

Current Approved CMS-10717	Initial Proposed CMS-10717 (Summary of Changes)	Type of Change	Explanation of Changes	Burden Impact
CDAG Protocol, Purpose	<ul style="list-style-type: none"> Modified purpose text 	Modify	Minor wording changes for clarity	None
CDAG Protocol, Audit Elements Tested	<ul style="list-style-type: none"> Removed Administration of Drug Management Program element, the associated compliance standards 1.6, 4.1-4.3, and Universe Table 7: Comprehensive Addiction and Recovery Act (CARA) At-Risk Determination (AR) 	Remove	Removed due to low volume of data received	High (reduction)
CDAG Protocol, Compliance Standards	<ul style="list-style-type: none"> Modified column title to remove criteria effective date Reduced the number of integrity testing samples due to removal of Table 7 Updated regulatory references throughout Updated sampling language to address the minimum number of samples that will be selected Compliance standard 2.3: Added language to address the appropriateness of the denial & added review for coordination of benefits 	Modify	Technical changes, Additions based on regulatory updates	Low

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	<ul style="list-style-type: none"> Compliance standard 3.2: Added review for appropriate classification Compliance standard 3.1: Added review of dismissal cases 			
CDAG Protocol, Compliance Standards	<ul style="list-style-type: none"> Added review of auto-forwarding of adverse at-risk redeterminations to the IRE to compliance standard 1.16 Added sampling and review of reopening cases 	Add	Additions based on audit experience	Low
CDAG Protocol, Universe Submissions	<ul style="list-style-type: none"> Modified universe submissions text 	Modify	Technical changes	None
CDAG Protocol, Universe Requests	<ul style="list-style-type: none"> Modified scope of universe request language and table footer 	Modify	Technical changes	None
CDAG Protocol, Universe Requests	<ul style="list-style-type: none"> Added General Record Layout Instructions 	Add	Clarified instructions, Changes based on audit experience	None
CDAG Protocol, Universe Table 1: Standard and Expedited Coverage Determination (CD) Record Layout	<ul style="list-style-type: none"> Clarified that each notification must be a separate line item Clarified that for requests denied in part to include data regarding the approval and effectuation of the 	Modify	Clarified instructions in specific fields, Added a few columns for increased clarity	Low

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	<p>favorable portion of the decision</p> <ul style="list-style-type: none"> • Added instruction to exclude appeals of dismissals or requests to vacate dismissals • Modified Enrollee ID field description • Modified PBP field description • Addition to NDC field description • Addition to Date & Time oral notification provided to enrollee field descriptions • Who made the request? field description: Added option of None for reopened cases 			
<p>CDAG Protocol, Universe Table 2: Standard and Expedited Coverage Determination Exception Requests (CDER) Record Layout</p>	<ul style="list-style-type: none"> • Clarified that each notification must be a separate line item • Clarified for requests denied in part to include data regarding the approval and effectuation of the favorable portion of the decision 	<p>Modify</p>	<p>Clarified instructions in specific fields, Added a few columns for increased clarity</p>	<p>Low</p>

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	<ul style="list-style-type: none"> • Added instruction to exclude appeals of dismissals or requests to vacate dismissals • Modified Enrollee ID field description • Modified PBP field description • Addition to NDC field description • Addition to Date & Time oral notification provided to enrollee field descriptions • Who made the request? field description: Added option of None for reopened cases 			
CDAG Protocol, Universe Table 3: Payment Coverage Determinations and Redeterminations (PYMT_D) Record Layout	<ul style="list-style-type: none"> • Clarified that each notification must be a separate line item • Added if the payment request also requires a clinical review, the clinical review aspect of the case is to be included in Universe Table 3 only • Clarified for requests denied in part to include 	Modify	Clarified instructions in instructions and in specific fields	Low

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	<p>data regarding the approval and effectuation of the favorable portion of the decision</p> <ul style="list-style-type: none"> • Added instruction to exclude appeals of dismissals or requests to vacate dismissals • Modified Enrollee ID field description • Modified PBP field description • Addition to NDC field description • Who made the request? field description: Added option of None for reopened cases 			
<p>CDAG Protocol, Universe Table 4: Standard and Expedited Redeterminations (RD) Record Layout</p>	<ul style="list-style-type: none"> • Clarified that each notification must be a separate line item • Clarified for requests denied in part to include data regarding the approval and effectuation of the favorable portion of the decision • Added instruction to exclude appeals of 	<p>Modify</p>	<p>Clarified instructions in specific fields, Added a few columns for increased clarity</p>	<p>Low</p>

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	<p>dismissals or requests to vacate dismissals</p> <ul style="list-style-type: none"> • Modified Enrollee ID field description • Modified PBP field description • Addition to NDC field description • Addition to Authorization or Claim Number field description • Addition to Date & Time oral notification provided to enrollee field descriptions • Who made the request? field description: Added option of None for reopened cases 			
<p>CDAG Protocol, Universe Table 5: Part D Effectuations of Overturned Decisions by IRE, ALJ or MAC (EFF_D) Record Layout</p>	<ul style="list-style-type: none"> • Modified Enrollee ID field description • Modified PBP field description • Addition to NDC field description • Modified Type of Request reversed by review entity field description 	<p>Modify</p>	<p>Clarified instructions</p>	<p>Low</p>

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<p>CDAG Protocol, Universe Table 6: Part D Standard and Expedited Grievances (GRV_D) Record Layout</p>	<ul style="list-style-type: none"> • Updated instructions to include any grievances older than 30 days as of the time of the engagement letter but that have not received a response • Clarified that each notification must be a separate line item • Updated instruction to include withdrawn and dismissed grievances • Modified Enrollee ID field description • Modified PBP field description • Updated Category of the issue field description to instruct to separate multiple categories with a comma • Addition to Date & Time oral notification provided to enrollee field descriptions • Added three new fields: Was the grievance withdrawn or dismissed?, Coverage Request 	<p>Modify</p>	<p>Clarified instructions, Changes based on audit experience</p>	<p>Medium</p>

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	Initiated?, and Date coverage request was initiated			
CDAG Protocol, All Universe Table Record Layouts	<ul style="list-style-type: none"> For date & time fields moved format instruction and example into the General Record Layout instructions 	Modify	Technical changes	None
CDAG Protocol, Audit Field Work Phase	<ul style="list-style-type: none"> Added Sample Selection section Modified Supporting Documentation Submissions text Modified Root Cause Analysis Submissions & Impact Analysis Submissions text 	Modify	Minor wording changes for clarity and transparency	None
N/A	<ul style="list-style-type: none"> Added two new Root Cause Analysis and Impact Analysis Templates in CDAG: <ul style="list-style-type: none"> CDAG CR Impact CDAG PCR Impact 	Add	Changes based on audit experience, Consistency	Medium
CPE Compliance Officer Questionnaire (CO-Q)	Remove	Remove	Removed due to creating one new questionnaire	Low (reduction)
N/A	<ul style="list-style-type: none"> Added new CPE Questionnaire 	Add	Merged questionnaires and modified for new audit approach	Low (reduction)

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	<ul style="list-style-type: none"> • Combined questions from the CO and FDR questionnaires • Streamlined questions to focus on oversight of program areas 			
CPE First Tier, Downstream, and Related Entities Operations Oversight Questionnaire (FDR-Q)	Removed	Remove	Removed due to creating one new questionnaire	Low (reduction)
CPE Protocol, Purpose	<ul style="list-style-type: none"> • Modified purpose text to state purpose of CPE is to operate in conjunction with other program areas and not as a standalone protocol 	Modify	To clarify audit intention	High (reduction)
CPE Protocol, Purpose	<ul style="list-style-type: none"> • Removed data request table relating to the collection of the supplemental documents 	Removed	Removed due to no longer collecting this information	Medium (reduction)
CPE Protocol, Universe Request	<ul style="list-style-type: none"> • Modified scope of universe requests to only include compliance oversight activities related to audit areas included in the engagement letter (e.g. FA, ODAG, CDAG and SNPCC) that the sponsoring organization conducted 	Modify	Clarified instructions based on CPE audit changes	Low

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	during the 1-year period preceding and including the date of the audit engagement letter.			
CPE Protocol, Universe Table 1 Record Layout	<ul style="list-style-type: none"> Clarified language to only include auditing, monitoring and investigation activities that were initiated, performed, or closed relating to audit areas included in the engagement letter. 	Modify	Clarified instructions based on CPE audit changes	Medium (reduction)
CPE Protocol, Universe Exclusion	<ul style="list-style-type: none"> Removed Exclusion items listed within the record layout 	Removed	Clarified instructions based on CPE audit changes	None
CPE Protocol, Universe Table 1 COA Record Layout Column F	<ul style="list-style-type: none"> Removed description of activity relating to training requirements 	Removed	Clarified instructions based on CPE audit changes	None
CPE Protocol, Universe Table 1 COA Record Layout Column I	<ul style="list-style-type: none"> Added additional General Record Layout Instructions 	Add	Clarified instructions based on CPE audit changes	Low (reduction)
CPE Protocol, Universe Table 1 COA Record Layout Column J	<ul style="list-style-type: none"> Modified language for clarity 	Modify	Clarified instructions in specific field for clarity.	None
CPE Program Audit Protocol and Data Request, Universe Table 1 COA Record Layout Column K	<ul style="list-style-type: none"> Modified language for clarity 	Modify	Clarified instructions in specific fields, Added a few columns for increased clarity	None

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CPE Protocol, Universe Table 1 COA Record Layout Column L	<ul style="list-style-type: none"> Field name changes for clarity Added two fields related to corrective actions 	Modify	Clarified instructions based on CPE audit changes	Low
CPE Protocol, Supplemental Document Request	<ul style="list-style-type: none"> Added language that we are only collecting the Compliance Questionnaire. 	Added	Clarified instructions based on CPE audit changes	Low
CPE Protocol, Pre-Audit field work-New	<ul style="list-style-type: none"> Added additional details related to new CPE approach to fieldwork Added descriptions of interviews during fieldwork for compliance 	Added	Added instructions based on CPE audit changes	Low (reduction)
CPE Protocol, Tracer Case Summary Submission	<ul style="list-style-type: none"> Removed Tracer Case Summary 	Removed	Removed Trace case summary section based on new CPE changes.	High (reduction)
CPE Organizational Structure and Governance Template	<ul style="list-style-type: none"> Modified template to make optional for Sponsoring organizations 	Modify	Modified text to indicate this is an optional document (not required)	Low (reduction)
FA Protocol, Purpose	<ul style="list-style-type: none"> Modified purpose text 	Modify	Minor wording changes for clarity	None
FA Protocol, Compliance Standards	<ul style="list-style-type: none"> Modified column title to remove criteria effective date Updated sampling language to remove the number of samples being 	Modify	Minor deletions to language	Low

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	targeted and address the minimum number of samples that will be selected <ul style="list-style-type: none"> Removed CMS Approved Plan Bid 			
FA Protocol, Universe Requests	<ul style="list-style-type: none"> Removed Universe Table 3: Prescription Drug Event (PDE) Data Removed any corresponding references to this table in the protocol 	Remove	Removed to decrease burden	High (reduction)
FA Protocol, Universe Submissions	<ul style="list-style-type: none"> Modified universe submissions text 	Modify	Technical changes	None
FA Protocol, Universe Requests	<ul style="list-style-type: none"> Modified table footer for Scope of Universe Requests 	Modify	Minor changes	None
FA Protocol, Record Layout Instructions	<ul style="list-style-type: none"> Added General Record Layout Instructions Added instructions for eligibility rejections 	Add	Clarified instructions based on audit experience	None
FA Protocol, Universe Table 1 and Universe Table 2	<ul style="list-style-type: none"> Clarified which fields should be populated as submitted by the pharmacy. Modified Enrollee ID field description Added drug name, strength, and dosage form 	Modify	Clarified instructions in specific fields, deleted information no longer needed, Added drug name and miscellaneous fields	Low

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	as submitted by the pharmacy <ul style="list-style-type: none"> Added miscellaneous fields to account for additional fields that may be necessary 			
FA Protocol, Universe Table 3	<ul style="list-style-type: none"> Minor updates in terminology to transition supplies Removed detailed definition of Medicare Beneficiary Identifier (MBI). 	Modify	Clarified instructions, deleted information no longer needed	Low
FA Protocol, All Universe Table Record Layouts	<ul style="list-style-type: none"> Updated date example to CCYY/MM/DD format (e.g., 2027/01/01) For date fields moved format instruction and example into the General Record Layout instructions 	Modify	Technical changes	None
FA Protocol, Audit Field Work Phase	<ul style="list-style-type: none"> Added Sample Selection section Modified Supporting Documentation Submissions text Modified Root Cause Analysis Submissions & Impact Analysis Submissions text 	Modify	Minor wording changes for clarity and transparency	None

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FA Protocol, Impact Analysis Record Layout	<ul style="list-style-type: none"> Updated the Scope of Impact Analysis Request for Formulary Administration to be consistent with Transition 	Modify	Changes based on audit consistency	Low
FA Protocol, Impact Analysis Requests	<ul style="list-style-type: none"> Remove Table 1IA and 2IA record layouts which will be replaced with new templates 	Remove	Remove impact analysis record layouts and replace with templates	None
FA Questionnaire	<ul style="list-style-type: none"> Removed question 5 and replaced with a new question 	Modify	Deleted question no longer necessary, and added new question	None
N/A	<ul style="list-style-type: none"> Added new FA Enrollee Impact Analysis Template 	Add	New template with same contents	None
Independent Validation Audit Work Plan Template	<ul style="list-style-type: none"> Modified language to be more inclusive and transparent Added additional text and instructions 	Modify	Clarified instructions to ensure accurate submissions and reduce errors	None
N/A	Independent Validation Audit Report Template (New)	Add	Created a new validation report template to increase transparency, reduce errors, and limit burden	Low (reduction)
ODAG Protocol, Purpose	<ul style="list-style-type: none"> Modified purpose text 	Modify	Minor wording changes for clarity	None

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ODAG Protocol, Data Analyzed During Audit	<ul style="list-style-type: none"> Indicated CMS intent to stop collecting most ODAG universes once other data is available from the Service Level Data of Initial Determinations and Appeals. 	Modify	Explanation of change to alleviate duplicative reporting	High (reduction)
ODAG Protocol, Compliance Standards	<ul style="list-style-type: none"> Modified column title to remove criteria effective date Modified Data request column to indicate both applicable audit universes and the Service Level Quarterly Data. Modified compliance standards and methods of evaluation to address changes in regulation Updated regulatory references throughout Updated sampling language to address the minimum number of samples that will be selected for elements Modified compliance standards for “Processing of Coverage Requests” to 	Modify	Technical changes, Additions based on regulatory updates, Modifications based on audit experience	Low

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	<p>ensure a unique compliance standard was associated with unique requirements.</p> <ul style="list-style-type: none"> • Added compliance standard 2.4 to address utilization management requirements and criteria • Added compliance standard 2.7 to address revised reopening rules 			
ODAG Protocol, Universe Submissions	<ul style="list-style-type: none"> • Modified universe submissions text to account for use of quarterly data when its available • Removed references to dual eligible special needs plans 	Modify	Technical changes	None
ODAG Protocol, Universe Requests	<ul style="list-style-type: none"> • Modified scope of universe request language • Added a universe for reopened Part C determinations • Removed the Part C Effectuations of Overturned decisions universe 	Modify	Removed two universes to reduce burden, added one universe to account for regulatory requirement updates	Low

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	<ul style="list-style-type: none"> Removed the Dual Eligible Special Needs Plan universe 			
ODAG Protocol, Universe Requests	<ul style="list-style-type: none"> Added General Record Layout Instructions 	Add	Clarified instructions for transparency, Changes based on audit experience	None
ODAG Protocol, Universe Table 1: Standard and Expedited Organization Determination (OD) Record Layout	<ul style="list-style-type: none"> Updated “inclusion” language to account for all types of initial organization determinations Modified field description for MBI to eliminate unnecessary text 	Modify	Clarified instructions in one field, and updated inclusion language to allow for appropriate oversight	Low
ODAG Protocol, Universe Table 2: Standard and Expedited Reconsiderations (RECON) Record Layout	<ul style="list-style-type: none"> Updated inclusion language to ensure that all appropriate reconsiderations are included Modified field description for MBI to eliminate unnecessary text 	Modify	Clarified instructions in one field, and updated inclusion language to allow for appropriate oversight	Low
ODAG Protocol, Universe Table 3: Payment Organization Determinations and Reconsiderations (PYMT_C) Record Layout	<ul style="list-style-type: none"> Modified field description for MBI to eliminate unnecessary text 	Modify	Clarified instructions one field	None

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ODAG Protocol, Universe Table 4: Part C Standard and Expedited Grievances (GRV_C) Record Layout	<ul style="list-style-type: none"> Updated instructions to include any grievances older than 30 days as of the time of the engagement letter but that have not received a response Updated instruction to include withdrawn and dismissed grievances Modified field description for MBI to eliminate unnecessary text Modified PBP field description Added three new fields: Was the grievance withdrawn or dismissed?, Coverage Request Initiated?, and Date coverage request was initiated 	Modify	Clarified instructions, Changes based on audit experience	Medium
ODAG Protocol, Universe Table 5: Reopened Part C Determinations (RCD)	<ul style="list-style-type: none"> Created new universe 	Add	Added universe based on regulatory requirements updates and oversight experience	Medium
ODAG Protocol, Audit Field Work Phase, Sample selection	<ul style="list-style-type: none"> Added Sample Selection section Added language discussing potential desk review of samples 	Modify	Minor wording changes for clarity and transparency and to reduce burden on audit	Medium (reduction)

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ODAG Protocol, Audit Field Work Phase, Supporting Documentation Submissions	<ul style="list-style-type: none"> Modified supporting documentation for transparency and clarity 	Modify	Modified for transparency	None
ODAG Protocol, Audit Field Work Phase, Timeliness Mitigation Analysis	<ul style="list-style-type: none"> Added a new tool and a section in the protocol for assessing potential mitigating factors when CMS utilizes quarterly service level data for purposes of timeliness 	Modify	Created a tool to assist CMS with assessing timeliness requirements when utilizing service level data	Low (reduction)
ODAG Protocol, Audit Field Work Phase, Root cause and Impact Analysis Submissions	<ul style="list-style-type: none"> Removed existing record layouts in the protocol for impact analyses 	Modify	Modified formatting for clarity, added fields for oversight	Low
N/A	<ul style="list-style-type: none"> Added two new Root Cause Analysis and Impact Analysis Templates in CDAG: <ul style="list-style-type: none"> ODAG CR Impact ODAG PCR Impact 	Add	Changes based on audit experience, Consistency	Low
N/A	<ul style="list-style-type: none"> Created a new ODAG Timeliness Mitigation Tool to allow CMS to conduct potential mitigating factors from Sponsoring organizations when timeliness is running using 	Add	Created to allow for collecting timeliness mitigation information	Low

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	the quarterly service level data collection			
Pre-audit Issue Summary Template	<ul style="list-style-type: none"> Updated date format example in column headings to 2027/01/01 	Modify	Technical changes	None
Root Cause Analysis Template	<ul style="list-style-type: none"> Modified RCA to be in excel instead of word Made wording changes to increase clarity 	Modify	Changed formatting, made edits for clarity	None
Attendance Log Template	<ul style="list-style-type: none"> No changes 	N/A	N/A	None
SNPCC Protocol, Purpose	<ul style="list-style-type: none"> Modified purpose 	Modify	Minor wording changes for clarity	None
SNPCC Protocol, Audit Elements Tested	<ul style="list-style-type: none"> Modified list to include 2 new elements (Timeliness and D-SNP) 	Modify	Technical changes, changes due to regulatory updates	None
SNPCC Protocol, Compliance Standards	<ul style="list-style-type: none"> Modified column title to remove criteria effective date Modified all audit element names (1) Timeliness (2) Care Management (3) D-SNP Coordination Updated sampling language to address the minimum number of samples that will be selected 	Modify	Streamlined information, clarified instructions	Low

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	<ul style="list-style-type: none"> • Modified all data requests and method of evaluation language for clarity • Updated criteria to include Associated Model of Care • Updated regulatory references throughout 			
SNPCC Protocol, Compliance Standards	<ul style="list-style-type: none"> • Added a new compliance standard to address the ICP timeliness requirement • Added 3 new compliance standards to review D-SNP coordination requirements <ul style="list-style-type: none"> ○ Integrated HRA requirements ○ D-SNP Medicaid coordination assistance ○ Notification of hospital or skilled nursing facility admissions • Added language for the annual face-to-face encounter requirement to an existing ICT compliance standard 	Add	Changes due to regulatory updates	Medium

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SNPCC Protocol, Audit Engagement and Universe Phase	<ul style="list-style-type: none"> • Modified universe submission instructions to clarify universe file formats and HPMS uploads. 	Modify	Minor wording changes for clarity	None
SNPCC Protocol, Audit Engagement and Universe Phase Universe Table 1	<ul style="list-style-type: none"> • Modified Table 1 description fields <ul style="list-style-type: none"> ○ Enrollee ID: Deleted MBI definition text ○ Enrollment effective date field name and description were modified for clarity 	Modify	Minor wording changes for clarity	None
SNPCC Protocol, Audit Engagement and Universe Phase, Universe Table 1	<ul style="list-style-type: none"> • Added new columns with descriptions: <ul style="list-style-type: none"> ○ Column F: First Tier, Downstream, and Related Entity ○ Column J: Most Recent Plan Change Effective Date for non-continuous enrollment ○ Column Q: Was there a hospital or SNF admission? ○ Column R: For D-SNP enrollees, were there any Medicaid specific services or needs identified (e.g., non- 	Add	Changes based on audit experience, clarification and regulatory updates	Medium

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	Medicare covered equipment or supplies, LTSS, behavioral health)?			
SNPCC Protocol, Audit Engagement and Universe Phase	<ul style="list-style-type: none"> Modified instructions for Supplemental Documentation Submissions and Requests to streamline documentation requests due dates 	Modify	Streamlined information, clarified instructions	None
SNPCC Protocol, Audit Field Work Phase	<ul style="list-style-type: none"> Added a section providing information about sample selection for webinar-based reviews and desk reviews Modified instructions for Supporting Documentation Submissions Modified Root Cause Analysis and Impact Analysis Submission instructions 	Add	Changes based on audit experience, clarity and transparency	None
SNPCC Protocol, Table 11A: Care Coordination Impact Analysis (CC-IA) Record Layout	<ul style="list-style-type: none"> Table removed from protocol and included as a separate excel table 	Delete	Changes based on audit experience, consistency	None

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SNPCC Protocol, Table 2IA: HRA Timeliness Impact Analysis (HRAT-IA) Record Layout	<ul style="list-style-type: none"> Table removed from protocol and included as a separate excel table Name of new table changed to 'HRA Timeliness Mitigation Analysis' 	Delete	Changes based on audit experience, consistency	None
SNPCC Protocol, HRA Timeliness Mitigation Analysis	<ul style="list-style-type: none"> Added new section to provide instructions for the HRA timeliness Mitigation Analysis excel workbook 	Add	Changes based on audit experience, consistency	None
SNPCC Protocol, Impact Analysis Submissions	<ul style="list-style-type: none"> Modified instructions to remove file type and file formatting, streamlining this instruction 	Modify	Streamlined information, clarified instructions	None
N/A	<ul style="list-style-type: none"> SNPCC_HRA Timeliness Mitigation Analysis Excel template added to replace Table 2IA in the protocol 	Add	Changes based on audit experience, consistency	None
N/A	<ul style="list-style-type: none"> SNPCC_ RCA and Impact Analysis Template Excel template added to replace Table 1IA in the protocol (for care management and D-SNP issues) Modified description fields in table Added 4 new IA data requests for D-SNP 	Add	Changes based on audit experience, consistency	Low

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SNPCC Questionnaire	<ul style="list-style-type: none"> • Revised questionnaire instructions for clarity 	Modify	Streamlined information, minor wording changes for clarity	None
SNPCC Questionnaire	<ul style="list-style-type: none"> • Modified 2 questions for clarity <ul style="list-style-type: none"> ○ #8- To describe the outreach policy pertaining to HRA administration and ICP development. ○ #9- To list all FDRs that conduct SNP related care coordination activities 	Modify	Minor wording changes for clarity	None
SNPCC Questionnaire	<ul style="list-style-type: none"> • Added Question #4 - Do you use an online member portal to share information with enrollees (i.e., health literacy, ICP)? If yes, how do you determine which enrollees have access and are able to use the portal? • Added Question #10- For D-SNPs) Does your organization arrange for State Medicaid carve-out services for specific populations, (e.g. LTSS and/or behavioral health)? 	Add	Changes based on audit experience and to align with updated audit protocol	Medium

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	If yes, please provide a brief overview of the program.			
N/A	Program Audit CMS Request for Additional Information	Add	Added new document for capturing CMS questions related to sample cases when review is conducted via desk review, increase transparency	Low (reduction)
Supporting Statement A: Background	<ul style="list-style-type: none"> • Removed references to industry wide timeliness in all of Supporting Statement A • Modified language for clarity • Included a footnote about a change to the CPE audit process • Solicited comment on ODAG field descriptions considering future use of quarterly CMS data to reduce duplicative requests 	Modify	Removed burden associated with industry wide timeliness, and modified language to account for auditing change	High (reduction)
Supporting Statement A: Justification	<ul style="list-style-type: none"> • Modified legal justification to add one additional citation 	Modify	Modified citations for clarity	None
Supporting Statement A: Information Users	<ul style="list-style-type: none"> • Modified language for simplicity and clarity 	Modify	Modified language for clarity	None

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Supporting Statement A: Duplication of Effort	<ul style="list-style-type: none"> Modified language to account for mid-package burden reduction change and prevent duplicative data gathering 	Modify	Modified language for clarity	None
Supporting Statement A: Burden Estimates	<ul style="list-style-type: none"> Updated wage estimates based on latest data from US Bureau of Statistics Modified formatting of burden estimates to include tables instead of paragraphs Modified hourly estimates based on process changes for program audits, and for use of CMS quarterly data in years 2 and 3 Modified validation estimates based on revised approach to validating correction outside of a formal validation audit Removed estimates related to industry timeliness monitoring 	Modify	Modified language for clarity, reduced burden for program audits, reduced burden for validation audits, removed burden for industry wide timeliness	High (reduction)
Supporting Statement A: Costs to Federal Government	<ul style="list-style-type: none"> Modified costs for CMS personnel based on updated GS schedule updates 	Modify	Modified burden based on audit experience and contracting needs	Medium

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	<ul style="list-style-type: none"> Modified hours per audit based on previous audit experience Modified contractor costs based on recent invoicing Modified number of contractor led audits based on modified audit approach 			
Supporting Statement A: Changes to Burden	<ul style="list-style-type: none"> Added tables for transparency with numbers/burden changes Explained burden reduction for program audits, including reduction in universes, use of quarterly data, and intent to audit via desk review (burden reduced from 701 hours to 382 hours) Explained reduction in burden for validation audits based on ability to validate through means other than a formal validation audit 	Modify	Modified language to explain burden reduction	High (reduction)
Supporting Statement A: Expiration Date	<ul style="list-style-type: none"> Revised list of documents 	Modify	Modified to increase transparency and reflect current auditing approach	None

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	<ul style="list-style-type: none"> • Added standalone IA documents for some program areas • Added a template document for CMS requests for additional information • Removed some CPE documents • Added validation audit templates 			
Initial Proposed CMS-10717 (Prior to 60 Day comments)	Response to 60 Day Comments CMS-10717 (Summary of Changes)	Type of Change	Explanation of Changes	Burden Impact
Supporting Statement A: Background	<ul style="list-style-type: none"> • Removed solicitation for comment on ODAG universes and specific changes that may be needed for new OD types 	Modified	Removed solicitation	None
Supporting Statement A: Federal Register	<ul style="list-style-type: none"> • Modified to account for 60 day comment period dates of publication 	Modified	Updated	None

Initial Proposed CMS-10717 (Prior to 60 Day comments)	Response to 60 Day Comments CMS-10717 (Summary of Changes)	Type of Change	Explanation of Changes	Burden Impact
Supporting Statement A: Burden Estimates, Wage Estimates	<ul style="list-style-type: none"> Modified citation/reference from 2024 US Bureau of Labor Statistics to the 2025 Labor Statistics, and updated all specific labor categories with the new 2025 rates by occupation to find the new hourly average rate 	Modified	Updated to most current labor rates	None
Supporting Statement A: Burden Estimate	<ul style="list-style-type: none"> Increased pre-fieldwork burden for Year 1 in response to concerns from commenters about including different ODs in the universes. Made corresponding changes to all other burden numbers in response to that change 	Modified	Increased burden estimate in response to comments	Medium (increase)
Supporting Statement A: Summarized Burden Estimate	<ul style="list-style-type: none"> Updated table to account for both the new burden in Year 1 and the new average hourly wage based on 2025 Labor rates 	Modified	Updated based on new numbers	None

Initial Proposed CMS-10717 (Prior to 60 Day comments)	Response to 60 Day Comments CMS-10717 (Summary of Changes)	Type of Change	Explanation of Changes	Burden Impact
Supporting Statement A: Costs to Federal Government	<ul style="list-style-type: none"> Modified government employee salaries based on new GS scale (2026) and made corresponding adjustments to the total costs in response 	Modified	Updated with new rates	None
Supporting Statement A: Changes in Burden	<ul style="list-style-type: none"> Modified both text and tables to account for the changes in burden in response to the 60-day comments. Explained increase in Year 1 pre-fieldwork burden estimates. 	Modified	Updated rationale for burden changes	None
Supporting Statement A: Publication/Tabulation Dates:	<ul style="list-style-type: none"> Removed a CMS webpage reference that is outdated 	Modified	Removed old link	None
Supporting Statement A: Expiration Date	<ul style="list-style-type: none"> Corrected an error by removing a reference to the CDAG Timeliness RCA which was not a document that was or is included in this PRA package proposal 	Modified	Removed reference to a document that is not in the package	None

Initial Proposed CMS-10717 (Prior to 60 Day comments)	Response to 60 Day Comments CMS-10717 (Summary of Changes)	Type of Change	Explanation of Changes	Burden Impact
CDAG Protocol, FA Protocol, ODAG Protocol, SNPCC Protocol: Program Audit Protocol, Purpose Section	<ul style="list-style-type: none"> Added language to ensure clarity in sampling, that CMS may need to add samples to either replace initial samples or to further investigate potential noncompliance 	Modified	Clarified sample selection	None
CDAG Protocol: Compliance Standard, Universe Integrity Testing	<ul style="list-style-type: none"> Updated Method of Evaluation to reflect less universe integrity samples in Tables 1 through 6 	Modified	Reduced number of samples	Medium (decrease)
CDAG Protocol: Compliance Standards	<ul style="list-style-type: none"> Updated applicable compliance standards to include a maximum sample set instead of a minimum sample set 	Modified	Clarified number of samples	None
CDAG Protocol: Compliance Standard 3.2	<ul style="list-style-type: none"> Modified the sample selection to 15 samples (from 20) 	Modified	Reduced number of samples	Low (decrease)
CDAG Protocol: Audit Engagement and Universe Submission Phase	<ul style="list-style-type: none"> Modified audit review period language for the universes to reflect that the review period ends with the date the audit 	Modified	Clarified instructions	None

Initial Proposed CMS-10717 (Prior to 60 Day comments)	Response to 60 Day Comments CMS-10717 (Summary of Changes)	Type of Change	Explanation of Changes	Burden Impact
	engagement letter is issued			
CDAG Protocol: Audit Engagement and Universe Submission Phase, General Record Layout Instructions	<ul style="list-style-type: none"> Modified instruction language to clarify NDC data submissions 	Modified	Clarified instructions	None
CDAG Protocol: Audit Engagement and Universe Submission Phase, Universe Tables 1, 2, 3, & 4	<ul style="list-style-type: none"> Modified inclusion instructions on how to enter partially denied/approved requests 	Modified	Clarified instructions	None
CDAG Protocol: Audit Engagement and Universe Submission Phase, Universe Tables 1, 2, 3, 4, 5 & 6, Plan Benefit Package (PBP) Field Description	<ul style="list-style-type: none"> Clarified to enter the PBP applicable for purposes of the request/grievance and added an option to enter 'None' 	Modified	Clarified instructions	None
CDAG Protocol: Audit Engagement and Universe Submission Phase, Universe Tables 1, 2, 3, 4 & 5, NDC Field Description	<ul style="list-style-type: none"> Clarified field description instructions on how to enter the associated NDC. Removed references to 	Modified	Clarified instructions	None

Initial Proposed CMS-10717 (Prior to 60 Day comments)	Response to 60 Day Comments CMS-10717 (Summary of Changes)	Type of Change	Explanation of Changes	Burden Impact
	pharmacy/delegate submitted data			
CDAG Protocol: Audit Engagement and Universe Submission Phase, Universe Tables 3 and 4	<ul style="list-style-type: none"> Updated field descriptions in corresponding columns to adjust the appeal filing timeframe from 60 days to 65 days 	Modified	Clarified instructions	None
CDAG Protocol: Audit Engagement and Universe Submission Phase, Universe Table 5 Instructions	<ul style="list-style-type: none"> Re-formatted exclusion language to separate out different exclusion categories 	Modified	Clarified instructions	None
CDAG Protocol: Audit Engagement and Universe Submission Phase, Universe Table 6 Instructions	<ul style="list-style-type: none"> Modified inclusion language to ensure consistency with ODAG and to clarify the types of grievances that should and should not be included 	Modified	Clarified instructions	None
CDAG Protocol: Audit Engagement and Universe	<ul style="list-style-type: none"> Clarified instructions in the field description to 	Modified	Clarified instructions	None

Initial Proposed CMS-10717 (Prior to 60 Day comments)	Response to 60 Day Comments CMS-10717 (Summary of Changes)	Type of Change	Explanation of Changes	Burden Impact
Submission Phase, Universe Table 6: Column ID V (Coverage Request Initiated?)	ensure accurate data submission			
CDAG Protocol: Audit Field Work Phase – Sample Selection	<ul style="list-style-type: none"> Modified language to add a timeframe for sample identification when an audit is done via desk review, and modified language to ensure transparency in case file submissions 	Modified	Clarified instructions	None
CDAG PCR Impact and CDAG CR Impact: Scope of Noncompliance	<ul style="list-style-type: none"> Added “...Please describe how this noncompliance impacted your organization including its impact to any entities, systems and/or processes, as well as any potential enrollee impact” 	Modified	Clarified instructions	None
FA Protocol: Compliance Standards	<ul style="list-style-type: none"> Modified sample selection information to include a maximum number of samples versus a minimum in all applicable compliance standards 	Modified	Clarified sampling instructions	None

Initial Proposed CMS-10717 (Prior to 60 Day comments)	Response to 60 Day Comments CMS-10717 (Summary of Changes)	Type of Change	Explanation of Changes	Burden Impact
FA Protocol: Audit Engagement and Universe Submission Phase, General Record Layout Instructions	<ul style="list-style-type: none"> Rearranged bulleted instructions to ensure clarity of population universes Tables 1 and 2 	Modified	Clarified instructions	None
FA Protocol: Audit Engagement and Universe Submission Phase, Universe Tables 1 and 2 record layouts, Column ID J	<ul style="list-style-type: none"> Updated field description to include the “full” drug name, and removed “as submitted by the pharmacy” 	Modified	Clarified instructions	None
FA Protocol: Audit Engagement and Universe Submission Phase, Universe Tables 1 and 2 record layouts: Column ID U, V, W	<ul style="list-style-type: none"> Removed columns 	Removed	Deleted fields	Low (decrease)
FA Protocol: Audit Field Work Phase, Sample Selection	<ul style="list-style-type: none"> Added language to address sample selection timeframes for purposes of desk review 	Added	Clarified instructions	None
FA Enrollee Impact Analysis: Scope of noncompliance	<ul style="list-style-type: none"> Defined what “Scope of noncompliance” meant for purposes of the impact field 	Added	Clarified instructions	None

Initial Proposed CMS-10717 (Prior to 60 Day comments)	Response to 60 Day Comments CMS-10717 (Summary of Changes)	Type of Change	Explanation of Changes	Burden Impact
CPE Protocol: Audit Engagement and Universe Submission Phase, Universe Requests	<ul style="list-style-type: none"> Added language that Sponsors may include activities performed by outside entities that are relevant to audited program areas 	Modified	Modified universe instructions	None
CPE Protocol: Audit Engagement and Universe Submission Phase, Universe Requests	<ul style="list-style-type: none"> Changed the 1-year lookback period for the universe to a 6-month lookback 	Reduction	Reduced universe period for compliance universe	Medium (decrease)
CPE Protocol: Audit Engagement and Universe Submission Phase, Universe Table1	<ul style="list-style-type: none"> Removed the columns in the record layout that discussed character limits for specific fields 	Modified	Modified field instructions.	None
CPE Protocol: Audit Engagement and Universe Submission Phase, Universe Table 1	<ul style="list-style-type: none"> Corrected lettering of the table to account for the removed Column C, re-ordered lettering accordingly 	Modified	Modified column lettering	None
CPE Protocol: Audit Engagement and Universe Submission Phase, Universe Table1, Column ID J	<ul style="list-style-type: none"> Clarified field instructions and replaced NA with TBD 	Modified	Modified field instruction	None
CPE Protocol: Audit Engagement and Universe	<ul style="list-style-type: none"> Minor wording changes to field description 	Modified	Modified field instruction	None

Initial Proposed CMS-10717 (Prior to 60 Day comments)	Response to 60 Day Comments CMS-10717 (Summary of Changes)	Type of Change	Explanation of Changes	Burden Impact
Submission Phase, Universe Table1, Column ID K				
CPE Protocol: Audit Engagement and Universe Submission Phase, Universe Table1, Column ID L	<ul style="list-style-type: none"> Added new column to associate activity with related program area from audit 	Added	Added new field into universe for clarity	Low (decrease)
CPE Protocol: Audit Field Work Phase, Second Compliance Interview	<ul style="list-style-type: none"> Clarified timing of second interview 	Modified	Modified language for clarity on timing	None
ODAG Protocol	<ul style="list-style-type: none"> Throughout the document, removed all references to “Quarterly data” to more closely align with terminology used in Service Level Data Collection of Initial Determinations and Appeal (OMB-0938-1489) 	Modified	Modified terminology	None

Initial Proposed CMS-10717 (Prior to 60 Day comments)	Response to 60 Day Comments CMS-10717 (Summary of Changes)	Type of Change	Explanation of Changes	Burden Impact
ODAG Protocol: Compliance Standard Universe Integrity Testing	<ul style="list-style-type: none"> Modified sample selection language to include a maximum instead of minimum 	Modified	Clarified sampling	None
ODAG Protocol: Program Audit Protocol, Compliance Standards 2.1, 3.1, and 3.2	<ul style="list-style-type: none"> Updated sampling language to include a maximum number of samples instead of a minimum. For compliance standard 2.1, also clarified types of cases that might be sampled 	Modified	Clarified number of samples and sample selection	None
ODAG Protocol: Program Audit Protocol, Compliance Standards:	<ul style="list-style-type: none"> Revised several compliance standards to make minor, non-substantive wording changes and/or formatting edits 	Modified	Minor wording/formatting changes	None
ODAG Protocol: Compliance Standard 1.4	<ul style="list-style-type: none"> Revised method of evaluation to clarify the notification timeframes relating to reconsiderations 	Modified	Clarified method of evaluation	None

Initial Proposed CMS-10717 (Prior to 60 Day comments)	Response to 60 Day Comments CMS-10717 (Summary of Changes)	Type of Change	Explanation of Changes	Burden Impact
ODAG Protocol: Program audit protocol, Compliance Standard 2.7	<ul style="list-style-type: none"> Modified method of evaluation language to ensure clarity on how CMS would review this standard on audit 	Modified	Revised the method of evaluation	None
ODAG Protocol: Audit Engagement and Universe Submission Phase, Universe Requests	<ul style="list-style-type: none"> Expanded the scope of universe request for Table 3 to 4 weeks for organizations with less than 500,000 enrollees and 2 weeks for organizations with greater than or equal to 500,000 enrollees 	Modified	Clarified instructions	Low (increase)
ODAG Protocol: Audit Engagement and Universe Submission Phase, Table 1 – Record Layout Instructions	<ul style="list-style-type: none"> Modified the instruction language to clarify the various types of organization determinations that must be included and excluded in universe table 1 and provide detailed examples 	Modified	Clarified instructions	None
ODAG Protocol: Audit Engagement and Universe Submission Phase, Table 1 Column ID V (Who made the request?)	<ul style="list-style-type: none"> Added the option of entering “P for Plan” 	Modified	Clarified instructions	None

Initial Proposed CMS-10717 (Prior to 60 Day comments)	Response to 60 Day Comments CMS-10717 (Summary of Changes)	Type of Change	Explanation of Changes	Burden Impact
ODAG Protocol: Audit Engagement and Universe Submission Phase, Table 1 Column ID H, I, and W	<ul style="list-style-type: none"> Clarified instructions in the field description to account for the various types of organization determinations that will be included in this universe 	Modified	Clarified instructions	None
ODAG Protocol: Audit Engagement and Universe Submission Phase, Table 1	<ul style="list-style-type: none"> Added two new columns (Column ID Z and Column ID AA) to ensure accurate understanding of universes and allow for better sampling 	Modified	Added additional data request	Low (increase)
ODAG Protocol: Audit Engagement and Universe Submission Phase, Table 2 – Record Layout Instructions	<ul style="list-style-type: none"> Modified the instruction language to specify the types of reconsiderations that must be included and excluded in universe table 2 	Modified	Clarified instructions	None
ODAG Protocol: Audit Engagement and Universe Submission Phase: Table 2 (Column ID H and Column ID I) and Table 3 (Column ID H)	<ul style="list-style-type: none"> Updated the field descriptions to adjust the appeal filing timeframe 	Modified	Clarified Instructions	None

Initial Proposed CMS-10717 (Prior to 60 Day comments)	Response to 60 Day Comments CMS-10717 (Summary of Changes)	Type of Change	Explanation of Changes	Burden Impact
ODAG Protocol: Audit Engagement and Universe Submission Phase, Table 2 Column ID AA	<ul style="list-style-type: none"> Updated field description to remove “pre-service” 	Modified	Clarified Instructions	None
ODAG Protocol: Audit Engagement and Universe Submission Phase, Table 3 – Record Layout Instructions	<ul style="list-style-type: none"> Modified the instruction language to clarify the inclusion and exclusion language, and clarify how Sponsors should populate the universe based on the dates in the payment request 	Modified	Clarified Instructions	None
ODAG Protocol: Audit Engagement and Universe Submission Phase, Table 3 Column ID K	<ul style="list-style-type: none"> Minor wording updates to the field description 	Modified	Clarified Instructions	None
ODAG Protocol: Audit Engagement and Universe Submission Phase, Table 4 – Record Layout Instructions	<ul style="list-style-type: none"> Clarified inclusion and exclusion language to ensure clarity on grievances that should be included in the universe 	Modified	Clarified Instructions	None
ODAG Protocol: Audit Engagement and Universe Submission Phase, Table 4:	<ul style="list-style-type: none"> Made minor field description changes to clarify reporting instructions and align with 	Modified	Clarified Field Description	None

Initial Proposed CMS-10717 (Prior to 60 Day comments)	Response to 60 Day Comments CMS-10717 (Summary of Changes)	Type of Change	Explanation of Changes	Burden Impact
Column IDs E, M, Q, R, S, T, V, W and X	CDAG grievance fields when possible			
ODAG Protocol: Audit Engagement and Universe Submission Phase, Table 5 – Record Layout Instructions	<ul style="list-style-type: none"> Updated inclusion and exclusion language to clarify the types of reopenings that should be included in the table 	Modified	Clarified instructions	None
ODAG Protocol: Audit Engagement and Universe Submission Phase, Table 5, Column ID I and J	<ul style="list-style-type: none"> Removed two columns (Column ID I and J) in order to align with CMS reporting requirements 	Modified	Removed columns for consistency	Low (decrease)
ODAG Protocol: Audit Engagement and Universe Submission Phase, Table 5	<ul style="list-style-type: none"> Added Column ID H, K, L, M, P and Q to align with CMS reporting requirements, and capture data in the same method that Sponsors are used to providing. Re-lettered all columns in response to removing and adding columns 	Modified	Added columns to align universe with reporting	None

Initial Proposed CMS-10717 (Prior to 60 Day comments)	Response to 60 Day Comments CMS-10717 (Summary of Changes)	Type of Change	Explanation of Changes	Burden Impact
ODAG Protocol: Audit Engagement and Universe Submission Phase, Table 5	<ul style="list-style-type: none"> Modified Column ID G, J, N, O and R to align with reporting requirement field descriptions and ensure consistency in reporting 	Modified	Modified field name and descriptions for consistency	None
ODAG Protocol: Audit Fieldwork Phase, Sample Selection	<ul style="list-style-type: none"> Clarified timeframes for samples for desk review, and added language to ensure transparency in case sample documentation for desk review 	Modified	Clarified instructions and added timeframe	None
ODAG PCR Impact and ODAG CR Impact: Scope of Noncompliance	<ul style="list-style-type: none"> Added "...Please describe how this noncompliance impacted your organization including its impact to any entities, systems and/or processes, as well as any potential enrollee impact" 	Modified	Clarified instructions	None
SNPCC Protocol, Program Audit Protocol, Compliance Standards:	<ul style="list-style-type: none"> Modified sampling instructions to indicate a maximum number of samples instead of a minimum on all impacted compliance standards 	Modified	Modified to reduce confusion on samples	None

Initial Proposed CMS-10717 (Prior to 60 Day comments)	Response to 60 Day Comments CMS-10717 (Summary of Changes)	Type of Change	Explanation of Changes	Burden Impact
SNPCC Protocol, Compliance Standards 3.1, 3.2, and 3.3:	<ul style="list-style-type: none"> Clarified which D-SNP types the compliance standard applies to 	Modified	Clarification of instructions	None
SNPCC Protocol, Program Audit Protocol, Compliance Standard 3.2:	<ul style="list-style-type: none"> Clarified field description language related to assessing this requirement 	Modified	Clarified instructions	None
SNPCC Protocol, Audit Engagement and Universe Submission Phase, Universe Table 1:	<ul style="list-style-type: none"> Removed Columns F, I, J, and R from the data collection 	Modified	Removed columns to reduce burden	Medium (decrease)
SNPCC Protocol, Audit Engagement and Universe Phase, Table 1:	<ul style="list-style-type: none"> Added Column M to capture the date of the initial ICP. Re-ordered/re-lettered all columns to account for additions and deletions 	Modified	Added for purposes of timeliness	Low (increase)
SNPCC Protocol, Audit Engagement and Universe Phase, Table 1:	<ul style="list-style-type: none"> Modified field description in Column ID O to clarify the types of hospitalizations and SNF admissions to include 	Modified	Clarified instructions	None

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SNPCC Protocol, Audit Field Work Phase, Sample Selection:	<ul style="list-style-type: none"> Modified language to include when samples would be provided to the Sponsor for live webinars and desk review 	Modified	Clarified instructions	None
SNPCC Protocol, Audit Field Work Phase, Timeliness Mitigation Analysis:	<ul style="list-style-type: none"> Modified language for transparency to include a use of an internal threshold 	Modified	Clarified for transparency	None
SNPCC Protocol, Audit Field Work Phase, Verification of Information Collection:	<ul style="list-style-type: none"> Modified language to include validating timeliness mitigation analyses if needed 	Modified	Clarified for transparency	None
SNPCC Impact	<ul style="list-style-type: none"> Added a “Was an ICP created” column to SNPCC Impact table at Column J (Was an ICP Created) 	Modified	Added field for clarity	None
SNPCC Impact	<ul style="list-style-type: none"> Removed enter NA if an ICP was not created as an option from Columns K, L, and M of SNPCC Impact. 	Modified	Clarified field instructions	None

Initial Proposed CMS-10717 (Prior to 60 Day comments)	Response to 60 Day Comments CMS-10717 (Summary of Changes)	Type of Change	Explanation of Changes	Burden Impact
SNPCC Impact	<ul style="list-style-type: none"> Removed Column Z (Was Medicaid service assistance needed and not provided?) 	Modified	Removed column	Low (decrease)
SNPCC Impact	<ul style="list-style-type: none"> Removed Column AA (Was Medicaid grievance and/or appeals assistance provided) 	Modified	Removed column	Low (decrease)
SNPCC HRATMA	<ul style="list-style-type: none"> Removed Number of IHRA outreach attempts required by MOC column (old Column I) from the HRATMA IHRA Mitigation Tab 	Modified	Removed column	None
SNPCC HRATMA	<ul style="list-style-type: none"> Removed Number of HRA outreach attempts required by MOC column from the HRATMA HRA Mitigation Tabs 	Modified	Removed column	None
Independent Validation Audit Work Plan (AWP) Template	<ul style="list-style-type: none"> In methodology clarified instructions to ensure that the sample threshold is included for universe integrity testing 	Modified	Clarified instructions	None
Root Cause Analysis	Scope of Noncompliance <ul style="list-style-type: none"> Added "...Please describe how this noncompliance 	Modified	Clarified instructions	None

Initial Proposed CMS-10717 (Prior to 60 Day comments)	Response to 60 Day Comments CMS-10717 (Summary of Changes)	Type of Change	Explanation of Changes	Burden Impact
	impacted your organization including its impact to any entities, systems and/or processes, as well as any potential enrollee impact”			