted or provided.	Technical Clarification	[Column ID] R [Table 2 Description] Enter the date oral notification was provided to enrollee. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None for dismissed requests or if no oral notification was provided.

Document in CMS-10717 (version 05/2020)	Original Language	Clarification or Change	Revised Language
ODAG Protocol Time oral notification provided to enrollee Tables 1-2: Column ID S	[Column ID] R [Table 1 Description] Enter the time oral notification was provided to enrollee. Submit in HH:MM:SS military time format (e.g., 23:59:59). Enter None if no oral notification was provided. [Table 2 Description] Enter the time oral notification was provided to enrollee. Submit in HH:MM:SS military time format (e.g., 23:59:59). Enter None if no oral notification was attempted or provided.	Technical Clarification	[Column ID] S [Table 1 Description] For all expedited requests and standard Part B drug requests, enter the time oral notification was provided to enrollee. Submit in HH:MM:SS military time format (e.g., 23:59:59). Enter None for standard requests, dismissed requests, or if no oral notification was provided. [Table 2 Description] For expedited requests, including expedited Part B drug requests, enter the time oral notification was provided to enrollee. Submit in HH:MM:SS military time format (e.g., 23:59:59). Enter None for dismissed requests or if no oral notification was provided.

Document in CMS-10717 (version 05/2020)	Original Language	Clarification or Change	Revised Language
ODAG Protocol Date written notification provided to enrollee Tables 1-2: Column ID T Table 3: Column ID P	[Table 1 Column ID] S [Description] Enter the date written notification of determination was provided (i.e. delivered) to enrollee. Written notification is considered provided on the date (and time, if applicable) the Sponsoring organization or delegated entity has deposited the notice in the courier drop box (e.g., U.S. Postal Service or FedEx bin). Do not enter the date a letter is generated or printed. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None if no written notification was provided. [Table 2 Column ID] S [Description] Enter the date written notification was provided (i.e. delivered) to enrollee. Do not enter the date a letter is generated or printed. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter NA dismissed requests. Enter None if written notification was not provided. [Table 3 Column ID] P [Description] Enter the date written notification was provided (i.e. delivered) to enrollee. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None if no written notification was provided.	Technical Clarification	[Table 1 Column ID] T [Description] Enter the date written notification of determination was provided to enrollee. Do not enter the date a letter is generated or printed. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None if no written notification was provided. [Table 2 Column ID] T [Description] Enter the date written notification was provided to enrollee. Do not enter the date a letter is generated or printed. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None if no written notification was provided. [Table 3 Column ID] P [Description] Enter the date written notification was provided to enrollee. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None if no written notification was provided.

Document in CMS-10717 (version 05/2020)	Original Language	Clarification or Change	Revised Language
ODAG Protocol Time written notification provided to enrollee Tables 1-2: Column ID U	[Column ID] T [Table 1 Description] Enter the time written notification of determination was provided (i.e. delivered) to enrollee. Written notification is considered provided on the date (and time, if applicable) the Sponsoring organization or delegated entity has deposited the notice in the courier drop box (e.g., U.S. Postal Service or FedEx bin). Do not enter the time a letter was generated or printed. Submit in HH:MM:SS military time format (e.g., 23:59:59). Enter NA for standard and dismissed cases. Enter None if no written notification was provided. [Table 2 Description] Enter the time written notification was provided (i.e. delivered) to enrollee. Do not enter the time a letter is generated or printed. Submit in HH:MM:SS military time format (e.g., 23:59:59). Enter NA for standard and dismissed requests. Enter None if written notification was not provided.	Technical Clarification	[Column ID] U [Table 1 Description] For all expedited requests and standard Part B drug requests, enter the time written notification of determination was provided) to enrollee. Do not enter the time a letter was generated or printed. Submit in HH:MM:SS military time format (e.g., 23:59:59). Enter None for standard requests, dismissed requests, or if no written notification was provided. [Table 2 Description] For all expedited requests, enter the time written notification was provided to enrollee. Do not enter the time a letter is generated or printed. Submit in HH:MM:SS military time format (e.g., 23:59:59). Enter None for standard requests, dismissed requests, or if no written notification was provided.

Document in CMS-10717 (version 05/2020)	Original Language	Clarification or Change	Revised Language
ODAG Protocol Issue Description and Type of Service Table 1: Column ID W Table 2: Column ID AA Table 3: Column ID T	[Table 1 Column ID] V [Table 2 Column ID] Y [Table 3 Column ID] S [Description] Provide a description of the service or item requested and why it was requested (if known). For denials, also provide an explanation of why the pre-service request was denied.	Technical Clarification	[Table 1 Column ID] W [Table 2 Column ID] AA [Table 3 Column ID] T [Table 1 and 2 Description] Provide a description of the service or item requested and why it was requested (if known). For denials, also provide an explanation of why the pre-service request was denied. For dismissed requests, provide the reason for dismissal. For Part B drugs requests, include the J-Code, National Drug Code (NDC), or both. [Table 3 Description] Provide a description of the service or item requested and why it was requested (if known). For denials, also provide an explanation of why the payment organization determination or payment reconsideration request was denied. For dismissed requests, please provide the reason for dismissal. For Part B drugs requests, include the J-Code, National Drug Code (NDC), or both.

Document in CMS-10717 (version 05/2020)	Original Language	Clarification or Change	Revised Language
ODAG Protocol Was an expedited request made but processed as standard? Tables 1-2: Column ID X	[Table 1 Column ID] W [Table 2 Column ID] Z [Table 1 and Table 2] [Field Length] 2 [Description] Enter: • Y for Yes if an expedited request was received but downgraded to standard • NA for all other requests (e.g. the request was received as expedited and processed as expedited, the request was received as standard)	Technical Clarification	[Table 1 Column ID] X [Table 2 Column ID] BB [Table 1 and Table 2] [Field Length] 4 Table 1 [Description] Enter: • Y for Yes if an expedited request was received but downgraded to standard • None for all other requests (e.g. the request was received as expedited and processed as expedited, the request was received as standard) Table 2 [Description] Enter: • Y for Yes if an expedited request was received but downgraded to standard • None for all other cases (e.g. the request was received as expedited and processed as expedited, the request was received as standard.) • For dismissed requests, populate based on how the request was received.

Document in CMS-10717 (version 05/2020)	Original Language	Clarification or Change	Revised Language
ODAG Protocol Was the request denied for lack of medical necessity? Table 1: Column ID Y Was the initial organization determination request denied for lack of medical necessity? Table 2: Column ID CC	[Table 1 Column ID] X [Table 2 Column ID] AA [Table 1 Field Length] 2 [Table 2 Field Length] 2 [Table 1 Description] Enter: • Y for Yes • N for No • NA if the request was approved or dismissed.	Technical Clarification	[Table 1 Column ID] Y [Table 2 Column ID] CC [Table 1 Field Length] 4 [Table 2 Field Length] 1 [Table 1 Description] Enter: • Y for Yes • N for No • None if the request was approved or dismissed.
ODAG Protocol Table 2: RECON Table Instructions	• Include all pre-service reconsideration requests the Sponsoring organization approved, denied, auto-forwarded to the IRE or dismissed during the universe request period. The date of the Sponsoring organization's determination (Column ID O) must fall within the universe request period. • Include all requests for supplemental services that meet the criteria defined in Chapter 4, Section 30.1 (e.g., dental, vision). • If a pre-service reconsideration includes more than one service, include all of the request's line items in a single row and enter multiple line items as a single reconsideration request. Enter any request denied in whole or in part as denied. • Enter all fields for a single request in the same time zone. For example, if the Sponsoring organization has systems in EST and CST, all data in a single line item must be in a single time zone. • Exclude all requests processed as organization determinations, payments, reopenings, withdrawals, or Part B drug requests. • Exclude all requests for concurrent reviews for inpatient hospital and inpatient SNF services, and notifications of admissions. • Exclude all requests for Value Added Items and Services.	Technical Clarification	• Include all pre-service reconsideration requests the Sponsoring organization approved, denied, auto-forwarded to the IRE or dismissed during the universe request period. The date of the Sponsoring organization's determination (Column ID P) must fall within the universe request period. • Include all pre-service reconsideration requests for supplemental services that meet the criteria defined at 42 CFR § 422.100(c)(2). • Include all pre-service reconsideration requests for Part B drugs. • If a pre-service reconsideration includes more than one service, include all of the request's line items in a single row and enter multiple line items as a single reconsideration request. Enter any request denied in whole or in part as denied. • Enter all fields for a single request in the same time zone. For example, if the Sponsoring organization has systems in EST and CST, all data in a single line item must be in a single time zone. • Exclude all requests processed as organization determinations, payment requests, reopenings, and withdrawals. • Exclude all requests for concurrent reviews for inpatient hospital and inpatient SNF services, and notifications of admissions. • Exclude all requests for Value Added Items and Services.

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ODAG Protocol Date reconsidered determination effectuated in the system Table 2: Column ID V	[Column ID] U [Description] Enter the date the reconsidered determination was effectuated in the system. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter NA if the determination was denied or dismissed.	Technical Clarification	[Column ID] V [Description] Enter the date the reconsidered determination was effectuated in the system. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None if the determination was denied or dismissed.
ODAG Protocol Time reconsidered determination effectuated in the system Table 2: Column ID W	[Column ID] V [Description] Enter the time the reconsidered determination was effectuated in the system. Submit in HH:MM:SS military time format (e.g., 23:59:59). Enter NA for standard cases or if the determination was denied.	Technical Clarification	[Column ID] W [Description] For all expedited requests, enter the time the reconsidered determination was effectuated in the system. Submit in HH:MM:SS military time format (e.g., 23:59:59). Enter None for standard cases, dismissed cases, or if the request was denied.
ODAG Protocol Date forwarded to IRE Table 2: Column ID X Table 3: Column ID R	[Table 2 Column ID] W [Table 2 Description] Enter the date the request was forwarded to the IRE. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter NF if the request was not forwarded to IRE. Enter NA if the beneficiary was notified of the approved reconsideration. [Table 3 Description] Enter the date the request was forwarded to the IRE. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter NF if the request was not forwarded to the IRE. Enter NA if the request was approved, or dismissed.	Technical Clarification	[Table 2 Column ID] X [Table 2 Description] Enter the date the request was forwarded to the IRE. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None if the beneficiary was notified of the approved reconsideration, or if the request was not forwarded to the IRE. [Table 3 Description] Enter the date the reconsideration request was forwarded to the IRE. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None for organization determination requests, or if the reconsideration request was approved, dismissed, or not forwarded to the IRE.

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ODAG Protocol Time forwarded to IRE Table 2: Column ID Y	N/A	Technical Clarification	[Column ID] Y [Field Type] CHAR Always Required [Field Length] 10 [Description] For all expedited requests, enter the time the request was forwarded to the IRE. Submit in HH:MM:SS military time format (e.g., 23:59:59). Enter None if the beneficiary was notified of the approved reconsideration or if the request was not forwarded to the IRE.

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ODAG Protocol Table 3: PYMT_C Table Instructions	• Include all payment organization determinations and payment reconsiderations the Sponsoring organization approved, denied or dismissed from non-contract providers or enrollees during the universe request period. • Submit payment organization determinations (claims) based on the date the claim was paid (Column O) or notification of the denial to the provider (if provider submitted the claim -Column Q) or member (if the member submitted the claim – Column P). • Include all payment requests for Part B drugs if applicable. • Include all payment requests for supplemental services (e.g., dental, vision). • If a payment organization determination or reconsideration includes more than one service, include all of the request's line items in a single row and enter the multiple line items as a single organization determination or reconsideration request. o Enter any request denied in whole or in part as denied. • Enter all fields for a single case in the same time zone. For example, if the Sponsoring organization has systems in EST and CST, all data in a single line item must be in a single time zone. • Exclude all payment requests processed as: o duplicate claims, o payment adjustments, o reopenings, o withdrawals, and o retrospective reviews. • Exclude all requests for Value Added Items and Services. • Exclude any payment requests that were denied due to: o invalid billing codes, o eligibility (i.e., enrollees who were not enrolled on the date of service, providers not accepting assignment), or o recoupment of payment, including pending determination of other primary insurance such as automobile, worker's compensation, etc.	Technical Clarification	• Include all payment organization determinations and payment reconsiderations the Sponsoring organization approved, denied or dismissed from non-contract providers, enrollees, and non-contract pharmacies during the universe request period. • Submit payment organization determinations (claims) based on the date the claim was paid (Column O) or notification of the denial to the provider (if provider submitted the claim - Column Q) or enrollee (if the enrollee submitted the claim – Column P). Submit payment reconsiderations based on the date the overturned reconsideration was paid or, for upheld reconsiderations, submit based on the date the case was forwarded to the IRE. Submit dismissed requests based on the date of the decision to dismiss (Column M). • Include all payment requests for Part B drugs if applicable. • Include all payment requests for supplemental services that meet the criteria defined at 42 CFR § 422.100(c)(2). • If a payment organization determination or reconsideration includes more than one service, include all of the request's line items in a single row and enter the multiple line items as a single organization determination or reconsideration request. o Enter any request denied in whole or in part as denied. • Enter all fields for a single case in the same time zone. For example, if the Sponsoring organization has systems in EST and CST, all data in a single line item must be in a single time zone. • Exclude all payment requests processed as: o duplicate claims, o payment adjustments, o reopenings, o withdrawals, and o retrospective reviews. • Exclude all requests for Value Added Items and Services. • Exclude any payment requests that were denied due to: o invalid billing codes, o eligibility (i.e., enrollees who were not enrolled on the date of service, providers not accepting assignment), or o recoupment of payment, including pending determination of other primary insurance such as automobile, worker's compensation, etc.

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ODAG Protocol Waiver of Liability (WOL) Receipt Date Table 3: Column ID J	[Description] Enter the date the WOL form was received for non-contracted provider payment appeals. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter NA for ODs and member submitted requests.	Technical Clarification	[Description] Enter the date the WOL form was received for non-contracted provider payment appeals. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None for ODs, enrollee submitted requests, or if a WOL was never received.
ODAG Protocol Was it a clean claim? Table 3: Column ID K	[Description] Enter: • Y for clean claim • N for unclean claim • NA if the claim was received from the enrollee [Field Length] 2	Technical Clarification	[Description] Enter: • Y for clean claim • N for unclean claim • None for payment reconsiderations [Field Length] 4
ODAG Protocol Request Determination Table 3: Column ID M	[Field Length] 8	Technical Clarification	[Field Length] 9
ODAG Protocol Date claim/reconsideration was paid Table 3: Column O	[Field Name] Date claim was paid [Description] Enter the date the claim was paid. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None if payment was not provided. Enter NA if the request was denied or dismissed.	Technical Clarification	[Field Name] Date claim/reconsideration was paid [Description] Enter the date the claim/reconsideration was paid. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None if payment was not provided, if the request was denied, or if the request was dismissed.
ODAG Protocol Date written notification provided to provider Table 3: Column ID Q	[Description] Enter the date written notification was provided (i.e. delivered) to provider. Do not enter the date a letter is generated or printed. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None if no written notification was provided. Enter NA if enrollee submitted request.	Technical Clarification	[Description] Enter the date written notification was provided to provider. Do not enter the date a letter is generated or printed. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None if no written notification was provided or if the enrollee submitted the request.

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ODAG Protocol Who made the request? Table 3: Column ID S	N/A	Technical Clarification	[Column ID] S [Field Name] Who made the request? [Field Type] CHAR Always Required [Field Length] 3 [Description] Enter who made the request: • E for enrollee • ER for enrollee's representative • NCP for requests by a non-contract provider NCP includes non-contract pharmacies.
ODAG Protocol Was the initial organization determination request denied for lack of medical necessity? Table 3: Column ID U	[Column ID] AF [Field Name] Was the request denied for lack of medical necessity? [Field Length] 2 [Description] Enter: • Y for Yes • N for No • NA if the request was approved.	Technical Clarification	[Column ID] U [Field Name] Was the initial organization determination request denied for lack of medical necessity? [Field Length] 4 [Description] Enter: • Y for Yes • N for No • None if the request was approved or dismissed.
ODAG Protocol Time the overturned decision was received Table 4: Column ID K	[Description] Enter the time the overturned decision was received. Submit in HH:MM:SS military time format (e.g., 23:59:59). Enter NA for Standard (pre-service) and Payment reconsideration cases.	Technical Clarification	[Description] For expedited requests and Part B drug requests, enter the time the overturned decision was received. Submit in HH:MM:SS military time format (e.g., 23:59:59). Enter None for Standard (pre-service) and Payment reconsideration cases.

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ODAG Protocol Date overturned decision or payment effectuated in the system Table 4: Column ID L	[Description] Enter the date overturned decision effectuated in the system. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter NE if the overturned decision was not effectuated.	Technical Clarification	[Description] Enter the date overturned decision effectuated in the system. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None if the overturned decision was not effectuated.
ODAG Protocol Time overturned decision or payment effectuated in the system Table 4: Column ID M	[Description] Enter the time overturned decision effectuated in the system. Submit in HH:MM:SS military time format (e.g., 23:59:59). Enter NA for Standard (pre-service) and Payment reconsideration cases, Enter NE if the overturned decision was not effectuated.	Technical Clarification	[Description] For expedited requests and Part B drug requests, enter the time the overturned decision was effectuated in the system. Submit in HH:MM:SS military time format (e.g., 23:59:59). Enter None for Standard (pre-service) and Payment reconsideration cases, or if the overturned decision was not effectuated.
ODAG Protocol Table 5: GRV_C Table Instructions	• Include all grievances the Sponsoring organization responded to during the universe request period. The date of the Sponsoring organization's response (Column ID R or S) must fall within the universe request period. • Exclude all grievances that were withdrawn during the universe request period. • Exclude complaints filed only within the Complaints Tracking Module (CTM) in HPMS. If a complaint was processed both within the CTM and was also received as a grievance, exclude the CTM complaint but include the grievance as processed by the Sponsoring organization.	Technical Clarification	• Include all grievances the Sponsoring organization responded to during the universe request period. The date of the Sponsoring organization's notification (Column ID Q or S) must fall within the universe request period. • Exclude all grievances that were withdrawn and dismissed during the universe request period. • Exclude complaints filed only within the Complaints Tracking Module (CTM) in HPMS. If a complaint was processed both within the CTM and was also received as a grievance, exclude the CTM complaint but include the grievance as processed by the Sponsoring organization.
ODAG Protocol Enrollee ID Table 5: Column ID C	[Field Length] 20	Technical Clarification	[Field Length] 11
ODAG Protocol Plan Benefit Package (PBP) Tables 5-6: Column E	Table 5 [Field Name] Plan ID [Description] Enter the plan number (e.g., 001). [Table 7 Description] The PBP (e.g., 001) of the organization.	Technical Clarification	Table 5 [Field name] Plan Benefit Package (PBP) [Table 5 and Table 6 Description] Enter the PBP (e.g., 001).

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ODAG Protocol Time the Grievance was received Table 5: Column ID H	[Description] Enter the time the grievance was received. Submit in HH:MM:SS military time format (e.g., 23:59:59). Enter NA for standard cases.	Technical Clarification	[Description] Enter the time the grievance was received. Submit in HH:MM:SS military time format (e.g., 23:59:59). Enter None for standard cases.
ODAG Protocol Grievance Description Table 5: Column ID N	[Description] Enter a description of the complaint.	Technical Clarification	[Description] Enter a description of the grievance.
ODAG Protocol Date oral notification provided to enrollee Table 5: Column ID Q	[Field Name] Date oral response provided to enrollee [Description] Enter the date oral notification was provided to the enrollee. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None if no oral notification was attempted or provided.	Technical Clarification	[Field Name] Date oral notification provided to enrollee [Description] Enter the date oral notification was provided to the enrollee. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None if no oral notification was provided.
ODAG Protocol Time oral notification provided to enrollee Table 5: Column ID R	[Field Name] Time oral response provided to enrollee [Description] Enter the time oral notification was provided to the enrollee. Submit in HH:MM:SS military time format (e.g., 23:59:59). Enter None if no oral notification was attempted or provided. Enter NA for standard and dismissed cases.	Technical Clarification	[Field Name] Time oral notification provided to enrollee [Description] Enter the time oral notification was provided to the enrollee. Submit in HH:MM:SS military time format (e.g., 23:59:59). Enter None for standard grievances or if no oral notification was provided.
ODAG Protocol Date written notification provided to enrollee Table 5: Column ID S	[Field Name] Date written response provided to enrollee [Description] Enter the date written response was provided (i.e. delivered) to enrollee. Do not enter the date a letter is generated or printed. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None if a written notification was not provided.	Technical Clarification	[Field Name] Date written notification provided to enrollee [Description] Enter the date written notification was provided to enrollee. Do not enter the date a letter is generated or printed. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None if a written notification was not provided.

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ODAG Protocol Time written notification provided to enrollee Table 5: Column ID T	[Field Name] Time written response provided. to enrollee [Description] Enter the time written response was provided (i.e. delivered) to enrollee.. Submit in HH:MM:SS military time format (e.g., 23:59:59). Enter NA for standard cases. Enter None if written notification was not provided.	Technical Clarification	[Field Name] Time written notification provided to enrollee [Description] Enter the time written notification was provided to enrollee. Submit in HH:MM:SS military time format (e.g., 23:59:59). Enter None for standard cases, or if written notification was not provided.
ODAG Protocol Universe Table 6: Standard and Expedited Pre-Service Part B Drug Organization Determinations and Reconsiderations (Part B Drugs)	Universe Table 6: Standard and Expedited Pre-Service Part B Drug Organization Determinations and Reconsiderations (Part B Drugs)	Technical Clarification - Removed Table	N/A
ODAG Protocol Table 6: AIP	[Table Name] Universe Table 7: Dual Special Needs Plan – Applicable Integrated Plan Reconsiderations (AIP).	Technical Clarification - Renamed Table	[Table Name] Universe Table 6: Dual Special Needs Plan – Applicable Integrated Plan Reductions, Suspensions, and Terminations (AIP) Record Layout
ODAG Protocol Table 6: AIP Table Instructions	• Include all integrated organization determinations the DSNP-AIPs notified the enrollee would be terminated, suspended, or reduced during the universe request period. The date of the DSNP-AIP Integrated Denial Notification (Column ID G) must fall within the universe request period. • Populate this Table with requests involving Medicare-coverable benefits only. • Exclude all pre-service reconsideration cases.	Technical Clarification	• Include all integrated organization determination cases where a previously approved service is being reduced, suspended, or terminated by the DSNP-AIP. The date of the DSNP-AIP Integrated Denial Notification (Column ID G) must fall within the universe request period. • Populate this Table with requests involving Medicare-coverable benefits only. • Exclude all pre-service cases.
ODAG Protocol Enrollee First Name Table 6: Column ID A	Table 7 [Field Name] Member First Name [Description] First name of the member.	Technical Clarification	Table 6 [Field Name] Enrollee First Name [Description] Enter the first name of the enrollee.
ODAG Protocol Enrollee Last Name Table 6: Column ID B	Table 7 [Field Name] Member Last Name [Description] Last name of the member.	Technical Clarification	Table 6 [Field Name] Enrollee Last Name [Description] Enter the last name of the enrollee.

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ODAG Protocol Contract ID Table 6: Column ID D	Table 7 [Description] The contract number (e.g., H1234) of the organization.	Technical Clarification	Table 6 [Description] Enter the contract number (e.g., H1234).
ODAG Protocol First Tier, Downstream, and Related Entity Table 6: Column F	[Table 7 Column ID] Z [Description] Insert the name of the First Tier, Downstream, and Related Entity that processed the plan level appeal (e.g., Independent Physician Association, Physicians Medical Group or Third Party Administrator). Answer NA if not applicable.	Technical Clarification - moved field up in order within the record layout for consistency relettered remaining Column IDs in the tables.	[Table 6 Column ID] F [Description] Enter the name of the First Tier, Downstream, and Related Entity (which is any party that enters into a written arrangement, acceptable to CMS, with the Sponsoring organization to provide administrative or health care services to an enrollee under the Part C or D program) that processed the request. Enter None if the Sponsoring organization processed the request.
ODAG Protocol Date DSNP-AIP notified enrollee of its decision to reduce, terminate, or suspend services. Table 6: Column ID H	[Table 7 Column ID] G [Field Name] Date DSNP-AIP notified enrollee of its decision to terminate, reduce or suspend services [Description] Indicate the date the DSNP-AIP notified the enrollee of the termination, suspension, or reduction. Submit in CCYY/MM/DD format (e.g., 2020/01/01).	Technical Clarification	[Table 6 Column ID] H [Field Name] Date DSNP-AIP notified enrollee of its decision to reduce, terminate, or suspend services. [Description] Enter the date the DSNP-AIP notified the enrollee of the reduction, suspension, or termination. Submit in CCYY/MM/DD format (e.g., 2020/01/01).
ODAG Protocol Effective date of reduction, termination, or suspension of services. Table 6: Column ID I	[Table 7 Column ID] H [Field Name] Effective date of termination/ reduction/ suspension of services. [Description] Indicate the intended date of action (that is, the date on which a termination, suspension, or reduction becomes effective). Submit in CCYY/MM/DD format (e.g., 2020/01/01).	Technical Clarification	[Table 6 Column ID] I [Field Name] Effective date of reduction, suspension, or termination of services. [Description] Indicate the intended date of action (that is, the date on which reduction, suspension, or termination became effective). Submit in CCYY/MM/DD format (e.g., 2020/01/01).

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ODAG Protocol Was the decision appealed? Table 6: Column ID J	[Table 7 Column ID] I [Description] Enter (Y) for Yes or (N) for No. If (N) is entered, populate all remaining fields with NA.	Technical Clarification	[Table 6 Column ID] J [Description] Enter: • Y for Yes • N for No If 'N' is entered, populate all remaining fields with None.
ODAG Protocol Who made the request? Table 6: Column ID K	[Table 7 Column ID] J [Description] Indicate whether the plan level appeal was made by a member (M), contract provider (CP), non-contract provider (NCP), or member's representative (MR). Note- the term "provider" encompasses physicians and facilities.	Technical Clarification	[Table 6 Column ID] K [Description] Enter who made the plan level appeal: • E for enrollee • ER for enrollee's representative • CP for requests by a contract provider • NCP for requests by a non-contract provider "Provider" includes physicians and facilities. Enter None if the decision was not appealed as indicated by N in column ID J.
ODAG Protocol Date the appeal was received Table 6: Column ID L	[Table 7 Column ID] K [Field Name] Date the request was received [Description] Provide the date the request was received by your organization. Submit in CCYY/MM/DD format (e.g., 2020/01/01).	Technical Clarification	[Table 6 Column ID] L [Field Name] Date the appeal was received [Description] Enter the date the request was received. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None if the decision was not appealed as indicated by N in column ID J.

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ODAG Protocol AOR/Equivalent Notice Receipt Date Table 6: Column ID M	[Table 7 Column ID] Y [Description] Date the Appointment of Representative (AOR) form or other appropriate documentation received by the DSNP-AIP. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Answer NA if no AOR form was required.	Technical Clarification - moved field up in order within the record layout for consistency with all ODAG record layouts & relettered remaining Column IDs in the tables.	[Table 6 Column ID] M [Description] Enter the date the Appointment of Representative (AOR) form or equivalent written notice was received by the Sponsoring organization. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None for dismissed requests, if no AOR or equivalent written notice was received or required, or if the decision was not appealed as indicated by N in column ID J.
ODAG Protocol Was the appeal processed as Standard or Expedited? Table 6: Column ID N	[Table 7 Column ID] L [Field Name] Was the request processed as Standard or Expedited? [Field Length] 1 [Description] Enter the manner by which the request was processed: • S for Standard • E for Expedited	Technical Clarification	[Table 6 Column ID] N [Field Name] Was the appeal processed as Standard or Expedited? [Field Length] 4 [Description] Enter the manner by which the appeal was processed: • S for Standard • E for Expedited Enter None if the decision was not appealed as indicated by N in column ID J.

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ODAG Protocol Was appeal made under the expedited timeframe but processed by the plan under the standard timeframe? Table 6: Column O	[Table 7 Column ID] M [Field Name] Was request made under the expedited timeframe but processed by the plan under the standard timeframe? [Field Length] 2 [Description] Yes (Y)/No (N) indicator of whether the request was received as expedited but was downgraded and processed under the standard timeframe (e.g., based on the DSNP-AIP deciding that the expedited plan level appeal was unnecessary). Answer NA if the request was received as a standard request.	Technical Clarification	[Table 6 Column ID] O [Field Name] Was appeal made under the expedited timeframe but processed by the plan under the standard timeframe? [Field Length] 4 [Description] Yes (Y)/No (N) indicator of whether the request was received as expedited but was downgraded and processed under the standard timeframe (e.g., based on the DSNP-AIP deciding that the expedited plan level appeal was unnecessary). Enter None if the request was received as a standard request or if the decision was not appealed as indicated by N in column ID J.
ODAG Protocol Was a timeframe extension taken? Table 6: Column ID P	[Table 7 Column ID] N [Field Length] 2 [Description] Yes (Y)/No (N)/ Not Applicable (NA) indicator of whether the DSNP-AIP extended the timeframe to make the appeal decision.	Technical Clarification	[Table 6 Column ID] P [Field Length] 4 [Description] Yes (Y)/No (N) indicator of whether the DSNP-AIP extended the timeframe to make the appeal decision. Enter None if the decision was not appealed as indicated by N in column ID J.
ODAG Protocol If an extension was taken, did the DSNP-AIP notify the enrollee of the reason(s) for the delay and of their right to file an expedited grievance? Table 6: Column ID Q	[Table 7 Column ID] O [Field Length] 2 [Description] Yes (Y)/No (N) indicator of whether the DSNP-AIP notified the member of the delay. Answer NA if no extension was taken.	Technical Clarification	[Table 6 Column ID] Q [Field Length] 4 [Description] Yes (Y)/No (N) indicator of whether the DSNP-AIP notified the enrollee of the delay. Enter None if no extension was taken or if the decision was not appealed as indicated by N in column ID J.

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ODAG Protocol Did the enrollee request continuation of benefits? Table 6: Column ID R	[Table 7 Column ID] P [Field Length] 2 [Description] Yes (Y)/No (N) indicator of whether the enrollee requested continuation of benefits. Answer NA if no request for continuation of benefits was made.	Technical Clarification	[Table 6 Column ID] R [Field Length] 4 [Description] Yes (Y)/No (N) indicator of whether the enrollee requested continuation of benefits. Enter None if someone other than the enrollee requested continuation of benefits or if the decision was not appealed as indicated by N in column ID J.
ODAG Protocol Were the benefits under appeal provided to the enrollee during the plan level appeal process? Table 6: Column ID S	[Table 7 Column ID] Q [Field Length] 2 [Description] Yes (Y)/No (N) indicator of whether the benefits under appeal were provided to the enrollee during the reconsideration process. Answer NA if no request for continuation of benefits was made.	Technical Clarification	[Table 6 Column ID] S [Field Length] 4 [Description] Yes (Y)/No (N) indicator of whether the benefits under appeal were provided to the enrollee during the reconsideration process. Enter None if no request for continuation of benefits was made or if the decision was not appealed as indicated by N in column ID J.
ODAG Protocol Request Disposition Table 6: Column ID T	[Table 7 Column ID] R [Field Length] 50 [Description] Status of the request. Valid values are: approved, denied, denied with IRE auto forward, or IRE auto-forward due to untimely decision. DSNP-AIPs should note any requests that are untimely and not yet resolved (still outstanding) as denied. All untimely and pending cases should be treated as denials for the purposes of populating the rest of this record layout's fields.	Technical Clarification	[Table 6 Column ID] T [Field Length] 9 [Description] Enter: • Approved • Denied • Dismissed Enter None if the decision was not appealed as indicated by N in column ID J.

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ODAG Protocol Date of DSNP-AIP decision Table 6: Column ID U	[Table 7 Column ID] S [Description] Date of the DSNP-AIP decision. Submit in CCYY/MM/DD format (e.g., 2020/01/01).	Technical Clarification	[Table 6 Column ID] U [Description] Date of the DSNP-AIP decision. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None if the decision was not appealed as indicated by N in column ID J.
ODAG Protocol Date Oral Notification Provided to enrollee Table 6: Column ID V	[Table 7 Column ID] T [Field Name] Date Oral Notification Provided to member [Description] Date oral notification provided to member. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Answer NA if no oral notification provided.	Technical Clarification	[Table 6 Column ID] V [Field Name] Date Oral Notification Provided to enrollee [Description] Date oral notification provided to enrollee. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None if no oral notification provided or if the decision was not appealed as indicated by N in column ID J.
ODAG Protocol Date written notification provided to enrollee/provider Table 6: Column ID W	[Table 7 Column ID] U [Field name] Date written notification provided to member/provider [Description] Date written notification provided to member, or if applicable the non-contract provider. The term “provided” means when the letter left the DSNP-AIP’s establishment by US Mail, fax, or electronic communication. Do not enter the date when a letter is generated or printed within the DSNP-AIP’s organization. If no proof of mailing is available, populate based on worst case scenario according to policies in place. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Answer NA if no written notification was provided.	Technical Clarification	[Table 6 Column ID] W [Field name] Date written notification provided to enrollee/provider [Description] Date written notification provided to enrollee, or if applicable the non-contract provider. Do not enter the date when a letter is generated or printed within the DSNP-AIP’s organization. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None if no written notification was provided or if the decision was not appealed as indicated by N in column ID J.

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ODAG Protocol Date reconsidered determination effectuated in the DSNP-AIP system Table 6: Column ID X	[Table 7 Column ID] V [Field Name] Date service authorization entered/effectuated in the DSNP-AIP system [Description] Date authorization/approval entered in the DSNP-AIP 's system. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Answer NA for denials and IRE auto-forwards.	Technical Clarification	[Table 6 Column ID] X [Field Name] Date reconsidered determination effectuated in the DSNP-AIP system [Description] Date reconsidered determination effectuated in the DSNP-AIP 's system. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None for denials and or if the decision was not appealed as indicated by N in column ID J.
ODAG Protocol Date forwarded to IRE if denied or untimely Table 6: Column ID Y	[Table 7 Column ID] W [Description] Date the AIP forwarded request to the IRE if request for Medicare service was denied or processed untimely. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Answer NA if approved or not forwarded to IRE.	Technical Clarification	[Table 6 Column ID] Y [Description] Date the AIP forwarded request to the IRE if request for Medicare service was denied or processed untimely. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Answer None if approved or not forwarded to IRE or if the decision was not appealed as indicated by N in column ID J.
ODAG Protocol If request denied, date services were terminated, reduced, suspended Table 6: Column ID Z	[Table 7 Column ID] X [Description] Date of the DSNP-AIP decision. Submit in CCYY/MM/DD format (e.g., 2020/01/01).	Technical Clarification	[Table 6 Column ID] Z [Description] Enter the date the services were terminated, reduced, suspended. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None if the decision was not appealed as indicated by N in column ID J.
ODAG Protocol Audit Field Work Phase	• If applicable, providing timely notification of dismissals to enrollees or another party, and informing enrollees and other parties about the right to request IRE review of the dismissal since Sponsoring organizations will no longer automatically forward such reconsideration cases to the IRE for review.	Technical Clarification	• If applicable, providing timely notification of dismissed requests to enrollees or another party, and informing enrollees and other parties about the right to request IRE review of the dismissed request since Sponsoring organizations will no longer automatically forward such reconsideration cases to the IRE for review.

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SNPCC Protocol Program Audit Protocol Purpose	To evaluate performance in the areas outlined in this Program Audit Protocol and Data Request related to Special Needs Plans Care Coordination (SNPCC). The Centers for Medicare and Medicaid Services (CMS) performs its program audit activities in accordance with the SNPCC Program Audit Data Request and applying the compliance standards outlined in this Program Audit Protocol and the Program Audit Process Overview document.	Technical Clarification	To evaluate performance in the areas outlined in this Program Audit Protocol and Data Request related to Special Needs Plans Care Coordination (SNPCC). The Centers for Medicare and Medicaid Services (CMS) performs its program audit activities in accordance with the SNPCC Program Audit Data Request and applying the compliance standards outlined in this Program Audit Protocol and the Program Audit Process Overview document. At a minimum, CMS will evaluate cases against the criteria listed below. CMS may review factors not specifically addressed below if it is determined that there are other related SNPCC requirements not being met.
SNPCC Protocol Compliance Standard Universe Integrity Testing	[Method of Evaluation] Select 10 cases from Universe Table 1. Prior to field work, CMS will schedule a webinar with the Sponsoring organization to verify accuracy of data within Table 1 for each of the sampled cases. Sample selections will be provided to the Sponsoring organization approximately one hour prior to the scheduled webinar.	Technical Clarification	[Method of Evaluation] Select 10 cases from Universe Table 1. Prior to field work, CMS will schedule a webinar with the Sponsoring organization to verify accuracy of data within Table 1 for each of the sampled cases. System data such as enrollment dates, dates of initial HRA, etc. will be verified. Sample selections will be provided to the Sponsoring organization approximately one hour prior to the scheduled integrity testing webinar.
SNPCC Protocol Compliance Standard 1.1	Conduct timeliness test at the universe level of enrollees who have been enrolled for at least 90 days, to determine whether the Sponsoring organization conducted an initial health risk assessment (IHRA) for each applicable enrollee within 90 days of enrollment. Request an impact analysis for any enrollee identified as having an untimely IHRA to quantify the outreach made by the Sponsoring organization in an attempt to conduct the IHRA within 90 days of enrollment.	Technical Clarification	Conduct a timeliness test at the universe level of enrollees who have been continuously enrolled for at least 90 days, to determine whether the Sponsoring organization conducted a timely initial health risk assessments (IHRAs) within 90 days (before or after) the effective date of enrollment. IHRA Timeliness assessments will be conducted using current enrollments, from Table 1. Assessments will be limited to individuals enrolled with effective dates within 12 months of the audit engagement letter. Request an impact analysis for any enrollee identified as having an untimely IHRA to quantify the outreach made by the Sponsoring organization in an attempt to conduct the IHRA within 90 days of enrollment. Impact analysis review period is limited to the 12 the month period prior to date of the engagement letter, to align with the timeliness test. **Outreach data points in Table 2IA are subject to validation, as requested by CMS.*

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SNPCC Protocol Compliance Standard 1.2	Conduct timeliness test at the universe level of enrollees who have been enrolled for at least 13 consecutive months, to determine whether the Sponsoring organization conducted an annual health risk assessment (AHRA) for each applicable enrollee within 365 days of the prior HRA. Request an impact analysis for any enrollee identified as having an untimely AHRA to quantify the outreach made by the Sponsoring organization in an attempt to conduct the AHRA within 365 days of the prior HRA completion date.	Technical Clarification	Conduct timeliness test at the universe level of enrollees who have either been continuously enrolled for 365 days or more, or new enrollees who missed the deadline to complete an initial HRA, to determine whether the Sponsoring organization conducted timely annual health re-assessment HRAs (AHRAs). Request an impact analysis for any enrollee identified as having an untimely AHRA to quantify the outreach made by the Sponsoring organization in an attempt to conduct the AHRA within 365 days of the prior HRA completion date, or date of enrollment, if no initial HRA was conducted.
SNPCC Protocol Compliance Standard 1.3	Sample selections will be provided to the Sponsoring organization approximately one hour prior to the scheduled webinar.	Technical Clarification	Sample selections will be provided to the Sponsoring organization the Thursday prior to the start of audit field work.
SNPCC Protocol Compliance Standard 1.6	Review case management notes, ICT documentation, and systems information such as utilization management, claims data, and prescription drug events (PDE) for each of the 30 selected samples to determine whether the Sponsoring organization implemented the ICP.	Technical Clarification	Review documentation which may include, but is not limited to case management notes, ICT documentation, and systems information such as utilization management, claims data, and prescription drug events (PDE) for each of the 30 selected samples to determine whether the Sponsoring organization implemented the ICP.
SNPCC Protocol Compliance Standard 1.7	Review documented ICT notes and communications (amongst ICT members and/or with enrollees/caregivers) pertaining to each of the 30 selected samples to determine how the enrollee or the caregiver/representative was involved in the ICP development.	Technical Clarification	Review documentation which may include, but is not limited to ICT notes and communications (amongst ICT members and/or with enrollees/caregivers) pertaining to each of the 30 selected samples to determine how the enrollee or the caregiver/representative was involved in the ICP development.
SNPCC Protocol Compliance Standard 1.8	Review systems for documented case management notes, ICT member notes and communications (e.g. documented phone calls, letters to/from providers regarding member care, etc.), and ICT meeting agendas/minutes pertaining to each of the 30 selected samples to determine whether the Sponsoring organization coordinated communication amongst its personnel, providers, and enrollees.	Technical Clarification	Review systems for documentation which may include but is not limited to case management notes, ICT member notes and communications (e.g. documented phone calls, letters to/from providers regarding member care, etc.), and ICT meeting agendas/minutes pertaining to each of the 30 selected samples to determine whether the Sponsoring organization coordinated communication amongst its personnel, providers, and enrollees.
SNPCC Protocol Compliance Standard 1.11	Review documentation for each of the 30 selected samples to determine whether the Sponsoring organization has knowledgeable, credentialed individuals performing HRA analysis and ICP development processes in accordance with their MOC.	Technical Clarification	Review documentation for each of the 30 selected samples to determine whether ICPs were developed and implemented by staff that met the professional requirements, including credentials, described in the MOC.
SNPCC Protocol Universe Requests	Scope of Universe Request* * CMS reserves the right to expand the review period to ensure sufficient universe size.	Technical Clarification	Scope of Universe Request

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SNPCC Protocol Table 1: SNPE Table Instructions	• List all current SNP enrollees as of the date of the audit engagement letter that have been enrolled with Sponsoring organization for at least 90 days and for 13 continuous months. • List each enrollee only once. • Include enrollees with disenrollment effective dates at the end of month in which you receive your audit engagement letter. • Exclude enrollments received before the date of the audit engagement letter that are not effective until the first day of the month following the audit engagement letter.	Technical Clarification	• List all current SNP enrollees as of the date of the audit engagement letter. • List each enrollee only once. • Include enrollees with disenrollment effective dates at the end of month in which the audit engagement letter is received. • Exclude enrollments received before the date of the audit engagement letter that are not effective until the first day of the month following the audit engagement letter.
SNPCC Protocol Enrollment Effective Date Table 1: Column ID G	[Description] Enter the effective date of the most current/continuous enrollment for the enrollee with the Sponsoring organization. Submit in CCYY/MM/DD format (e.g., 2020/01/01). For a PBP change or consolidation event the Sponsoring organization must use the pre-event effect date for the enrollee. (e.g., If an enrollee is effective 4/1/2010 and stays in D- SNP through 12/31/2016 but moves to C-SNP effective 1/1/2017. We would expect to see 04/01/2010 in the universe).	Technical Clarification	[Description] Enter the effective date of the most current/continuous enrollment for the enrollee with the Sponsoring organization. Submit in CCYY/MM/DD format (e.g., 2020/01/01).
SNPCC Protocol Most Recent Plan Change Effective Date Table 1: Column ID H	N/A	Technical Clarification - Added field and relettered remaining Column IDs in the table	Field Type: CHAR Always Required Field Length: 10 Description: Enter the date of last plan change within the continuous SNP enrollment. Submit in CCYY/MM/DD format (e.g.,2020/01/01) For a PBP change or consolidation event the Sponsoring organization must use the post-event effect date for the enrollee. Enter None if there were no PBP or plan consolidation events.
SNPCC Protocol Date of previous HRA Table 1: Column ID J	[Description] This is the date of the most recently completed HRA prior to the date entered in Column ID H.	Technical Clarification	[Description] This is the date of the most recently completed HRA prior to the date entered in Column ID I.

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SNPCC Protocol Date Initial HRA (IHRA) was completed Table 1: Column ID K	[Description] Enter the date of the enrollee's first HRA completion (prior to or after enrolling). HRA completion date is the date the HRA is returned completed to the Sponsoring organization by either the enrollee or the enrollee's representative. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter NA if no HRA was completed. Enter EXC-10 if the IHRA date is greater than 10 years ago.	Technical Clarification	[Description] Enter the date of the enrollee's first HRA completion (within 90 days before or after the effective date of enrollment). HRA completion date is the date the HRA is returned completed to the Sponsoring organization by either the enrollee or the enrollee's representative. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None if no HRA was completed within 90 days before or after the effective date of enrollment. Enter EXC-10 if the IHRA date is greater than 10 years ago.
SNPCC Protocol Date of most recent Individualized Care Plan (ICP) Table 1: Column ID M	[Description] Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None if the enrollee did not receive an ICP.	Technical Clarification	[Description] Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None if the Sponsoring organization did not develop an ICP. If care plan is continuous, enter the date of the most recent update.
SNPCC Protocol Impact Analysis Requests Table 2IA Scope of Impact Analysis Request	Submit a list of enrollees who did not receive a timely initial and/or annual HRA during the 26-week period preceding the date of the audit engagement letter through the date the issue was identified on audit.	Technical Clarification	Submit a list of enrollees who did not receive a timely initial and/or annual HRA within the 12 month period prior to the date of the engagement letter. Populate untimely cases with the appropriate outreach information for initial and/or annual HRAs as identified during the timeliness test.
SNPCC Protocol Table 1IA CC-IA Table Instructions	• Include all enrollees missing either a completed HRA, ICP, or ICT as specified in the request for an impact analysis.	Technical Clarification	• Include all enrollees impacted by the care coordination issue as specified in the request for an impact analysis.
SNPCC Protocol Initial ICP Date Table 1IA: Column ID K	[Description] Enter the date the initial ICP was completed. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None if no initial ICP created.	Technical Clarification	[Description] Enter the date the initial ICP was completed. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None if an initial ICP was not completed.
SNPCC Protocol Date of Most Recent ICP revision Table 1IA: Column ID L	[Description] Enter the date the most recent ICP was completed. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter NA if most recent ICP not completed.	Technical Clarification	[Description] Enter the date the ICP was most recently revised. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter NA if the enrollee's ICP has not been completed or revised since the initial ICP was completed per Column ID K.

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SNPCC Protocol Basis of most recent ICP Table 1IA: Column ID M	[Description] Enter ICP basis: • Initial • Annual, or • Change in Status Enter NA if no ICP conducted.	Technical Clarification	[Description] Enter basis for most recent ICP revision in Column ID L: • Initial • Annual, or • Change in Status Enter NA if the enrollee's ICP has not been completed or revised since the initial ICP was completed per Column ID K.
SNPCC Protocol Date of previous ICP revision Table 1IA: Column ID N	[Description] Enter the date the previous ICP was completed. Submit in CCYY/MM/DD format (e.g., 2020/01/01) In the case of an ICP that was created on January 1, but then updated on March 1 of the same year, March is the most recent, and January is the "previous" Enter NA if no previous ICP was conducted.	Technical Clarification	[Description] Enter the date the enrollee's ICP was previously revised compared to Column ID L. Submit in CCYY/MM/DD format (e.g., 2020/01/01) In the case of an ICP that was revised on January 1, but then revised again on March 1 of the same year, March is the date of the most recent ICP revision, and January is the date of the previous ICP revision. Enter NA if the enrollee's ICP has not been completed or revised since the ICP was revised per Column ID L.
SNPCC Protocol Basis of previous ICP Table 1IA: Column ID O	[Description] Enter previous ICP basis: • Initial • Annual, or • Change in Status Enter NA if no previous ICP conducted.	Technical Clarification	[Description] Enter basis for previous ICP revision: • Initial • Annual, or • Change in Status Enter NA if the enrollee's ICP has not been completed or revised since the ICP was revised per Column ID L.
SNPCC Protocol Did all members of enrollee's ICT receive annual MOC training? Table 1IA: Column ID W	[Field Name] Did all members of enrollee's ICT receive annual MOC training.	Technical Clarification	[Field Name] Did all members of enrollee's ICT receive annual MOC training?
SNPCC Protocol Table 2IA HRAT-IA Table Instructions	• Include all enrollees without a completed HRA or with an untimely HRA as specified in the request for impact analysis. The look back period is 26 weeks, sponsoring organizations conducting HRA events within the 26 week look back period on a single enrollee should populate the IA record layout with the most recent HRA event that occurred during the applicable timeframe.	Technical Clarification	• Include all enrollees without a completed HRA or with an untimely HRA to quantify outreach attempts, as specified in the request. • Impact analysis review period is the 12 month period prior to date of the engagement letter. Sponsoring organizations conducting HRA events within the 12-month period on a single enrollee should populate the IA record layout with the most recent HRA event that occurred during the applicable timeframe.

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SNPCC Protocol Date the HRA - Unable to Contact (UTC) Letter was sent to non-responding enrollee Table 2IA: Column ID V	[Description] Enter the date the UTC letter was sent. Submit in CCYY/MM/DD format (e.g., 2020/01/01) or enter NA, if no letter sent. This column should reflect only the most recent HRA event that occurred during the 26 week look back period.	Technical Clarification	[Description] Enter the date the UTC letter was sent. Submit in CCYY/MM/DD format (e.g., 2020/01/01) or enter NA, if no letter sent.
SNPCC Supplemental Questionnaire	3. Describe staffing responsibilities for administering HRAs and developing ICPs.	Technical Clarification-question removed & renumbered remaining questions	[Question 3 removed]
SNPCC Supplemental Questionnaire	7. Describe the process of verifying licensure for credentialed personnel.	Technical Clarification-question removed & renumbered remaining questions	[Question 7 removed]
SNPCC Supplemental Questionnaire	9. Describe the process for tracking the distribution of MOC training materials to ICT providers.	Technical Clarification-question removed & renumbered remaining questions	[Question 9 removed]
SNPCC Supplemental Questionnaire	10. Describe the internal system utilized for ensuring that ICTs are comprised of appropriate disciplines, as described in the MOC, and that ICTs coordinate care and communicate with each other and enrollees regarding the ICP.	Technical Clarification-question removed & renumbered remaining questions	[Question 10 removed]
SNPCC Supplemental Questionnaire	11. If there are ICT meetings where beneficiary ICPs and care coordination are discussed, what is the period of time expected between initial ICP development and presentation to the ICT?	Technical Clarification-question removed & renumbered remaining questions	[Question 11 removed]
SNPCC Supplemental Questionnaire	12. Describe outreach policy pertaining to HRA administration and ICP development.	Technical Clarification	7. Describe the outreach policy pertaining to HRA administration and ICP development. Describe the process for beneficiaries that cannot or do not want to be contacted.

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SNPCC Supplemental Questionnaire	14. What is the period of time expected between HRA (or completion of outreach efforts if beneficiary is unreachable) and ICP development? If there are differences in ICP development timing expected based on risk stratification level, please explain.	Technical Clarification-question removed	[Question 14 removed]
Supporting Statement A Footnote, page 1	[1] The ODAG protocol also evaluates the integrated organization determinations, appeals, and grievances of sponsoring organizations offering an applicable integrated SNP plan with exclusively aligned enrollment as defined at 42 CFR § 561.	Corrected the partial omission of regulation citation	[1] The ODAG protocol also evaluates the integrated organization determinations, appeals, and grievances of sponsoring organizations offering an applicable integrated SNP plan with exclusively aligned enrollment as defined at 42 CFR § 422.561.
Supporting Statement A Section 2	The information gathered during this audit will be used by the Medicare Parts C and D Oversight and Enforcement Group (MOEG) within the Center for Medicare (CM) and CMS Regional Offices to assess sponsoring organizations' compliance with Medicare program requirements. If outliers or other data anomalies are detected, Regional Offices will work in collaboration with (MOEG) and other divisions within CMS for follow-up and resolution. Additionally, MA and Part D organizations will receive the audit results and will be required to implement corrective action to correct any identified deficiencies.	Technical Clarification	The information gathered during this program audit will be used by the Medicare Parts C and D Oversight and Enforcement Group (MOEG) within the Center for Medicare (CM) and CMS Regional Offices to assess sponsoring organizations' compliance with Medicare program requirements. Specifically, as part of its FA review, MOEG reviews samples of rejected claims to ensure that the point-of-sale rejections are appropriate; its purpose is to ensure Part D organizations are administering their formulary and transition benefit in accordance with their CMS-approved formulary and the overriding regulations. MOEG's ODAG and CDAG reviews focus on the timeliness of coverage decisions and grievances related to requests for services and drugs. ODAG and CDAG universes are collected and reviewed at the universe level to ensure organizations are meeting the notification and effectuation timeframe requirements outlined in regulation, and samples are reviewed to ensure proper procedures are followed in processing these requests, such as providing appeal rights for denied requests, ensuring the appropriate level of review when initial requests are denied for lack of medical necessity, etc. As part of its CPE review, MOEG uses audit universes and information collected via questionnaires to assess the extent to which Part C and Part D organizations have adopted and implemented an effective compliance program, inclusive of measures that prevent, detect, and correct non-compliance with CMS' program requirements. And finally, if the audited MA organization offers a SNP, MOEG's review evaluates a sample of SNP enrollees to ensure the SNP is coordinating care, administering health risk assessments, updating individual care plans, and assigning interdisciplinary care teams in accordance with the CMS-approved model of care. If outliers or other data anomalies are detected, MOEG requires audited organizations to provide impact analyses to better understand and report the scope of the noncompliance. These MA and Part D organizations then receive their audit results, are required to implement corrective actions, and to demonstrate correction of all conditions cited in the final audit report by undergoing a validation audit. If the validation audit demonstrates substantial correction of the conditions, MOEG will communicate its decision to close the audit in a letter to the MA and Part D organization. Any new or isolated issues of non-compliance that remain will be referred to the CMS Account Manager for follow-up. Regional Offices will work in collaboration with MOEG and other divisions within CMS for resolution.

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Supporting Statement A Section 6	42 CFR part 423 subpart K and 422 subpart K stipulate that CMS must oversee a sponsoring organization's continued compliance with CMS requirements. In general, CMS attempts to audit each sponsoring organization once every 4 years. However, the frequency with which an audit occurs for a sponsoring organization can be based on a variety of factors, including the identification of compliance issues, referral for program audit, the size of the organization, and amount of time since last audit. In addition, CMS conducts annual timeliness monitoring of Part C organization determinations and appeals, and Part D coverage determinations and appeals. Less frequent collection of the data from sponsoring organizations would severely limit CMS' ability to perform accurate and timely oversight, monitoring, and compliance and auditing activities around the Parts C and D Medicare benefits and could result in an increased potential for harm to Medicare beneficiaries.	Technical Clarification	42 CFR part 423 subpart K and 422 subpart K stipulate that CMS must oversee a sponsoring organization's continued compliance with CMS requirements. In general, CMS attempts to audit coverage for at least 95 percent of MA and Part D covered enrollees by conducting program audits at the parent organization level within a given audit cycle. Each audit cycle averages 4 years in duration, and organizations with the most MA and Part D enrollees tend to be audited at the beginning of each audit cycle. Organizations with less MA and Part D enrollees, or organizations that have never been subject to a program audit, tend to be scheduled in the latter half of the cycle. Given the variance in total enrollment, the number of audits conducted each year can range from 13 to 40 audits, and the frequency with which an audit occurs can also be influenced by the identification of compliance issues, referral for program audit, a spike in the size of an organization, and the amount of time since the last audit. In addition, CMS conducts annual timeliness monitoring of Part C organization determinations and appeals . Less frequent collection of the data from sponsoring organizations would severely limit CMS' ability to perform accurate and timely oversight, monitoring, compliance, and auditing activities around the Parts C and D Medicare benefits and could result in an increased potential for harm to Medicare beneficiaries.
Supporting Statement A Section 8	The 60-day notice published in the Federal Register on [TBD] (84 FR INSERT).	Updated to reflect changes resulting from public comment	The 60-day notice published in the Federal Register on December 6, 2019 (84 FR 66912). CMS received 42 public submissions, which included 662 comments. We then combined the 662 comments into 329 unique comments and provided responses in the comment and response summary that is included in this collection request. We adopted many of the commenters' suggestions and believe that those corresponding edits simplify and clarify the collection instruments. First, we removed the rejected claims transition record layout for the previous contract year from the FA Data Request, as well as the Part B Drugs record layout from the ODAG Data Request to further streamline our review and data collection. Then, we identified additional opportunities to clarify and standardize field definitions and locations within the FA, CDAG, and ODAG record layouts. Next, we redefined field descriptions within the SNPE record layout, as found in the SNPCC Data Request, to align our data collection and evaluation with the 2020 Part C Reporting Requirements. Finally, we renamed the CPE Program Audit Protocol and Data Request document for consistency and clarification of the audit scope, and spelled out frequently used acronyms to reduce confusion within the CPE questionnaires. Please refer to the Crosswalk of Changes for a complete summary of updates made to this collection request since the December 6, 2019 publication. The 30-day notice published in the Federal Register on [TBD] (85 FR INSERT).

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Supporting Statement A Section 12 Burden Estimates (Hours & Wages) Wage Estimates	May 2018 BLS wage estimates	Updated wage data	May 2019 BLS wage estimates
Supporting Statement A Section 14 Cost to Federal Government	[Staff Time] 2019 OPM General Schedule wage data: **1,193,934** [Contractor Costs] **$7,493,7768**	Updated wage data	[Staff Time] 2020 OPM General Schedule wage data: **1,217,400** [Contractor Costs] **$8,513,400**
Supporting Statement A Section 15 Changes to Burden	New collection, not applicable to changes to burden at this time.	Updated to reflect changes resulting from public comment	As indicated in Section 8 above, we adopted many of the technical changes that were suggested in public comment in the interest of simplifying and clarifying the collection instruments. First, we removed the rejected claims transition record layout for the previous contract year from the FA Data Request, as well as the Part B Drugs record layout from the ODAG Data Request to further streamline our review and data collection. Then, we identified additional opportunities to clarify and standardize field definitions and locations within the FA, CDAG, and ODAG record layouts. Next, we redefined field descriptions within the SNPE record layout, as found in the SNPCC Data Request, to align our data collection and evaluation with the 2020 Part C Reporting Requirements. Finally, we renamed the CPE Program Audit Protocol and Data Request document for consistency and clarification of the audit scope, and spelled out frequently used acronyms to reduce confusion within the CPE questionnaires. These changes resulted in no change to burden. As summarized in the 60-day collection request, we estimate the total hourly burden for routine program audits **at 701 hours** to reflect the entirety of the audit process. The total number of **routine program audits** is estimated at 25 and the corresponding **total burden is 17,525 hours.** The total hourly burden for the industry wide timeliness monitoring project remains at 120.5 hours per respondent. As described above, the number of respondents for this timeliness monitoring project is 154 sponsoring organizations per year. **Consequently, the total burden for the industry wide monitoring effort is 18,557 hours.**