Thank you for the opportunity to comment on CMS-10717 on Medicare Part C Program Audit Protocols. I appreciate the Department's work in ensuring that Medicare Advantage enrollees receive services and benefits as required by law. It is clear upon reviewing CMS' warnings and enforcement reports that the Department takes Medicare Parts C &D Oversight seriously. I believe efforts to collect service level data can heighten the Department's ability in this important oversight function, but only if the Department decides which data will be submitted and audited.

I'd like to call attention to concerning trends that providers have been experiencing over the past few years, specifically policies and payment dispute processes that categorize adverse organization determinations that reduce payment instead as MAO "internal disputes." CMS requires Medicare Advantage Organizations to report encounter data to CMS using the same transaction standards that providers use to report FFS Medicare data. HIPAA generally requires this through multiple codeset standards. As CMS incorporates Part C data into Medicare quality metrics, it is imperative to have confidence in the data integrity coming from Medicare Advantage. However, providers have observed MAOs doing the following which undermine CMS' data integrity and do nothing to promote care coordination:

- Not following Medicare status rules at 412.3(d) and widely using proprietary criteria that do not meet the requirements at 422.101(b)(6) for internal coverage criteria. Proprietary criteria do not meet the requirements because the evidence base generally does not exist to meet the requirements, as one of the major criteria writers wrote in response to MOEG's 2024 Annual Data Submission and Audit Protocol Data Request (CMS-10913).
- Denying readmission admissions without regard to preventability at the time of index hospital discharge, with apparent variable reporting of these readmissions to CMS and/or HEDIS
- Creation of a lower severity inpatient designation to pay rates comparable to observation without having to afford member appeal rights for a "normal-severity" inpatient denial
- Changing AMA CPT code descriptors for E&M services to deny or downgrade claims
- Denying claim diagnoses to downgrade MS-DRG assignments without adhering to requirements at 422.101(b)(6) for internal coverage criteria
- Denying member appeal rights on concurrent (often emergent) services
- Denying line-item cost-outlier charges not for medical necessity, but for bundling, despite cost-to-charge ratios being calculated on a hospital's established chargemaster required to be used for all payors
- Creating a parallel denials and appeals process (an internal dispute process) separate from the CMS ODAG process that can circumvent provider and

member access into the CMS ODAG pathway. This involves both an MAO's internal dispute process itself and a first-tier, downstream, and related (FDR) entity audit vendor's dispute process of the FDR's own findings. When coupled with Maximus not accepting any 2nd level reconsiderations from any party except the MAO itself, a large and probably unknown number of adverse ODs will be invisible to Maximus or CMS simply if the MAO considers a denial to not be an adverse OD, or if the denial remains buried within an internal dispute process. This parallel denial and dispute process is often not limited contracted providers, but involves non-contracted providers as well who also lack direct CMS recourse.

- Notices of Dismissals, incorporated into regulation in 2022, have not achieved the desired effect of protecting beneficiaries because an MAO need only not issue a Notice of Dismissal to prevent entry into the ODAG pathway. CMS has not permitted Maximus to review any dismissal of an OD or reconsideration request if an MAO does not issue a Notice of Dismissal.

My sampling of this past year's warnings and corrective action plan letters did not demonstrate findings related to these issues, which many providers consider to be widespread. My conclusion is that the audit universes historically used by MOEG to collect data do not contain the above practices.

As MOEG transitions to Service Level Data Collection, I suspect it will still take a proactive approach to identifying the above issues, so long as MAOs still decide what is or is not an OD or an appeal. I recommend that MOEG investigate services that providers submit on shadow claims to MACs but either do not appear in MAO encounter data or are downgraded somehow from the shadow claim submission. A "missing encounter" universe should quickly demonstrate which MAOs are engaging in many of the above behaviors. Artificial intelligence can likely quicken analysis to identify broader trends in missing or discrepant data to help guide oversight functions.

Providers are also a valuable source of information. CMS OPOLE just created an online portal for provider complaint submissions regarding MAO plans. Encounters that generate provider complaints can be another rich universe to sample activities that occur parallel to but not within the ODAG process.

In summary, my recommendations to improve the MOEG audit protocols are:

1) Create a data universe from encounter discrepancies between shadow claims and MA encounter data
2) Create a data universe from provider submitted complaints to CMS
3) Work with CMS Division of Appeals Policy to create an avenue for CMS or Maximus review of cases that MAOs consider not to be ODs or reconsiderations or where an MAO fails to issue a Notice of Dismissal

4) Data-mine specifically for evidence of non-adherence to inpatient status rules at 412.3, internal coverage criteria rules at 422.101(b)(6), and denials of readmission inpatient encounters that do not follow CMS policy at QIO Manual Ch 4, Section 4240. Enrollees do not benefit from these activities, as they serve only to deny or underpay for services that are already delivered.

Thank you for the opportunity to comment on CMS' Part C UM Annual Data Submission and Audit Protocol Data processes.

PUBLIC SUBMISSION

As of: 2/23/26, 10:52 AM
Received: February 19, 2026
Status: Draft
Category: Health Plan or Association
Tracking No. mlt-s5ye-s9sc
Comments Due: February 20, 2026
Submission Type: API

Docket: CMS-2025-1856
Medicare Part C and Part D Program Audit and Industry-Wide Part C Timeliness Monitoring Project (TMP) Protocols (CMS-10717)

Comment On: CMS-2025-1856-0001
Medicare Part C and Part D Program Audit and Industry-Wide Part C Timeliness Monitoring Project (TMP) Protocols (CMS-10717)

Document: CMS-2025-1856-DRAFT-0021
Comment on CMS-2025-1856-0001

Submitter Information

Name: Anonymous Anonymous

General Comment

Thank you for the opportunity to submit feedback.

Please see our comments below related to the ODAG proposed changes.

We request clear transition guidance on when CMS will rely on service level data vs. Plan submitted universes, including data quality standards, timelines, and potential need for sponsor-side reconciliation when results differ.

Clarify sample selection and timeliness methodology for desk reviews, including how the Timeliness Mitigation Tool will affect potential findings.

Seek detailed definition and scope for the new Reopened Determinations universe, including required elements, data sources, and minimum sample expectations.

CMS did not revise the ODAG record layout field descriptions at this time due to sponsors preparing system updates for the upcoming CMS-10905 “Service Level Data for Initial Determinations and Appeals” collection. However, CMS did update the inclusion instructions in several ODAG tables—including Table 1 (Initial Determinations) to reflect the 2025 regulatory clarification of what qualifies as an organization determination (OD). We ask CMS if minor field description updates are needed to help ensure ODAG data extracts align with the new inclusion instructions and reduce interpretation variability across sponsors.

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COMMENTS ON CMS-10717 MEDICARE PART C AND PART D PROGRAM AUDIT AND INDUSTRY-WIDE PART C TIMELINESS MONITORING PROJECT (TMP) PROTOCOLS

General Comments on All Program Areas

- We request that CMS provide a more detailed explanation of the proposed desk review audit process. A significant concern is the potential operational burden on plans, as many of our personnel and resources are shared across program areas. The creation of over 100 case files for review would be a substantial undertaking. We have found webinar-based audits to be an efficient and effective alternative, reducing administrative burden and allowing for real-time clarification. We encourage CMS to maintain this approach.
- We note a change in the sample size requirements between Part C and Part D in the proposed protocols. Historically, CMS has maintained consistent sample sizes for both parts. We request clarification on whether this change is intentional and, if so, the rationale for the differing sample sizes going forward.
- We have observed a deviation from the historically consistent 'Scope of Universe' timeframes for Part C and Part D universe tables. Could CMS clarify the rationale for proposing different reporting periods and how this aligns with the proposal to use the Service Level Data Collection for Part C Tables 1-3?

Part C Organization Determinations, Appeals, and Grievances (ODAG)

- To avoid duplicative reporting, we request clarification on the handling of 'reopenings' for Universe Tables 1-3. The current table layouts do not explicitly exclude them, which could lead to overlap with data reported in Table 5. Please advise if reopenings should be excluded from Universe Tables 1-3 to ensure data integrity.
- Regarding the proposal to replace Universe Tables 1-3 with the Service Level Data Collection, we request more information on the implementation timeline. Could CMS provide the mandatory start date for this data collection and the final date for submitting Universe Tables 1-3 for program audits? As the Service Level Data Collection is still in a pilot phase, we strongly recommend that CMS finalize the technical specifications before it becomes the required data source for audits.

- We seek clarification regarding 'Audit Element Timeliness 1.1'. This element specifies a 14-day calculation for items not subject to prior authorization. However, Universe Table 1 does not include a field to indicate whether a service requires prior authorization. Please advise on how CMS will calculate timeliness for cases submitted via Universe Table 1, given the absence of this data point.
- We request clarification on the scope of reviews to be included as organization determinations within Universe Table 1. Specifically, please confirm if the following scenarios fall within "The MA organization's refusal, pre- or post-service or in connection with an initial organization decision made concurrently with an enrollee's receipt of services, to provide or pay for services, in whole or in part, including the type or level of services, that the enrollee believes should be furnished or arranged for by the MA organization.": Concurrent review decisions that result in a change in the level of care (e.g., from inpatient to observation status); Partial denials of an admission, such as inpatient days that are denied due to benefit exhaustion; and post-service or retrospective denials.
- Instructions for Universe Table 1 state to include "Failure of the MA organization to approve, furnish, arrange for, or provide payment for health care services in a timely manner, or to provide the enrollee with timely notice of an adverse determination, such that a delay would adversely affect the health of the enrollee." Is it CMS' expectation that claims/payment data is included in Universe Table 1?

We thank CMS for consideration of our comments.

Blue Cross Blue Shield Blue Care Network of Michigan

Nonprofit corporations and independent licensees of the Blue Cross and Blue Shield Association

To whom it may concern,

Blue Cross Blue Shield of Michigan appreciates the opportunity to provide feedback on the Medicare Part C and Part D Program Audit Protocols, CMS-2025-1856.

We thank you in advance for your review of our comments and clarification requests below.

ODAG

1. The utilization of service level data in lieu of ODAG Tables 1-3 causes significant challenges for plans as they will have to be prepared to produce multiple, different data sets depending on the timing of receipt of engagement.

2. The plan requests clarification concerning the ODAG look-back period for CMS's application of quarterly service level data, when available. Depending on when the data is reviewed, the Service Level Data may not accurately represent current activity, including claim adjustments or appeals

3. CMS's calculation of the plan burden anticipates a reduction in hours from year one to years two and three, based on the exclusion of the prior ODAG Table 4: Part C Effectuations of Overturned Decisions by IRE, ALJ, or MAC (EFF_C) and leveraging data from the Service Level Data submissions for Tables 1- 3. However, this does not fully capture additional operational lift or system modification challenges to account for the new reporting elements:

    - Table 4: Part C Effectuations of Overturned Decisions by IRE, ALJ, or MAC (EFF_C)was removed, but it is replaced by what was previously Table 5: Part C Standard and Expedited Grievances (GRV_C) with the inclusion of three additional data elements that were previously excluded.
    - The new Table 5: Reopened Part C Determinations (RCD) introduces a new universe of data elements which were previously excluded from audit reporting.

    The estimates assume burden reduction by relying on data from quarterly service-level determination collections (ODAG Tables 1, 2, and 3), but that data does not cover the additional collection and validation for the data in new Tables 4: Part C

Standard and Expedited Grievances (GRV_C)and 5: Reopened Part C Determinations (RCD). These tables will still require distinct plan-level reporting, not derived from previously leveraged data.

These comments are provided to ensure the burden analysis reflects the complete scope of reporting modifications introduced under the proposed protocols.

4. Based on the Contract Year 2026 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly (CMS-4208-F), retrospective organization determination decisions are payment decisions and are subject all applicable subpart M requirements related to payment organization determinations, including payment timeframes. Under subpart M, the timeframe for processing a payment organization determination is 30 days. However, in ODAG Audit Element: Timeliness, 1.1, a timeframe for processing retrospective/post-service (non-claim) requests is not listed. Can CMS clarify the processing timeframe for retrospective/post-service (non-claim) organization determination requests?

5. ODAG Table 2 is titled "Standard and Expedited *Pre-Service* Reconsiderations (RECON) Record Layout"; however, the instructions indicate to include all reconsideration determinations of adverse organization determinations. Can CMS please clarify if all adverse organization determinations, not just limited to pre-service, should be included?

6. For ODAG Table 4: Part C Standard and Expedited Grievances (GRV_C), can CMS provide additional details or clarification on the expectation for column W "Coverage Request Initiated" and column X "Date coverage request initiated"? Is it CMS' intent to understand if a coverage request was initiated as a result of the member's grievance request? Or is CMS' intent to understand if a coverage request was received at any point during the contract year?

7. In the ODAG Audit Field Work Phase, CMS indicates that Plans must provide documentation related to requests received via Application Programming Interface (API). Can CMS clarify the type of documentation it expects to receive?

Blue Cross Blue Shield Blue Care Network of Michigan

Nonprofit corporations and independent licensees of the Blue Cross and Blue Shield Association

CDAG

1. Based on the method of evaluation for CDAG compliance standard 1.16, is CMS expecting plans to incorporate at-risk determinations, which were formerly in CDAG Table 7:CARA universe, in CDAG Tables 1-4?
2. Could CMS expand upon how the CDAG audit scope period will be chosen given that the proposed scope is not tied to the engagement notice date?
3. Please clarify what "Enter the PBP effective on the date of service" means for non-claims CDAG Tables 1, 2, 4, and 5? Is the intent to enter the PBP that is in effect at the time of receipt of the request?
4. Please provide expectations if a desk level audit is conducted. Will CMS provide templates, instructions, etc.?
5. Please confirm CDAG universes will not be flagged for data integrity if a case designated as "Denied" in the Table has an effectuation date entered in the Table due to partial approval.

FA

1. What is the expectation for the "other requested data" fields U , V, and W for FA Table 1: Rejected Claims Formulary Administration (RCFA) and Table 2: Rejected Claims Transition (RCT)?

PUBLIC SUBMISSION

As of: 1/29/26, 2:01 PM
Received: January 21, 2026
Status: Draft
Category: Government - Other
Tracking No. mko-s9ze-j292
Comments Due: February 20, 2026
Submission Type: API

Docket: CMS-2025-1856
Medicare Part C and Part D Program Audit and Industry-Wide Part C Timeliness Monitoring Project (TMP) Protocols (CMS-10717)

Comment On: CMS-2025-1856-0001
Medicare Part C and Part D Program Audit and Industry-Wide Part C Timeliness Monitoring Project (TMP) Protocols (CMS-10717)

Document: CMS-2025-1856-DRAFT-0004
Comment on CMS-2025-1856-0001

Submitter Information

Email: ethan_anderson@bcbst.com
Organization: BlueCross BlueShield of Tennessee

General Comment

The draft audit protocols has removed the following language from ODAG Table 2:

Exclude all requests for concurrent reviews for inpatient hospital and inpatient SNF services, and notifications of admissions.

Would these types of requests now be captured in Table 2, or are these requests to be reported on Table 1?

PUBLIC SUBMISSION

As of: 1/29/26, 2:03 PM
Received: January 23, 2026
Status: Draft
Category: Government - Other
Tracking No. mkq-x3l8-r66j
Comments Due: February 20, 2026
Submission Type: API

Docket: CMS-2025-1856
Medicare Part C and Part D Program Audit and Industry-Wide Part C Timeliness Monitoring Project (TMP) Protocols (CMS-10717)

Comment On: CMS-2025-1856-0001
Medicare Part C and Part D Program Audit and Industry-Wide Part C Timeliness Monitoring Project (TMP) Protocols (CMS-10717)

Document: CMS-2025-1856-DRAFT-0005
Comment on CMS-2025-1856-0001

Submitter Information

Email: ethan_anderson@bcbst.com
Organization: BlueCross BlueShield of Tennessee

General Comment

For the new fields added to the Grievance Universe (‘Coverage Request Initiated?’ and ‘Date coverage request was initiated’), does CMS expect plans to report any instance where a coverage determination was initiated in connection with the grievance, including cases where the CSR initiates a coverage request during the member’s initial call, as well as cases where the A&G department initiates a coverage request after reviewing the grievance? Or should this field only reflect coverage requests initiated by A&G after grievance review?

PUBLIC SUBMISSION

As of: 2/3/26, 7:54 AM
Received: February 02, 2026
Status: Draft
Category: Government - Other
Tracking No. ml5-mozg-2hid
Comments Due: February 20, 2026
Submission Type: Web

Docket: CMS-2025-1856
Medicare Part C and Part D Program Audit and Industry-Wide Part C Timeliness Monitoring Project (TMP) Protocols (CMS-10717)

Comment On: CMS-2025-1856-0001
Medicare Part C and Part D Program Audit and Industry-Wide Part C Timeliness Monitoring Project (TMP) Protocols (CMS-10717)

Document: CMS-2025-1856-DRAFT-0006
Comment on CMS-2025-1856-0001

Submitter Information

Email: ethan_anderson@bcbst.com
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General Comment

On page 4 of the proposed Medicare Part C and Part D Compliance Program Effectiveness (CPE) Program Audit Protocol and Data Request, it seems CPE will no longer be a standalone audit, how will CPE be evaluated? Will it be evaluated during the CDAG, ODAG, SNPCC and FA program audit sessions?

PUBLIC SUBMISSION

As of: 2/3/26, 7:55 AM
Received: February 02, 2026
Status: Draft
Category: Government - Other
Tracking No. ml5-msq5-wmvb
Comments Due: February 20, 2026
Submission Type: Web

Docket: CMS-2025-1856
Medicare Part C and Part D Program Audit and Industry-Wide Part C Timeliness Monitoring Project (TMP) Protocols (CMS-10717)

Comment On: CMS-2025-1856-0001
Medicare Part C and Part D Program Audit and Industry-Wide Part C Timeliness Monitoring Project (TMP) Protocols (CMS-10717)

Document: CMS-2025-1856-DRAFT-0007
Comment on CMS-2025-1856-0001

Submitter Information

Email: ethan_anderson@bcbst.com
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General Comment

In regards to the proposed CPE program audit protocols, when it comes to compliance oversight activities, what investigational activities would be considered in scope?

PUBLIC SUBMISSION

As of: 2/3/26, 7:56 AM
Received: February 02, 2026
Status: Draft
Tracking No. ml5-mvvz-xowd
Comments Due: February 20, 2026
Submission Type: Web

Docket: CMS-2025-1856
Medicare Part C and Part D Program Audit and Industry-Wide Part C Timeliness Monitoring Project (TMP) Protocols (CMS-10717)

Comment On: CMS-2025-1856-0001
Medicare Part C and Part D Program Audit and Industry-Wide Part C Timeliness Monitoring Project (TMP) Protocols (CMS-10717)

Document: CMS-2025-1856-DRAFT-0008
Comment on CMS-2025-1856-0001

Submitter Information

Email: ethan_anderson@bcbst.com
Organization: BlueCross BlueShield of Tennessee

General Comment

For the proposed CPE Universe Table 1: Compliance Oversight Activities Record Layout, would a PBM's investigational activities be included?

PUBLIC SUBMISSION

As of: 2/3/26, 7:57 AM
Received: February 02, 2026
Status: Draft
Category: Government - Other
Tracking No. ml5-myu3-d8l3
Comments Due: February 20, 2026
Submission Type: Web

Docket: CMS-2025-1856
Medicare Part C and Part D Program Audit and Industry-Wide Part C Timeliness Monitoring Project (TMP) Protocols (CMS-10717)

Comment On: CMS-2025-1856-0001
Medicare Part C and Part D Program Audit and Industry-Wide Part C Timeliness Monitoring Project (TMP) Protocols (CMS-10717)

Document: CMS-2025-1856-DRAFT-0009
Comment on CMS-2025-1856-0001

Submitter Information

Email: ethan_anderson@bcbst.com
Organization: BueCross BlueShield of Tennessee

General Comment

In the current CPE Audit protocols, Table 1's column C has the option of selecting Compliance or FWA. With the removal of column C in the proposed protocols, does this mean FWA activities will no longer be included?

PUBLIC SUBMISSION

As of: 2/3/26, 7:58 AM
Received: February 02, 2026
Status: Draft
Category: Government - Other
Tracking No. ml5-n1hu-qmoj
Comments Due: February 20, 2026
Submission Type: Web

Docket: CMS-2025-1856
Medicare Part C and Part D Program Audit and Industry-Wide Part C Timeliness Monitoring Project (TMP) Protocols (CMS-10717)

Comment On: CMS-2025-1856-0001
Medicare Part C and Part D Program Audit and Industry-Wide Part C Timeliness Monitoring Project (TMP) Protocols (CMS-10717)

Document: CMS-2025-1856-DRAFT-0010
Comment on CMS-2025-1856-0001

Submitter Information

Email: ethan_anderson@bcbst.com
Organization: BlueCross BlueShield of Tennessee

General Comment

On page 9 of the proposed CPE audit protocols, under the preliminary compliance officer interview, part of the interview includes discussion of the organization’s internal audit practices and oversight activities. Some organizations have an Internal Audit department that is separate from the Compliance department. In that structure, would the expectation be to discuss the audit activity and oversight mechanisms of each of those departments or just geared towards the Compliance department.

PUBLIC SUBMISSION

As of: 2/18/26, 2:36 PM
Received: February 13, 2026
Status: Draft
Category: Government - Other
Tracking No. mll-ccu6-mzc3
Comments Due: February 20, 2026
Submission Type: API

Docket: CMS-2025-1856
Medicare Part C and Part D Program Audit and Industry-Wide Part C Timeliness Monitoring Project (TMP) Protocols (CMS-10717)

Comment On: CMS-2025-1856-0001
Medicare Part C and Part D Program Audit and Industry-Wide Part C Timeliness Monitoring Project (TMP) Protocols (CMS-10717)

Document: CMS-2025-1856-DRAFT-0013
Comment on CMS-2025-1856-0001

Submitter Information

Email: ethan_anderson@bcbst.com
Organization: BlueCross BlueShield of Tennessee

General Comment

Regarding ODAG Table 1: The express exclusion of concurrent reviews for impatient hospital and SNF services language was removed. New bullets suggest identifying any number of refusals or downgrades to requested services. Are there any limits to including concurrent reviews?

PUBLIC SUBMISSION

As of: 2/18/26, 2:39 PM
Received: February 17, 2026
Status: Draft
Category: Government - Other
Tracking No. mlq-mr7e-s7gt
Comments Due: February 20, 2026
Submission Type: API

Docket: CMS-2025-1856
Medicare Part C and Part D Program Audit and Industry-Wide Part C Timeliness Monitoring Project (TMP) Protocols (CMS-10717)

Comment On: CMS-2025-1856-0001
Medicare Part C and Part D Program Audit and Industry-Wide Part C Timeliness Monitoring Project (TMP) Protocols (CMS-10717)

Document: CMS-2025-1856-DRAFT-0015
Comment on CMS-2025-1856-0001

Submitter Information

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Organization: BlueCross BlueShield of Tennessee

General Comment

With respect to Universe Table 1 (Standard and Expedited Organization Determinations), our organization currently submits data at the line level, and we generally support CMS's clarification regarding reporting of partially favorable determinations and notification level detail.

However, we request additional guidance to ensure consistent implementation across sponsors. Clarification and examples would be helpful to confirm CMS expectations for reporting partially favorable determinations involving multiple services, mixed outcomes, or multiple notifications, and how these should align with quarterly service level data during the transition period.

Additional clarity will help ensure consistent reporting, accurate data validation, and alignment with CMS's stated goal of effective oversight while minimizing unnecessary burden.

PUBLIC SUBMISSION

As of: 2/23/26, 11:05 AM
Received: February 19, 2026
Status: Draft
Category: Government - Other
Tracking No. mlt-s78e-qe20
Comments Due: February 20, 2026
Submission Type: API

Docket: CMS-2025-1856
Medicare Part C and Part D Program Audit and Industry-Wide Part C Timeliness Monitoring Project (TMP) Protocols (CMS-10717)

Comment On: CMS-2025-1856-0001
Medicare Part C and Part D Program Audit and Industry-Wide Part C Timeliness Monitoring Project (TMP) Protocols (CMS-10717)

Document: CMS-2025-1856-DRAFT-0022
Comment on CMS-2025-1856-0001

Submitter Information

Email: ethan_anderson@bcbst.com
Organization: BlueCross BlueShield of Tennessee

General Comment

3.1 Integrated HRA Standard (AIP DSNPs)
CMS's expectation for a single integrated HRA conflicts with legal, operational, timing, and systems based constraints.
Key Constraints & Risks:
1. State LTSS Assessments Cannot Be Integrated
State mandated LTSS/CHOICES assessments cannot be altered or merged with Medicare HRAs.
Risk: A unified HRA could place plans in direct conflict with state Medicaid requirements.
2. Misaligned Medicare & Medicaid Assessment Timelines
Medicare HRAs (90 days + annual) do not align with LTSS annual/semiannual cycles.
Risk: Forced alignment increases noncompliance exposure.
3. LTSS Assessment Scope Exceeds Medicare HRA Requirements
LTSS tools include functional, cognitive, environmental, caregiver, and eligibility components not required by Medicare.
Risk: Without CMS clarification, audit interpretation may vary.
4. Documentation Lives in Separate, Non Interoperable Systems
Medicare HRAs and LTSS assessments are stored in different plan, state, or vendor platforms.
Risk: Auditors may expect a single artifact that cannot legally or operationally exist.
5. Member Experience Concerns
Combining LTSS and Medicare HRA encounters would result in prolonged visits and reduced completion rates.
Risk: Lower engagement and poorer person centered outcomes.
6. States May Reject Unified HRA Tools
Even if created, states may not accept Medicare based HRAs for LTSS eligibility or service authorization.
Risk: Increased administrative burden rather than integration.
BCP Position:
BCP uses the state required LTSS/ECF assessment—which includes all CMS required HRA domains—to drive a unified, integrated care plan. Supplemental Medicare specific documentation is added only when required. Integration is achieved through care planning and coordination, not a single form.

3.2 Medicaid Assistance Standard
Clarifications Requested:
• Define what constitutes “offered to coordinate and provide Medicaid assistance.”
• Define when the requirement applies (“where applicable”).
• Confirm plan responsibilities vs. state responsibilities in integrated models.
• Confirm acceptable documentation (case notes, call logs, warm handoffs, consent/refusal, system screenshots).
• Clarify timeliness expectations.
BCP Practice:
BCP provides education, coordination, and documentation of all Medicaid-related interactions, including refusals or lack of identified needs.

Universe Table 1 – ICP Date (Column O)
BCP maintains a continuous, longitudinal ICP updated annually and as clinically indicated.
Clarification requested: Confirm that plans should report the most recent longitudinal ICP update, and exclude short term or transition specific plans.

Plan Change Effective Date (Column J)
Complexities arise because Medicare and Medicaid enrollment operate independently across multiple systems.
Operational Risks Identified:
• Multiple systems generate conflicting effective dates.
• Medicaid eligibility changes may occur while Medicare enrollment remains continuous.
• PBP changes do not clearly constitute reenrollment.
• Retroactive corrections alter dates after reporting.
Resulting Risk: High potential for inconsistent reporting or audit misinterpretation.
BCP Approach:
Use the Medicare reenrollment date (MARx) when a true Medicare disenrollment/reenrollment occurs; otherwise report None.
Clarifications Requested:
• What determines noncontinuous enrollment (Medicare, Medicaid, LTSS, or FIDE status)?
• Which date CMS intends to be reported when dates differ?
• Whether PBP changes count as reenrollment.
• How retroactive Medicaid updates should be handled.

FDRs Assigned to the Beneficiary (Column F)
State directed LTSS/Medicaid providers often participate in care coordination but are not FDRs under CMS definitions, creating inconsistent audit interpretations.
Clarifications Requested:
• Limit required reporting to contracted FDRs supporting the Model of Care.
• Exclude state directed Medicaid/LTSS providers from FDR categorization.
Proposed Protocol Language:
CMS should evaluate only contracted FDRs and allow documentation of coordination with state directed providers without classifying them as FDRs.

Audit Fieldwork Timing:One hour live sample pulls create material risk of incomplete or misfiled documentation due to:
• 300–450 required artifacts per sample
• multisystem retrieval
• HPMS formatting requirements
Plan Position (Risk Statement):
One hour pulls increase the risk of inaccurate or incomplete submissions without improving audit outcomes. A two business day timeframe aligns with CMS desk review standards and best supports accuracy and audit quality.

PUBLIC SUBMISSION

As of: 2/23/26, 11:14 AM
Received: February 19, 2026
Status: Draft
Category: Government - Other
Tracking No. mlt-tr99-ddtd
Comments Due: February 20, 2026
Submission Type: API

Docket: CMS-2025-1856
Medicare Part C and Part D Program Audit and Industry-Wide Part C Timeliness Monitoring Project (TMP) Protocols (CMS-10717)

Comment On: CMS-2025-1856-0001
Medicare Part C and Part D Program Audit and Industry-Wide Part C Timeliness Monitoring Project (TMP) Protocols (CMS-10717)

Document: CMS-2025-1856-DRAFT-0023
Comment on CMS-2025-1856-0001

Submitter Information

Email: ethan_anderson@bcbst.com
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General Comment

If there are material changes to the audit protocols, will CMS make the changes to the actual protocols or will the changes only be reflected in the Comments. It makes it easier for the plans if CMS makes the changes within the protocol.

PUBLIC SUBMISSION

As of: 2/23/26, 11:15 AM
Received: February 19, 2026
Status: Draft
Category: Government - Other
Tracking No. mlt-tta0-0213
Comments Due: February 20, 2026
Submission Type: API

Docket: CMS-2025-1856
Medicare Part C and Part D Program Audit and Industry-Wide Part C Timeliness Monitoring Project (TMP) Protocols (CMS-10717)

Comment On: CMS-2025-1856-0001
Medicare Part C and Part D Program Audit and Industry-Wide Part C Timeliness Monitoring Project (TMP) Protocols (CMS-10717)

Document: CMS-2025-1856-DRAFT-0024
Comment on CMS-2025-1856-0001

Submitter Information

Email: ethan_anderson@bcbst.com
Organization: BlueCross BlueShield of Tennessee

General Comment

ODAG Comments
1. ODAG Timeliness Audit Element Compliance Standard 1.1 on page 4 of 30, a field on Table 1: Standard and Expedited Organization Determinations (OD) to identify a “service or item not subject to the prior authorization rule” versus a “service or item subject to the prior authorization rules” was not identified, so how can one calculate timeliness for:
• For a service or item not subject to the prior authorization rules in § 422.122, 14 calendar days (28 calendar days if an extension was taken) after receiving the request
• For a service or item subject to the prior authorization rules in § 422.122, 7 calendar days (or 21 calendar days if an extension was taken) after receiving the request.
Could a field be added for “Service or Item subject to the prior authorization rule? Y for Yes and N for No”
2. Instead of putting the timeliness standard for expedited grievances of 24 hours under ODAG Audit Element Classification of Requests 3.2 on page 8 of 30, to align with evaluating grievance timeliness standards, and to avoid plan confusion, will CMS consider relocating evaluation of the expedited grievance timeliness standard of 24 hours under ODAG Audit Element Timeliness 1.7 on page 6 of 30?
3. ODAG Audit Element Processing of Coverage Requests 2.4, on page 9 of 30, under Data Request, because the Quarterly Data: Initial Determinations and Reconsiderations report is only a replacement for Table 1-3, it looks like Universe Table 5: Reopened Determinations (RCD) should be placed after Quarterly Data: Initial Determinations and Reconsiderations instead of before like in other sections.
4. ODAG Audit Element Processing of Coverage Requests 2.7, on page 10 of 30, under Data Request, because the Quarterly Data: Initial Determinations and Reconsiderations report is only a replacement for Table 1-3, it looks like Universe Table 5: Reopened Determinations (RCD) should be placed after Quarterly Data: Initial Determinations and Reconsiderations instead of before like in other sections.
5. ODAG Audit Element Classification of Requests 3.1, on page 10 of 30, under Criteria, there is a reference to 42 CFR § 423.564. This reference refers to Part D. Should the reference be 42 CFR § 422.564?

PUBLIC SUBMISSION

As of: 2/23/26, 11:16 AM
Received: February 20, 2026
Status: Draft
Category: Government - Other
Tracking No. mlv-76jp-rv1t
Comments Due: February 20, 2026
Submission Type: Web

Docket: CMS-2025-1856
Medicare Part C and Part D Program Audit and Industry-Wide Part C Timeliness Monitoring Project (TMP) Protocols (CMS-10717)

Comment On: CMS-2025-1856-0001
Medicare Part C and Part D Program Audit and Industry-Wide Part C Timeliness Monitoring Project (TMP) Protocols (CMS-10717)

Document: CMS-2025-1856-DRAFT-0027
Comment on CMS-2025-1856-0001

Submitter Information

Email: ethan_anderson@bcbst.com
Organization: BlueCross BlueShield of Tennessee

General Comment

he ODAG audit protocols indicate that the “Data Request” will consist of either the universe table or the Quarterly Data. However, the HPMS memo dated 12/16/2025 regarding the Service Level Data Collection for Initial Determinations and Appeals Pilot lists the quarterly data submission due dates as 05/25, 08/31, 11/30, and 02/22 (of the following year). Given that CMS typically issues program audit notifications between February and August, how will these quarterly reports be utilized for audits beginning in 2027? For example, if a plan receives an audit notification between February and May, the quarterly data would not yet have been submitted.

PUBLIC SUBMISSION

As of: 2/23/26, 11:19 AM
Received: February 20, 2026
Status: Draft
Tracking No. mlv-7k0m-u1ss
Comments Due: February 20, 2026
Submission Type: Web

Docket: CMS-2025-1856
Medicare Part C and Part D Program Audit and Industry-Wide Part C Timeliness Monitoring Project (TMP) Protocols (CMS-10717)

Comment On: CMS-2025-1856-0001
Medicare Part C and Part D Program Audit and Industry-Wide Part C Timeliness Monitoring Project (TMP) Protocols (CMS-10717)

Document: CMS-2025-1856-DRAFT-0028
Comment on CMS-2025-1856-0001

Submitter Information

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General Comment

1. For Timeliness Audit Element 1.1 in the ODAG Table 1 universe, how will CMS determine timeliness for services or items not subject to the prior authorization requirements under §422.122—where the standard is 14 calendar days (or 28 days if an extension is taken)—given that the universe layout does not include a field indicating whether a service or item was subject to prior authorization rules?
2. Can CMS explain the difference between supplemental services and value added items and services?

Section/Title	Commentor
CDAG Program Audit Protocol and Data Request, Universe Table 6: Part D Standard and Expedited Grievances (GRV_D) Record Layout	Erin Meador
ODAG Universe Table 4: Part C Standard and Expedited Grievances (GRV_C) Record Layout	Erin Meador
Attendance Sheets	Medicare Compliance
Audit Field Work	Medicare Compliance
SNPCC Universe Table 1: Special Needs Plans Enrollees (SNPE) Record Layout	Medicare Compliance
SNPCC Universe Table 1: Special Needs Plans Enrollees (SNPE) Record Layout	Medicare Compliance
SNPCC Universe Table 1: Special Needs Plans Enrollees (SNPE) Record Layout	Medicare Compliance
ODAG	Medicare Compliance
SNPCC	Michelle Jungling
CPE	Medicare Compliance

Part D Formulary and Benefit Administration (FA) Audit Elements Tested Compliance Standards 1.1 and 2.1	Tyler Rieger
Part D Formulary and Benefit Administration (FA) Universe Table 1: Rejected Claims Formulary Administration (RCFA) Record Layout Universe Table 2: Rejected Claims Transition (RCT) Record Layout	Tyler Rieger
Part D Formulary and Benefit Administration (FA) Universe Table 1: Rejected Claims Formulary Administration (RCFA) Record Layout Universe Table 2: Rejected Claims Transition (RCT) Record Layout	Tyler Rieger
Part D Coverage Determinations, Appeals, and Grievances (CDAG) Audit Elements Tested Compliance Standards 2.1, 2.3, 3.1, and 3.2	Tyler Rieger

Part D Coverage Determinations, Appeals, and Grievances (CDAG) Universe Table 1: Standard and Expedited Coverage Determination (CD) Record Layout Universe Table 2: Standard and Expedited Coverage Determination Exception Requests (CDER) Record Layout Universe Table 4: Standard and Expedited Redeterminations (RD) Record Layout Universe Table 5: Part D Effectuations of Overturned Decisions by IRE, ALJ or MAC (EFF_D) Record Layout	Phuong Ta
Part D Coverage Determinations, Appeals, and Grievances (CDAG) Universe Table 3: Payment Coverage Determinations and Redeterminations (PYMT_D) Record Layout	Phuong Ta

Part D Coverage Determinations, Appeals, and Grievances (CDAG)	
Universe Table 1: Standard and Expedited Coverage Determination (CD) Record Layout	
Universe Table 2: Standard and Expedited Coverage Determination Exception Requests (CDER) Record Layout	Phuong Ta
Universe Table 4: Standard and Expedited Redeterminations (RD) Record Layout	
Part D Coverage Determinations, Appeals, and Grievances (CDAG)	
Universe Table 5: Part D Effectuations of Overturned Decisions by IRE, ALJ or MAC (EFF_D) Record Layout	Phuong Ta
Part C Organization Determinations, Appeals, and Grievances (ODAG)	
Audit Elements Tested Compliance Standards 2.1, 2.3, 3.1, and 3.2	Tyler Rieger

Part C Organization Determinations, Appeals, and Grievances (ODAG) 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	Phuong Ta
Part C Organization Determinations, Appeals, and Grievances (ODAG) Universe Table 1: Standard and Expedited Pre-service Organization Determinations (OD) Record Layout	Tyler Rieger

Functional Area

Grievances

Grievances

All

All

Care Management

Care Management

Care Management

Organization Determinations and Reconsiderations

CM Universe Table 1

Compliance

Centene Pharmacy Services

Centene Pharmacy Services

Centene Pharmacy Services

Centene Pharmacy Services

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Centene Pharmacy Services

Business Comment(s)

The introduction of the new Universe fields—Column V (Coverage Request Initiated?) and Column W (Date Coverage Request Was Initiated)—will require material system enhancements for the Sponsoring Organization to ensure accurate, consistent, and compliant implementation.

The introduction of the new Universe fields—Column V (Coverage Request Initiated?) and Column W (Date Coverage Request Was Initiated)—will require material system enhancements for the Sponsoring Organization to ensure accurate, consistent, and compliant implementation.

If CMS utilizes Microsoft Teams or a comparable platform to conduct webinars, can attendance records be obtained directly from the platform, thereby eliminating the need for separate attendance logs?

Will Sponsoring Organizations be provided an opportunity to offer input regarding CMS's determination to conduct audit fieldwork via webinar as opposed to a desktop review? The Sponsoring Organization has concerns that a desktop review format may limit its ability to provide additional information or real-time clarification to CMS, as necessary, during the review process.

With respect to population of Column ID F (First Tier, Downstream, and Related Entity), is CMS requesting that the Sponsoring Organization list all entities that support Care Coordination activities (e.g., outreach support for HRA completion)? Additionally, should this include Utilization Management (UM) delegations, or only Care Management (CM)-related delegated entities?

May Column ID F (First Tier, Downstream, and Related Entity) include more than one entity, if applicable?

For population of Column ID I (Most Recent Plan Change Effective Date) and Column ID J (Most Recent Plan Change Effective Date for Non-Continuous Enrollment), can CMS provide additional clarification? Examples of applicable scenarios for Column IDs H through J would be helpful to ensure accurate reporting.

For Program Audits conducted in the 2027 plan year, does CMS intend to collect universes through the 2027 audit protocols in lieu of the quarterly "Service Level Initial Determination and Appeals" submissions? Additionally, will this approach differ for the 2028 plan year or subsequent years?

Confirm CMS' intent for Universe Column ID - L. Description states "this is the date of the most recently completed HRA prior to the date entered in Column ID I (Most recent plan change effective date)", is this correct?

With respect to Compliance Program Effectiveness, Universe Table 1: Compliance Oversight Activities (COA) Record Layout, is it CMS's intent to remove universe Column C, "Compliance or FWA"? If so, should the remaining column identifiers be revised to reflect sequential lettering?

The number of samples selected has changed from 30 in RCFA, 15 in RCT for new enrollees and 15 in RCT for continuing enrollees to "a minimum of" 30, 15 and 15. The addition of "a minimum of" without a maximum leaves an opening for significantly more samples to be selected. Would CMS consider establishing a maximum as well language indicating a count of samples between 30/15/15 and X? Would CMS also consider providing the sample selections more than an hour ahead of time if more than 30/15/15 samples are selected? The financial burden indicated in Supporting Statement Part A may also be underreported if more than 30/15/15 samples are selected.

[Column ID J - Field Name: Drug Name, Strength, and Dosage Form]
The drug name, strength, and dosage form are not submitted by the pharmacy. They are not part of the NCPDP claim submission fields. The pharmacy only submits the NDC. Different PBMs may report the drug name, strength, and dosage forms in different formats including shortening words to meet claims processing system field length limitations. There is not a standard. Can CMS please clarify the field description including removing the "as submitted by the pharmacy" language?

[Column IDs U, V, W - Field Name: <Other requested data>]
CMS added three fields to the record layouts for RCFA and RCT to be used for "Other Requested Data". Can CMS please define what other data may be requested? Without knowing what data might be requested here, plans would not know whether that data would be feasible to obtain and include within the 15 business days. Additionally, plan, PBM, and commercially available data validation and quality assurance tools would need to be modified depending on the data requested. Is CMS able to provide a full list of data that may be requested? The financial burden indicated in Supporting Statement Part A may also be underreported depending on the complexity of the information requested. The financial burden for the first year of this package may be significantly under reported if available data validation and quality assurance tools need to be modified.

The number of samples selected has changed from 10 approval cases, 30 denial cases, 10 dismissal cases and 20 grievance cases and to "a minimum of" 10, 30, 10, 20. The addition of "a minimum of" without a maximum leaves an opening for significantly more samples to be selected. Would CMS consider establishing a maximum as well language indicating a count of samples between 10/30/10/20 and X? Would CMS also consider providing the sample selections more than an hour ahead of time if more than 10/30/10/20 samples are selected?The financial burden indicated in Supporting Statement Part A may also be underreported if more than 10/30/10/20 samples are selected

[Column ID G - Field Name: NDC]
Would CMS please consider revising the NDC field description to better align with how NDCs are applicable in CD and RD requests rather than using the same field desription used in Formulary Adminstration universe tables where NDCs are a required submission field in pharmacy claims?
The description appears to be written as if pharmacy is submitting the request however, the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance does not allow for a pharmacy to submit a Coverage Determination (CD) or Redetermination (RD) request. These tables relate to member, member's representative, or member's precriber submitted CD or RD requests regardless of whether a pharmacy claim was attempted prior to the submission of the CD or RD. NDCs are rarely included CD or RD requests as requests are typically for the drug regardless of NDC. We undertand that it is not the desire of CMS for this field to be left blank when NDCs are not included in CD or RD requests but instead the desire is for plans to provide an NDC representative of the requested drug. Plans can often identify a representative NDC but that would not be a submitted NDC. Additionally plans receive CD and RD requests where plans are unable to identify an NDC from a related submitted claim or are unable to identify a representative NDC due to unclear information received with the CD or RD request. Can CMS please clarify what plans should enter in the NDC field when plans have exhausted attempts to find a representative NDC, or when requests are received for something that is not a drug and has no NDC?
Furthermore, since CDs and RDs are not submitted by pharmacies, a pharmacy could not submit a value greater than 11 characters and "valueXeeded" would not have a place in these tables.
[Column ID G - Field Name: NDC]
Would CMS please consider revising the NDC field description to better align with how NDCs are applicable in CD and RD requests rather than using the same field desription used in Formulary Adminstration universe tables where NDCs are a required submission field in pharmacy claims?
The description appears to be written as if pharmacy is submitting the claim, but this table relates to a member or member's representative submitted direct member reimbursement request regardless of whether a pharmacy claim was attempted prior to the submission of the payment request. While NDCs are typically necessary for plans to approve payment requests, requests may be denied due to lack of an NDC. Can CMS please clarify if it is the expection that this field be submitted blank when plans are unable to determine the NDC for the reimbursement request?

[Table 1 - Column ID W & X - Field Name: Date effectuated in
the system & Time effectuated in the system]
[Table 2 - Column ID Z & AA - Field Name: Date effectuated in the system & Time effectuated in the system]
[Table 4 - Column ID Z & AA - Field Name: Date effectuated in the system & Time effectuated in the system]
There are situations were effectuations are not necessary for requests that were approved.
Plans receive Coverage Determination (CD) or Redetermination (RD) requests for drugs which are already on the formulary without any utilization managment (UM) edits or when UM requirements have already been meet. Can CMS please provide clarity as to what should be populated when effectuation in the system is not needed? May plans enter "None" in these cases similar to what is allowed in Table 5 or can CMS define a different variable for this situation?

[Record layout guidance - Exclude any cases that were re-opened by the Sponsoring organization or that were dismissed or upheld by the IRE, ALJ, or MAC.]
Would CMS please consider including language that addresses cases that were re-opened by the IRE/ALJ/MAC that were ultimately dismissed or upheld.

The number of samples selected has changed from a set number of denial cases, dismissal cases and grievance cases and to "a minimum of". The addition of "a minimum of" without a maximum leaves an opening for significantly more samples to be selected. Would CMS consider establishing a maximum as well language indicating a count of samples between 40 denial, 10 dismissal, and 15 grievance and X? Would CMS also consider providing the sample selections more than an hour ahead of time if more than 40/10/15 samples are selected? The financial burden indicated in Supporting Statement Part A may also be underreported if more than 40/10/15 samples are selected.

[Record layout guidance]
Would CMS please consider including the removed language clarifying that reopened and withdrawn requests should be excluded from Tables 1 and 2 as well as the removed language clarifying that reopened requests should be excluded from Table 3. Acknowelging that there is now an additional table specific to reopened cases, over clarification on Tables 1, 2, and 3 would still be helpful and potentially create fewer furture questions.

[Column ID V - Field Name: Who made the request?] When organization determinations (OD) or reconsideration (RC) requests are received for Part B drugs when the location of service is a pharmacy, the contract/non-contract status of the provider/facility who made the request is not considered as part of the decision to approve or deny a request as the status of the provider will not affect the member's ability to obtain the drug from a pharmacy. As such prior auth processing systems may not capture the contract/non-contract status of the provider/facility who made the request. Would CMS please consider adding an option to the field description to allow for plans to indicate when a Part B drug is being requested by a provider when the location of service is a pharmacy and the contract/non-contract status is not considered. e.g., "PRX for provider requests for Part B drugs filled at community, mail-order, LTC, I/T/U pharmacies"

PUBLIC SUBMISSION

As of: 1/8/26, 1:14 PM
Received: January 06, 2026
Status: Draft
Category: Health Plan or Association
Tracking No. mk3-1eti-y5la
Comments Due: February 20, 2026
Submission Type: Web

Docket: CMS-2025-1856
Medicare Part C and Part D Program Audit and Industry-Wide Part C Timeliness Monitoring Project (TMP) Protocols (CMS-10717)

Comment On: CMS-2025-1856-0001
Medicare Part C and Part D Program Audit and Industry-Wide Part C Timeliness Monitoring Project (TMP) Protocols (CMS-10717)

Document: CMS-2025-1856-DRAFT-0003
Comment on CMS-2025-1856-0001

Submitter Information

Name: Anonymous Anonymous

General Comment

CPE Protocol instructions for Table 1 "Submit a list of compliance oversight activities related to all program audit areas included in the audit engagement letter (e.g., FA, ODAG, CDAG, and SNPCC that the Sponsoring organization conducted or completed during the 1 year period preceding and including the date of the audit engagement letter." Does CMS expect plans to only include activities that Compliance conducted and not activities conducted by the operational areas within for example ODAG?

PUBLIC SUBMISSION

As of: 2/18/26, 2:44 PM
Received: February 18, 2026
Status: Draft
Category: Health Care Industry - PI015
Tracking No. mls-5bqy-6peu
Comments Due: February 20, 2026
Submission Type: API

Docket: CMS-2025-1856
Medicare Part C and Part D Program Audit and Industry-Wide Part C Timeliness Monitoring Project (TMP) Protocols (CMS-10717)

Comment On: CMS-2025-1856-0001
Medicare Part C and Part D Program Audit and Industry-Wide Part C Timeliness Monitoring Project (TMP) Protocols (CMS-10717)

Document: CMS-2025-1856-DRAFT-0018
Comment on CMS-2025-1856-0001

Submitter Information

Name: Anonymous Anonymous

General Comment

1. CPE Program Audit Protocol and Data Request, Universe Request
CMS modified the 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 during the 1-year period preceding and including the date of the audit engagement letter.
Comment: Instead of changing the look back period from 6 months to 1-year, I would like to propose keeping the look back period at 6 months as this period would be most relevant to the current data being audited and would contain any open or closed activities for the period. A 6-month look-back period yields the most accurate and relevant reflection of current compliance oversight activities. Extending to 1 year increases the likelihood that the universe includes outdated processes no longer in use, which can obscure CMS's ability to evaluate true current-state performance.
Maintaining a 6-month look-back reduces unnecessary administrative burden without diminishing CMS's visibility into current compliance activities.

2. Universe Column ID K, Corrective Action Required
CMS modified Description to:
Enter:
• Y (for Yes) if any identified deficiencies required correction.
• N (for No) if none of the deficiencies required correction.
Enter NA if no deficiencies were identified or if the compliance department is still assessing whether correction is needed.
Comment: Plans were using the N (for No) option for when no deficiencies were identified or if the compliance department is still assessing whether correction is needed.
Propose modifying the Description to stay in line with current practice to:
Enter:
• Y (for Yes) if any identified deficiencies required correction.
• N (for No) if none of the deficiencies required correction, if no deficiencies were identified, or if the compliance department is still assessing whether correction is needed.
Maintaining the established meaning of "N" supports continuity, preserves workflow efficiencies, and avoids unnecessary system or training changes across the industry.

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February 20, 2026

William N. Parham, III
Director
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Centers for Medicare & Medicaid Services
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Baltimore, MD 21244-1850

RE: Proposed Revisions to the Part C and Part D Program Audit Protocols (CMS-10717)

Dear Director Parham:

CVS Health appreciates the opportunity to comment on the Department of Health and Human Services (HHS), Centers for Medicare & Medicaid Services' (CMS) Paperwork Reduction Act (PRA) notice seeking comments on proposed revisions for the Medicare Part C and D program audit protocols issued in the *Federal Register* on December 22, 2025.

Our comments aim to ensure the integrity and consistency of data collected by CMS while simultaneously reducing the administrative burden these audits place on Part C and Part D plans. We request CMS incorporate the recommendations we have provided in the attached appendix when issuing the final audit protocol guidance.

Thank you for considering our comments and requests. We appreciate CMS' willingness to continue engaging with the industry as it updates its data collection and oversight efforts. Please do not hesitate to contact us with any questions about these comments.

Sincerely,

Melissa Schulman
Senior Vice President
Government & Public Affairs
CVS Health

APPENDIX:
60-Day Comments for Proposed Revisions for Medicare Part C and Part D
Program Audit Protocols (CMS-10717)

Section	Protocol Topic/ Reference	Issue Identified	Comment	Recommendation to CMS
CMS Program Audit Protocols All Program Areas Except CPE	Method of Evaluation	Sample Size	Revising sample size language from "up to" to "minimum of" without an upper limit may lead to inconsistent audit application and disproportionate operational burden across Sponsoring Organizations.	To reduce administrative burden and ensure consistency, we recommend CMS retain the current number of samples per program area as indicated in the current protocols. (OMB Approval 0938-1395 - Expires 01/31/2027). In the event CMS does not adopt this recommendation, we recommend CMS establish a maximum sample size. Clarity of the sample size is necessary to promote audit consistency, predictability, and proportionality. Additionally, for CDA, we recommend CMS clarify how reopening cases are incorporated into sample selection.
	Audit Field Work Phase – Sample Selection	Desk Review	The protocol states that desk reviews may be conducted with "enough advanced notice," but does not define a minimum notice period. This lack of specificity may result in inconsistent expectations and audit readiness challenges.	We strongly recommend CMS not use desk reviews as this approach would be administratively burdensome and resource-intensive on plans. Rather, we recommend CMS continue to leverage webinar technology. As the past several years have demonstrated, CMS' use of webinar technology has proven to be an effective and efficient means to conduct these audits.

Section	Protocol Topic/ Reference	Issue Identified	Comment	Recommendation to CMS
CMS Program Audit Protocols Part D Formulary and Benefit Administration (FA)	Sample Size Terminology ("Minimum of")	No maximum sample size defined	Revising sample size language from "up to" to "minimum of" without an upper limit may lead to inconsistent audit application and disproportionate operational burden across Sponsoring Organizations.	In addition to our recommendation above regarding sample size, we recommend that CMS review and revise the algorithm used for sampling to ensure targeting criteria produce valid testable samples. In the past, additional samples have been required because samples initially selected by CMS did not meet the criteria necessary for testing.
	Tables 1, 2: Eligibility Rejections / Claim Denials	Risk of misidentifying beneficiaries	Inclusion of claim denials crosswalked via BIN/PCN/Group may associate data with non-enrolled individuals due to inaccurate pharmacy submitted data.	We recommend CMS clarify that beneficiary-level data is expected only when enrollment and eligibility are validated in Sponsor systems.
	Tables 1, 2: Use of "NA"	Privacy and data integrity concerns	Submission of beneficiary level data when an enrollee cannot be identified creates privacy and data accuracy risks.	We recommend CMS confirm that beneficiary-specific data is not required when enrollment cannot be validated.
	Tables 1, 2: New Data Columns (U, V, W)	Undefined data requirements	New, unspecified "Other Requested Data" fields require ad hoc reporting and manual manipulation, increasing risk of inconsistency.	We recommend CMS clarify when fields are required, define use-cases, and specify acceptable data sources.

Section	Protocol Topic/ Reference	Issue Identified	Comment	Recommendation to CMS
CMS Program Audit Protocols Part D Formulary and Benefit Administration (FA)	Tables 1, 2: New Data Columns (U, V, W)	Unclear authority and scope	The protocol does not specify who may request additional data fields or the frequency and limits of such requests.	We recommend CMS define authority (CMS vs. Sponsor), scope, and limited circumstances for requesting additional data.
	Tables 1, 2: Pharmacy-Submitted Demographics	Data misalignment	Requiring pharmacy-submitted demographics instead of enrollment data may cause discrepancies, especially for demographic-related rejections.	We recommend CMS reconsider the requirement or clarify alternative approaches aligned with enrollment systems.
	Tables 1, 2: Col J: Drug Name Field	Operational infeasibility	Pharmacies submit NDCs, not drug names, in standard claims processing.	We recommend CMS clarify that submission of the NDC alone satisfies the drug name requirement.
	RCA and IA: "Scope of Non-Compliance"-Compliance"	Undefined audit term	Template introduces "scope of non-compliance" without definition.	Given that Program Audits aim to ensure beneficiaries receive the services and protections as required by plan contracts with CMS and the Medicare program, we recommend CMS define scope of non-compliance as beneficiary impact (i.e., X number of beneficiaries impacted out of Y total beneficiaries).

Section	Protocol Topic/ Reference	Issue Identified	Comment	Recommendation to CMS
CMS Program Audit Protocols Part D Coverage Determinations, Appeals, and Grievances (CDAG)	Tables 1-5: PBP Effective Date	Ambiguity for pre-benefit requests	Pre-benefit requests may not have a date of service, yet tables reference PBP effective on date of service.	We recommend CMS change the field description to state the following: *Enter the PBP effective on the date of the request.*
	Tables 1-4: "Who Made the Request?"	Reopened case handling unclear	It is unclear whether "None" applies to all Sponsor-reopened cases or only some.	We recommend CMS confirm "None" should be used for all Sponsor-reopened cases.
	Tables 3,4 Filing Timeframe (Good Cause)	Regulatory inconsistency	Protocol references 60 days, conflicting with current 65-day guidance.	We recommend CMS update the field description to align with current regulatory requirements.

Section	Protocol Topic/ Reference	Issue Identified	Comment	Recommendation to CMS
CMS Program Audit Protocols Part D Coverage Determinations, Appeals, and Grievances (CDAG)	Table 3: Record Layout Instructions	Requests denied in part	It is unclear what constitutes "denied in part" for payment requests.	We request that CMS clarify, or provide examples, regarding how plans should classify reimbursement outcomes in scenarios where a claim is partially paid due to benefit design. For example, a beneficiary submits a paper claim with a receipt for $100. The plan adjudicates the claim, applies a portion toward the deductible, and reimburses the remaining amount less the applicable copay. Where the beneficiary did not request reimbursement for a specific dollar amount, should the plan report this outcome as an approval or a denial? In a separate scenario, a beneficiary submits a paper claim with a receipt for $150 and explicitly requests reimbursement for the full amount less a $25 copay. The plan determines that only $100 of the claim is covered and reimburses $75. Should this outcome be reported as an approval or a denial?
	Table 6: Grievances >30 Days	Extension treatment unclear	Protocol does not specify whether grievances under approved 14-day extensions are included.	We recommend CMS clarify whether extended grievances are within scope given the General Record Layout Instructions state to exclude requests that are pending a decision.

Section	Protocol Topic/ Reference	Issue Identified	Comment	Recommendation to CMS
CMS Program Audit Protocols Part D Coverage Determinations, Appeals, and Grievances (CDAG)	Table 6: Col V: Coverage Request Initiated	Timing of coverage request unclear	Protocol does not specify the timing of the coverage request.	We recommend CMS confirm that this field applies to a coverage request submitted *after* receipt of a grievance.
CMS Program Audit Protocols Part C Organization Determinations, Appeals, and Grievances (ODAG)	Table 1: Record Layout Instructions	Universe inclusions and exclusions	Instructions are unclear on types of initial organization determinations to include. Instructions no longer list reopenings and withdrawals as excluded from this universe.	We recommend CMS clarify that initial organization determinations mean/include pre-service and initial concurrent reviews. We recommend CMS confirm that reopenings and withdrawals are now to be <u>included</u> in Table 1 given that reopenings are included in Table 5.
	Table 1: Col M: Request Determination	Response value limitation	No response values for reopenings, withdrawals.	If reopenings and withdrawals are to be included in Table 1, we recommend CMS add response values to accommodate these dispositions inclusive of “dismissed” for withdrawals.

Section	Protocol Topic/ Reference	Issue Identified	Comment	Recommendation to CMS
CMS Program Audit Protocols Part C Organization Determinations, Appeals, and Grievances (ODAG)	Table 1: Col W: Issue Description and Type of Service	Type of service unclear	Use of the word "pre-service" unclear.	We recommend CMS clarify its use of "pre-service." As proposed, only "pre-service" denials would require an explanation.
	Table 2: Record Layout Instructions	Universe inclusions and exclusions	The word "pre-service" remains in the title of the table yet is removed in the instructions. Instructions no longer exclude concurrent reviews for inpatient hospital and inpatient SNF services, and notifications of admissions from this universe. Instructions no longer list reopenings and withdrawals as excluded from this universe.	We recommend CMS insert "pre-service" in the instructions for consistency and clarity. We recommend CMS clarify if post-acute/QIO appeals are to be included in this table or just pre-service and initial concurrent reviews. We recommend CMS confirm that reopenings and withdrawals are now to be <u>included</u> in Table 2 given that reopenings are included in Table 5.

Section	Protocol Topic/ Reference	Issue Identified	Comment	Recommendation to CMS
CMS Program Audit Protocols Part C Organization Determinations, Appeals, and Grievances (ODAG)	Table 2: Col G: Authorization or Claim Number	Scope of request	Unclear how to handle appeals involving multiple claims and/or authorizations.	Given that an appeal can involve numerous claims and/or authorizations, we recommend CMS clarify if providing the claim and/or authorization for the primary request suffices.
	Table 2: Col M: Request Determination	Response value limitation	No response values for reopenings, withdrawals.	If reopenings and withdrawals are to be included in Table 2, we recommend CMS add response values to accommodate these dispositions inclusive of "dismissed" for withdrawals.
	Table 2: Col AA: Issue Description and Type of Service	Type of service unclear	Use of the word "pre-service" unclear.	We recommend CMS clarify its use of "pre-service." As proposed, only "pre-service" denials would require an explanation.
	Table 3: Record Layout Instructions	Universe inclusions and exclusions	Instructions no longer list reopenings and withdrawals as excluded from this universe.	We recommend CMS confirm that reopenings and withdrawals are now to be <u>included</u> in Table 3 given that reopenings are included in Table 5.
	Table 4: Col W: Coverage Request Initiated	Timing of coverage request unclear	Protocol does not specify the timing of the coverage request.	We recommend CMS clarify if this field applies to a coverage request submitted *after* receipt of a grievance.

Section	Protocol Topic/ Reference	Issue Identified	Comment	Recommendation to CMS
CMS Program Audit Protocols Part C Organization Determinations, Appeals, and Grievances (ODAG)	Table 5: Record Layout Instructions	Universe inclusions and definition	New table appears duplicative of existing reporting.	While we appreciate CMS efforts to reduce plan burden, we note this newly created table appears to counter that effort in that plans already provide detailed yearly Part C ODR Reopening reporting. In addition, it remains unclear how CMS defines "reopening" for the purposes of this table (i.e., is it the same as the definition for existing reporting?) and which reopenings (i.e., level 1 or 2 reopenings) plans should use to populate the table. In the interest of burden reduction and efficiency, we recommend CMS leverage existing reporting and remove this proposed table from the ODAG protocol.
	Old Table 4 (EFF_C)	Universe removed	Proposed protocol no longer contains this table.	We recommend CMS confirm the removal of this table was intentional. Additionally, we recommend CMS clarify if and how it intends to examine these data (i.e., use another ODAG table or create another table).
	Old Table 7 (TERM)	NA	NA	We recommend CMS clarify if it intends to still use this table for Program or Focused Audits. If yes, to afford the industry an opportunity to comment, we recommend CMS include this table as part of the 30-day PRA for this proposed collection.

Section	Protocol Topic/ Reference	Issue Identified	Comment	Recommendation to CMS
CMS Program Audit Protocols Special Needs Plans Care Coordination (SNPCC)	Audit Field Work Phase – Sample Selection	Sample review preparation time.	Given the volume and complexity of the 30 cases selected, including beneficiaries with significant medical, behavioral, and social risk factors—providing plans with just one hour of advance notice for case review does not allow for sufficient time to adequately review documentation, validate clinical accuracy, and ensure complete and accurate case presentation.	To ensure the integrity of the review process, we recommend CMS allow plans at least 72 hours advance notice to review the samples, compile relevant clinical information, and quality check all documentation for accuracy and completeness.

CPE Protocols

1. On page 1 of Supporting Statement A 10717, CMS states that "Starting in 2027, validation activities may be conducted through either an audit or through *other activities* including a more streamlined documentation and data review." What other activities will CMS be using to validate corrective action plans have been completed accurately and timely? Can CMS please provide examples?

2. On page 14 of Supporting Statement A 10717, CMS noted the following modification, "Spreading the review of the FA, CDAG, ODAG, and SNPCC (if applicable) program areas over the course of two weeks by eliminating the CPE tracer reviews which allows for Sponsoring organizations to better allocate staffing." Did CMS eliminate tracers completely or only portions of a tracer from the audit?

3. Is the expectation that those performing the audits have a clinical background? For example, if conducting an appeals & grievances audit, would the auditor need to be able to determine if an appeal was denied due to clinical reasons or would an audit of the timeliness of the appeals process suffice?

4. For the CPE IA universe – Is the expectation that for every deficiency identified in column I (number of deficiencies) we will provide a corresponding description of corrective action required in the new column L? For example, if we have 5 deficiencies in column I should we have 5 CAPs listed in column L? If one CAP corrects more than one deficiency, do we need to list that CAP more than once in column L?

5. On page 9-10 of the Master Crosswalk, CMS notes that they have "Removed data request table relating to the collection of the supplemental documents." Can CMS clarify what supplemental documents this is referring to? Are these supplemental documents for tracers?

6. On page 9 of the CPE Audit Protocols, under Preliminary Compliance Office Interview, additional discussion topics may include "Internal audit practices and oversight mechanisms." Can CMS expand upon and provide examples for what "Internal audit practices and oversight mechanisms" they are looking for?

7. Is the FWA Universe no longer reflecting provider-based investigations involving claims, billing patterns, or general SIU/provider fraud? If yes, how does this directly tie to activities within ODAG, CDAG, FA, and SNPCC?

8. In the CPE Audit Protocol Table 1, Column L contains a new field which requests a "Description of Corrective Action Required." This field has a 1,000-character limit; however, this may not be sufficient to explain the description of all corrective actions required, pending upon the issue. We would recommend that CMS increase the character limit for the field in Column L.

ODAG Protocols

1. In Table 5 of the proposed ODAG protocols, Column M requests the Reasons for Reopening: NM for new and material evidence; CE for clerical error; PA for payment adjustment (reopened approval and adjusted payment); FF for suspected fraud or similar fault; and O for Other. We request that CMS include definitions for each of these reasons for Reopening.

Eva DuGoff
Executive Director – Health Policy

February 20, 2026

Centers for Medicare & Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Attention: Document Identifier: CMS-10717/OMB Control Number: 0938-1395
Room C4-26-05
7500 Security Boulevard, Baltimore, Maryland 21244-1850
Submitted electronically: www.regulations.gov

Re: Medicare Part C and Part D Program Audit and Industry-Wide Part C Timeliness Monitoring Project (TMP) Protocols (CMS-10717; OMB 0938-1395)

To Whom It May Concern:

Health Care Service Corporation (HCSC) appreciates the opportunity to provide comments on the revisions to the Medicare Part C and Part D Program Audit and Industry-Wide Part C Timeliness Monitoring Project (TMP) Protocols (CMS-10717) published in the *Federal Register* (90 FR 59834) on December 22, 2025. In the attached, HCSC offers several requests for clarification and recommendations on the modifications.

HCSC is the largest non-investor-owned health insurer in the United States. HCSC's Medicare business offers a full suite of products for every need, budget, and lifestyle. We serve more than 4.3 million Medicare beneficiaries nationwide. This includes offering Medicare Advantage plans in 30 states, Medicare Supplement plans in 48 states and the District of Columbia, and standalone Prescription Drug Plans in 48 states, the District of Columbia, and the U.S. territory of Puerto Rico. At HCSC, we are deeply committed to providing our Medicare Advantage and Part D members with a high-quality care experience.

Thank you for considering our comments. We appreciate CMS' continued engagement with the stakeholders on these topics.

Sincerely,

Eva DuGoff

Eva DuGoff
Executive Director-Health Policy

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CMS-10717; OMB 0938-1395

Comments on Medicare Part C and Part D Program Audit Protocols

ODAG Protocol

Under the audit element "Processing of Coverage Requests", CMS notes that the method of evaluation to be: "Select a minimum of 40 denied requests from the audit universes or the quarterly data submissions. The number of requests from each universe will vary and will be used to assess compliance standards 2.1 through 2.7 as applicable." **HCSC asks for additional clarification** about this element. Is there a maximum number of samples that the sponsoring organization can expect to receive per audit universe?

Under the Compliance Standard, "Universe Integrity Testing", CMS notes that the method of evaluation to be "Select 10 cases from each submitted audit universe and/or from the quarterly service level data universes (when available)." **HCSC asks for additional clarification** about this element: Is 10 the number of samples the sponsoring organization can expect to receive per audit table, or can there be additional samples? Furthermore, how does this data element interact with the Compliance Standard: 2.1 (discussed above) method of evaluation which states "a minimum of 40 denied requests" will be selected.

Under the guidance for "Universe Table 5: Reopened Part C Determinations (RCD) Record Layout" (PDF page 25 or 30), CMS notes to Sponsoring Organizations: "Include only reopenings that were initiated by the Sponsoring organization or an FDR on behalf of the Sponsoring organization. Do not include re-openings that were requested by the enrollee or a provider." HCSC notes that reopening data is submitted and available in Part C reporting, this includes all requested reopenings completed by the sponsoring organization. It seems that the changes to Table 5 do not align with Part C as we are being asked to submit only reopenings requested by the organization or FDR. Part C reopening table lists all requested reopenings (including re-openings requested by the enrollee or a provider). **HCSC recommends that it would be more efficient to align Table 5 with Part C reporting. An advantage of aligning Part C reopenings table and Table 5 is that it would reduce the burden on the health plan to implement a new table when the data is already reported.**

SNPCC Protocol

Under the Compliance Standard "Universe Integrity Testing: Universe Table 1: Special Needs Plan Enrollees", CMS notes that the method of evaluation to be "Select a minimum of 10 cases from Universe Table 1." **HCSC asks for additional clarification**: Is there a maximum number of cases that can be selected?

Under the Care Management Audit Element, Compliance Standard 2.1: Universe Table 1: Special Needs Plans Enrollees (SNPE)", CMS notes that the method of evaluation to be: "Select a minimum of 30 samples from Table 1 that reflect the general composition of membership in each of the Sponsoring organization's plan types or PBPs." **HCSC asks for additional clarification**: Is there a maximum number of cases that can be selected?

Under the Audit Field Work Phase document (PDF page 14 of 16), CMS provides that "If the audit fieldwork is done live via webinar, the Sponsoring organization will receive notice of the selected samples 1 hour in advance of the live review." **HCSC asks for additional clarification:** If there is a minimum of 30 cases as stated, does this mean we should expect at least 30 cases 1 hour prior to live webinar? Currently the samples are sent two days prior to the review. Changing the time frame to 1 hour is a substantial change. If a live webinar audit is conducted, please provide additional description with the expected number of hours or days.

Under the Audit Field Work Phase document (PDF page 14 of 16), CMS provides that ""CMS may conduct all or part of the review via desk review. If desk review is conducted, the Sponsoring organization will receive samples with enough advanced notice to prepare and submit full or partial case files." **HCSC asks for additional clarification**: If a desk review audit is conducted, what does CMS consider to be enough advanced notice? Please provide additional description with the expected number of hours or days.

CPE Program Protocol

On PDF page 4 of 9, CMS describes the Scope of Universe request in the table as "Submit a list of compliance oversight activities related to all program audit areas included in the audit engagement letter (e.g., FA, ODAG, CDAG, and SNPCC that the Sponsoring organization conducted or completed during the 1 year period preceding and including the date of the audit engagement letter." We understand that this modifies the 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 during the 1-year period preceding and including the date of the audit engagement letter. The current language for the Scope of Table 1 – COA is: "Submit a list of all compliance oversight activities that occurred during the 26- week period preceding and including the date of the audit engagement letter." **HCSC recommends that** CMS align the COA table look back to 6 months. The rationale for retaining the existing scope is that the 6-month look back period will align with the scope of the program areas tested during fieldwork creating a streamlined conversation with the Compliance staff. Additionally, this will align with questions 12 and 13 of the Compliance Program Effectiveness Questionnaire relating to identified issues.

On PDF page 6 of 9, for the Universe Table 1 COA Record Layout Column G, CMS description reads: "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, 2027, that is the date that would be used for the date the activity started." The current language uses the date January 1, 2020. **HCSC asks for clarification on this change:** Please clarify the effective date of the proposed audit protocol changes.

FA Protocol

On PDF page 10 of 17, CMS describes the Enrollment Effective Date for Column ID E in the table as "Enter effective date of enrollment for the enrollee (PBP level). Enter the enrollment date relevant to the contract and plan ID of the enrollee at the time of the claim." **HCSC asks for additional clarification**: Does CMS explicitly require the date from the plan's enrollment system rather than the adjudication system?

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Humana

February 19, 2026

William N. Parham, III
Director, Paperwork Reduction Staff
Office of Strategic Operations and Regulatory Affairs
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

RE: Medicare Part C and Part D Program Audit and Industry-Wide Part C Timeliness Monitoring Project (TMP) Protocols (CMS-10717; Docket ID: CMS-2025-1856)

Dear Mr. Parham:

This letter is in response to the Centers for Medicare and Medicaid Services (CMS) agency information collection notice "Medicare Part C and Part D Program Audit and Industry-Wide Part C Timeliness Monitoring Project (TMP) Protocols (CMS-10717)" as issued on December 22, 2025.

Humana Inc., headquartered in Louisville, Kentucky, is a leading health care company that offers a wide range of insurance products and health and wellness services that incorporate an integrated approach to lifelong well-being. Humana currently serves approximately 7 million beneficiaries enrolled in our Medicare Advantage (MA) plans and 3.8 million beneficiaries enrolled in our Medicare Part D Prescription Drug Plans (PDPs). As one of the nation's top contractors for MA, we are distinguished by our long-standing, comprehensive commitment to Medicare beneficiaries across the United States. These beneficiaries – a large proportion of whom depend upon the MA program as their safety net – receive integrated, coordinated, quality, and affordable care through our plans. Our perspective is further shaped by the comprehensive medical coverage we provide for Medicaid beneficiaries in seven states.

Part D Coverage Determinations, Appeals and Grievances (CDAG) Program Audit Protocol and Data Request

Universe Table 6: Part D Standard and Expedited Grievances (GRV_D) Record Layout

> **Humana Comment:** Humana recommends revising the logic to state: "Include all grievances the Sponsoring organization responded/issued notification or should have responded/issued the notification during the universe request period." We believe that stating the logic in this manner correctly excludes valid extensions taken that are not yet untimely.

Part C Organization Determinations, Appeals, and Grievances (ODAG)

Universe Table 1: Standard and Expedited Organization Determinations (OD) Record Layout

Humana Comment: Humana appreciates the continued direction to list organization determinations based on authorization number such that "[i]f an initial 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."

Universe Table 2: Standard and Expedited Pre-service Reconsiderations (RECON) Record Layout

Humana Comment: The proposed protocols under CMS's guidance for the *Date the Request was Received* (Column H) and *Time the Request was Received* (Column I) reference a 60-day timeframe; however, this contradicts current guidelines under 50.3 Good Cause Exception for Late Filing under Part C & D Organization/Coverage Determinations, Appeals & Grievances chapter of the Medicare Managed Care guidelines, which states: "Plans may accept a request for a standard or expedited level 1 appeal after the 65-day* timeframe if a filing party shows good cause." Humana recommends that CMS update the proposed protocols to align with current CMS guidance.

Universe Table 2: Standard and Expedited Pre-service Reconsiderations (RECON) Record Layout; Universe Table 3: Payment Organization Determinations and Reconsiderations (PYMT_C) Record Layout

Humana Comment: Humana recognizes that CDAG is still excluding an appeal of a dismissal or request to vacate and ODAG previously excluded these as well. Humana recommends that ODAG continue to exclude an appeal of a dismissal or request to vacate to avoid administrative burden.

Universe Table 3: Payment Organization Determinations and Reconsiderations (PYMT_C) Record Layout

Humana Comment: The proposed protocol exclusion instructions in Table 3 no longer include 'reopenings,' which contradicts previous versions of the protocols. To ensure clarity and minimize duplication in reporting reopenings in both Table 3 and Table 5, Humana recommends that CMS re-add 'reopens' in the list of excluded payment requests.

Universe Table 4: Part C Standard and Expedited Grievances (GRV_C) Record Layout

Humana Comment: Humana recommends revising the logic to state: "Include all grievances the Sponsoring organization responded/issued notification or should have responded/issued the notification during the universe request period." We believe that stating the logic in this manner correctly excludes valid extensions taken that are not yet untimely.

Universe Table 5: Reopened Part C Determinations (RCD) Record Layout

Humana Comment: The Table 5 Record Layout instructions state: "Include all organization or reconsidered determinations (for both coverage and payment) the Sponsoring organization

reopened and revised during the universe request period." However, Column ID N 'Reopened Disposition' separately includes a response option of "ANR for Approved without revision from the original approval." Given that these two statements are contradictory as currently stated, Humana recommends updating the Column ID N description to remove "ANR for Approved without revision from the original approval" to align with the general layout instructions.

Sample Selection – CMS proposes to add a section providing information about sample selection for webinar-based reviews and desk reviews ("If the audit field work is done live via webinar, the Sponsoring organization will receive notice of the selected samples 1 hour in advance of the live review. CMS may conduct all or part of the review via desk review. If desk review is conducted, the Sponsoring organization will receive samples with enough advanced notice to prepare and submit full or partial case files").

Humana Comment: Humana acknowledges that CMS has indicated the possibility of conducting all or part of the audit via desk review. In light of this, Humana requests clarification regarding the logistics and expectations for desk reviews. Specifically, if a desk review is conducted, when will Sponsoring Organizations receive the minimum of 40 samples for review, and should we expect that the subsequent live file review will consist of a smaller subset of those samples? Extra time will be required to prepare and package desk audit materials for submission. For example, screenshots of voluminous files may be required, which then must be appropriately collated and saved into PDF files. Acceptable formats and file naming conventions will need to be defined by guidance.

<u>Special Needs Plans Care Coordination (SNPCC) Program Audit Protocol and Data Request</u>

CMS is proposing to modify audit element names: Timeliness, Care Management, and D-SNP Integration

Humana Comment: Humana supports CMS's proposal to carve out the three audit elements tested within the Special Needs Plan (SNP) Care Coordination Program Audit Protocol and Data Request (Timeliness, Care Management and Dual Eligible Special Needs Plan (D-SNP) Integration). We believe this approach will streamline the audit process.

To further improve data generation requests and promote transparency, Humana requests that CMS provide additional clarity regarding the threshold at which the Health Risk Assessment (HRA) Mitigation Analysis will be required. Specifically, if a plan's compliance rate for initial or annual HRAs meets or exceeds a defined performance benchmark – such as 85% compliance with IHRA completion or annual timeliness – would CMS waive the requirement for the HRA Mitigation Analysis for that reporting period?

Establishing and communicating such thresholds would help plans better anticipate and prepare for audit requirements, minimize unnecessary data submissions, and ensure that resources are focused on areas with the greatest potential impact on enrollee care. We appreciate CMS's commitment to transparency and continuous improvement in audit processes and encourage the agency to include specific performance standards for triggering the HRA Mitigation Analysis.

CMS is proposing to update sampling language to address the minimum number of samples that will be selected.

> **Humana Comment:** Humana appreciates and generally supports CMS's goal to improve sampling methodology related to data integrity testing of the SNPCC Universe. However, we do not see explicit clarification regarding whether plans should expect a data integrity sampling size greater than 10 due to inclusion of the words "minimum of 10". We request that CMS clarify under what circumstances the minimum sample size may differ from 10, as well as the parameters that will be used to determine when an increase in sampling is warranted.

Compliance Standard 1.3: ICP Timeliness Test

CMS is proposing adding a new compliance standard to conduct timeliness test at the universe level of enrollees who have been enrolled for at least 90 days to ensure the Sponsoring Organization developed an Individualized Care Plan (ICP) within 90 days of conducting a comprehensive initial HRA or 90 days after the effective date of enrollment, whichever is later.

> **Humana Comment:** Humana supports engaging SNP enrollees as quickly as possible within the first 90 days of enrollment, including developing a plan of care within 90 days of enrollment or completion of the HRA, whichever is later. However, we note that the SNP record layout currently requires Sponsoring Organizations to report only the date of the most recent ICP. As a result, some enrollees may have their most recent ICP date fall outside the required 90-day window or HRA completion date.
>
> We encourage CMS to clarify how timeliness testing of ICPs will be conducted to ensure that Sponsoring Organizations who adhere to routine outreach and ICP update requirements are not subject to unnecessary impact analysis submissions given that the SNP record layout does not support the fields necessary for such timeliness testing.

Audit Element 2.1 Care Management

Select a minimum of 30 cases for Data Integrity Testing

> **Humana Comment:** Humana appreciates and generally supports CMS's efforts to enhance the sampling methodology for the care management audit element. In the proposed rules, we do not see explicit guidance regarding whether plans should expect a care management sample size greater than 30, which has been the limit under prior guidance. Humana requests that CMS clarify under what circumstances the minimum sample size may differ from 30 and specify the criteria or parameters that would prompt an increase in sampling.

Compliance Standard 2.2

Determine whether the Sponsoring Organization developed a comprehensive ICP that meets all the following: person-centered and based on the enrollee's preferences, including for delivery of services and benefits, and the needs identified in the HRA: Identifies person-centered goals and objectives (as prioritized by the enrollee), including measurable outcomes as well as specific services and benefits to be provided: A description of services specifically tailored to the enrollee's needs.

> **Humana Comment:** Humana acknowledges CMS's efforts to align care management audit elements with 42 CFR § 422.101(f) and shifting care plans from a medical model to a person-centered model for SNP enrollees. While we recognize that person-centered care plans are

appropriate for certain populations, such as D-SNP enrollees and those with well-controlled chronic conditions, we note that for other populations, such as Institutional Special Needs Plan (I-SNP) and Chronic Condition Special Needs Plan (C-SNP) enrollees, a medically focused care plan may be more appropriate due to the complexity and nature of their conditions and needs. A balance between medical model and person-centered elements may be the most appropriate manner in which to develop the care plan. Given this, we seek clarification regarding whether the intent of the audit element is to ensure that at least one goal within the care plan is person-centered, particularly in cases where the enrollee's care plan may require goals focused on medical needs identified through Health Risk Assessments.

Additionally, we would appreciate guidance on whether there are any future expectations for in-person encounters as part of the person-centered care planning process.

Compliance Standard 2.3
Review the selected samples to determine whether the enrollees' ICPs were reviewed and/or modified as warranted by changes in enrollees' health status.

Humana Comment: Humana supports CMS's addition clarifying the care management audit element with the inclusion of "as warranted" language. In order to provide further clarity for context, Humana requests confirmation that a Sponsoring Organization will be evaluated according to the definition of "as warranted" per its approved Model of Care. We believe that without defining the Model of Care as the clear source for determining "as warranted", there is a risk for inconsistency in evaluation of this audit element. This addition would help ensure alignment with established organizational processes and documentation standards.

Compliance Standard 2.5
Review the selected samples to determine if the enrollee/caregiver/ representative was involved in the ICP development.

Humana Comment: Humana supports the addition of language to care management audit element 2.5 specifying "whether the Sponsor documented attempts to contact the enrollee or their refusal to participate." To further enhance clarity and consistency, we request that CMS consider including the phrase "in accordance with the Model of Care or as defined in supporting documentation," recognizing that the number and frequency of contact attempts may vary between Sponsors. This addition would help ensure alignment with established organizational processes and documentation standards.

Compliance Standard 2.7
CMS is proposing to add language for the annual face-to-face encounter requirement to an existing ICT compliance standard: "A face-to-face encounter was offered, and provided if the enrollee consented, within 12 months of enrollment, and annually thereafter."

Humana Comment: Humana recognizes the importance of enrollees having face-to-face encounters and considers these encounters to be a critical component of the overall care management strategy.

Humana requests clarification regarding the scope of the audit element, specifically whether adherence to this element should align with the processes outlined in the Models of Care.

Humana seeks confirmation that the required encounter may occur between each enrollee and a member of the enrollee's Interdisciplinary Care Team (ICT), the plan's case management and coordination staff, or contracted plan health care providers.

Additionally, as the timing of face-to-face encounters is not prescribed by CMS within Model of Care requirements or Federal regulations, Humana requests confirmation on the interpretation of the term "annually." Specifically, we seek to understand whether "annually" may be satisfied by either one encounter per calendar year, or by implementing a rolling 365-day process, and if both approaches are sufficient to meet the standard. As this will impact processes, tracking and reporting, additional clarification will help promote alignment across Sponsors.

In addition, previous guidance from CMS has acknowledged that Sponsoring Organizations may not be able to comply with the mandate for an annual face-to-face encounter in cases where enrollees refuse, or where the Sponsoring Organization is unable to reach the enrollee despite reasonable efforts. Humana encourages CMS to update the audit element to include language indicating compliance "in accordance with the Model of Care" to acknowledge that the Sponsoring Organization has appropriately documented attempts to contact the enrollee or their refusal. This will provide context whereby the absence of a qualified encounter would not be considered a violation of the regulation when Sponsoring Organizations are in compliance with their respective Models of Care.

Compliance Standard 3.1
Review each applicable integrated plan (AIP) D-SNP sample and determine if an integrated HRA was used for Medicare and Medicaid, rather than a separate HRA for each program.

Humana Comment: Humana supports the alignment of the D-SNP integration element with 42 CFR § 422.101(f) to determine if an integrated HRA was used for Medicare and Medicaid, rather than a separate HRA for each program. Humana encourages CMS to include clarifying language to specify that this integration element applies to HRAs completed for D-SNP Applicable Integrated Plans (AIPs) on or after Calendar Year 2027, unless a D-SNP State Managed Care contract or State requirement mandates the use of an integrated HRA prior to CY2027.

Compliance Standard 3.2
Review documentation for each D-SNP sample to ensure the Sponsor offered to coordinate and provide Medicaid assistance where applicable for the dually eligible enrollees.

Humana Comment: Humana supports CMS's ongoing efforts to enhance care management strategies for D-SNP enrollees, particularly by improving the coordination and provision of Medicaid assistance where applicable. Humana requests that CMS consider updating D-SNP Coordination audit element 3.2 to focus specifically on D-SNP AIPs. Currently, systems and access to other Medicaid Managed Care Organization (MCO) information and/or Fee for Service Medicaid information for coordination-only D-SNP enrollees can present significant operational challenges for Sponsoring Organizations. This is largely due to the lack of universal access to enrollee-level Medicaid plan data, which impedes effective coordination and oversight by care coordination staff. Refining the audit element to prioritize the Aligned Integrated Plans would better align with the intent of care integration.

Additionally, Humana seeks clarification regarding CMS's use of the term "offered" in the context of coordinating and providing Medicaid assistance. Specifically, we request that CMS clarify whether providing written notification to the enrollee – informing them of available Medicaid assistance and instructions for accessing such support – constitutes sufficient evidence to meet the intent of this audit element.

It is important for Sponsoring Organizations to understand if documented written outreach satisfies compliance requirements from a care coordination approach, or if additional actions (such as telephonic outreach or documented two-way communication) are expected by CMS. This will help promote consistency among Sponsoring Organizations and reduce any potential unintended cost or administrative burden.

Compliance Standard 3.3

Review documentation for each coordination only (CO) D-SNP sample to ensure the Sponsoring Organization or other entity notified the State Medicaid agency, individuals or entities designated by the State Medicaid agency, or both, of the enrollee's hospital and/or skilled nursing facility admission.

Humana Comment: Humana appreciates CMS's ongoing efforts to streamline regulatory requirements within the SNP Care Coordination program audit protocols. However, Humana has concerns that this proposed D-SNP coordination audit element may duplicate existing reporting requirements established in the Medicare Part C Technical Specifications given that similar information is already collected under Section X: D-SNP Transmission of Admission Notifications.

Additionally, CMS reviews whether Sponsoring Organizations have developed and implemented care transition protocols to support continuity of care, as specified in the Model of Care under care management audit element 2.8. While CMS SNPCC audit protocols focus on Transitions of Care processes for all enrollees, each state sets specific parameters and criteria for reporting admissions, discharges and transfers. These parameters vary widely state to state and may exclude certain enrollee populations. For example, some states exclude partial dual eligible enrollees from the admissions, discharge and transfer reporting. Other states only require reporting for high-risk enrollees.

This audit element in Standard 3.3 focuses on data notifications. These notifications can be submitted by the Sponsoring Organization, the state or other third parties. When submitted by the state or third parties, the Sponsoring Organization may not have ready access to that documentation to share in a sample review audit. To reduce any potential for duplicate reporting as noted above, and help reduce the financial and administrative burden on Sponsoring Organizations, Humana recommends that CMS consider removing this data element for Standard 3.3.

Universe Field F

First Tier, Downstream, and Related Entity assigned to the beneficiary (e.g., Independent Physician Association, Physicians Medical Group or Third-Party Administrator, any/all third party, downstream, or related organizations that the Sponsor contracts within order to implement and/or manage the Model of Care). Enter NA if not applicable.

Humana Comment: Humana recognizes the importance of tracking First Tier, Downstream, and Related Entities (FDRs) assigned to enrollees for the effective implementation and management

of the Model of Care. However, CMS previously removed this field from the record layout with the adoption of the 2021 audit protocol updates for care coordination. Adding it back will create cost and administrative burden for Sponsor Organizations.

In addition, the required SNPCC Supplemental Questionnaire describes FDRs that support the Sponsoring Organization's Model of Care. Evidence of FDRs at the enrollee level would appear as SNPCC samples are reviewed. Many Sponsor Organizations serve enrollees with continuous enrollment exceeding ten years, during which FDR relationships may change over time. Given the extended duration of enrollment and the evolving nature of FDR relationships over time, reintroducing this field would create an unnecessary administrative burden for organizations, and introduce additional risk for inconsistency across Sponsoring Organizations, particularly since CMS determined its removal was appropriate in 2021.

If CMS were to move forward with requiring this element, we request that CMS provide clarification of what time period the FDR field should cover. For example, is it CMS's expectation that the field only reflect FDRs assigned for each enrollee at the point in time when the universe is created, or is the expectation to list any/all FDRs assigned to the enrollee for the prior 12 months, or another timeframe?

Universe Field J – For dis-enrollments and re-enrollments within 365 days, enter date of re-enrollment. Submit in CCYY/MM/DD format (e.g., 2027/01/01). Enter None if there were no breaks in enrollment

Humana Comment: Humana appreciates CMS providing Sponsoring Organizations with the opportunity to identify enrollees who have potentially disenrolled and re-enrolled within 365 days, as well as CMS's efforts to align requirements with the language outlined in the Medicare Part C Technical Specifications. Similar information is already defined by CMS under Section IV. SNPs Care Management, specifically regarding the reporting of completion of initial and annual HRAs.

However, Humana recommends that, rather than requiring entry of the re-enrollment date, which, based on interpretation of the universe field would duplicate the "SNP Enrollment Effective Date," CMS should consider updating the field to a simple indicator. For example, Organizations would enter "Y" for Yes if the enrollee disenrolled and re-enrolled within 365 days, or "N" for No if the enrollee had no breaks in enrollment. This approach would reduce redundancy and administrative burden while still capturing the necessary information and promoting consistency among Sponsoring Organizations.

Universe Field Q – Was there a hospital or SNF admission. "Enter Y for Yes if the enrollee had a hospitalization or SNF admission within the 26-week period preceding the date of the audit engagement letter. Enter N for No if the enrollee did not have an admission."

Humana Comment: Humana requests that CMS provide additional clarification and guidance regarding this universe field to promote consistent and accurate reporting across Sponsoring Organizations. Specifically, we ask that CMS clearly define whether the term "hospitalization" refers solely to acute inpatient stays or also includes Long-Term Acute Care stays, inpatient rehabilitation stays, and behavioral health hospitalizations. The current lack of definition regarding the scope of "hospitalization" creates challenges for organizations in capturing and reporting enrollee data accurately and uniformly.

Additionally, Sponsoring Organizations may offer I-SNPs for enrollees residing in skilled nursing facilities. Humana suggests that CMS clarify in guidance as to whether an affirmative "Y" response would be expected for this universe field for enrollees who already reside in a Skilled Nursing Facility (SNF) at time of enrollment, separate from an admission that occurs post enrollment but within the 26 week period prior to the audit engagement letter, or if enrollees who reside in a SNF at time of enrollment should receive a "N" indicator on the universe.

Universe Field R – For D-SNP enrollees, were there any Medicaid specific services or needs identified (e.g. non-Medicare covered equipment or supplies, LTSS, behavioral health)? Enter Y for Yes if there were any Medicaid specific services or needs identified within the 26-week period preceding the date of the audit engagement letter; Enter N for No if there were no Medicaid specific services or needs identified; Enter NA if enrollee is not a dual or a partial-benefit dually eligible individual.

Humana Comment: Humana supports CMS's commitment to ensuring that Sponsoring Organizations appropriately identify and address the needs of enrollees through the completion of HRAs, and that these needs are accurately reflected within each enrollee's plan of care.

However, Medicaid-specific services vary state by state and can change year after year. CMS does not require Sponsoring Organizations under 42 CFR § 422.101(f) to include the identification of Medicaid-specific services or needs within the HRA tool. Medicaid-specific needs are typically identified and addressed during the plan of care development process in collaboration with the enrollee, which is qualitative in nature, and primarily conducted through direct conversations with the enrollee (rather than through quantitative measures). Requiring this as a "Yes or No" element on the Universe introduces potential for reporting challenges and inconsistency across Sponsoring Organizations and may place additional cost and administrative burden on Sponsoring Organizations. In addition, for any plan that covers LTSS benefits, the answer to this field would always be "Y".

Additionally, the current definition concerning the exclusion of partial benefit dually eligible individuals and non-dual enrollees introduces uncertainty regarding accurate field population. Frequent changes in Medicaid eligibility and ongoing enrollee deeming periods present challenges for accurate universe submission. Therefore, Humana encourages CMS to reconsider the necessity of this field and remove the requirement as a universe element.

If CMS elects to implement this element, Humana requests that CMS establish clear and objective definitions or standards for what constitutes Medicaid-specific services and needs identified. This clarification will help ensure consistent interpretation and reporting across Sponsoring Organizations. Further, if CMS's intention is to target enrollees with specific Medicaid eligibility levels, Humana recommends applying it only to individuals enrolled in dual eligible AIP plans. Guidance should explicitly clarify which D-SNP populations are excluded, and that C-SNP and I-SNP enrollees are excluded. Lastly, Humana recommends that CMS consider the amount of time Sponsor Organizations may need in order to align reporting requirements with this element and consider delaying this change to future protocol updates and HRA requirements.

Sample Selection – CMS proposes to add a section providing information about sample selection for webinar-based reviews and desk reviews ("If the audit field work is done live via webinar, the Sponsoring organization will receive notice of the selected samples 1 hour in advance of the live review. CMS may conduct all or part of the review via desk review. If desk review is conducted, the Sponsoring organization will receive samples with enough advanced notice to prepare and submit full or partial case files").

Humana Comment: Humana submits the following concerns regarding the proposed change to the audit process – specifically, the elimination of the practice of sending sample selections the Thursday prior to the commencement of audit field work, and the new requirement to provide selected samples only one hour in advance of the live review.

Receiving the sample selection in advance—specifically on the Thursday before audit field work begins—enables organizations to thoroughly review enrollee files and focus on each enrollee's individual story. This lead time is essential for identifying and assembling key documentation that demonstrates the impact of care coordination on enrollee outcomes and overall health improvements. With sufficient preparation time, organizations can present a complete and accurate picture of care, including personalized care management activities, coordinated support across interdisciplinary teams, and the individualized attention provided to enrollees.

By contrast, limiting the lead time for enrollee care coordination chart reviews to only one hour may inhibit CMS from obtaining a comprehensive and accurate view of enrollee care and plan performance. Care management charts typically span extensive timeframes and involve collaboration across multiple segments within an organization. Transitioning from a four-day preparation period to a one-hour window significantly disrupts established audit preparation workflows and may affect the accuracy and efficiency of the audit process. Providing sample selections in advance does not alter the underlying care delivered; rather, it allows organizations to compile and organize existing records so that CMS can evaluate the program based on a full and accurate evidentiary record. For these reasons, Humana requests that CMS reconsider the proposed one-hour lead time and retain, or adopt a similar advance-notice standard to, the current practice of providing sample selections on the Thursday prior to the start of audit field work.

Additionally, we acknowledge that CMS has indicated the possibility of conducting all or part of the audit via desk review. In light of this, Humana requests clarification regarding the logistics and expectations for desk reviews. Specifically, if a desk review is conducted, when will Sponsoring Organizations receive the minimum of 30 samples for review, and should we expect that the subsequent live file review will consist of a smaller subset of those samples? Extra time will be required to prepare and package desk audit materials for submission. For example, screenshots of voluminous files may be required, which then must be appropriately collated and saved into PDF files. Acceptable formats and file naming conventions will need to be defined by guidance.

As this approach represents a new process for SNP care coordination audits, additional guidance from CMS would be greatly appreciated to ensure Sponsoring Organizations can prepare appropriately and maintain compliance.

SNPCC HRA Timeliness Mitigation Analysis

Number of IHRA outreaches attempted – Enter number of Intelligent Health Risk Assessment (IHRA) outreach attempts completed on or before the IHRA due date in numerical format.

> **Humana Comment:** Humana requests further clarification concerning the phrase "before the IHRA due date" to confirm that it includes the period of time preceding the enrollment effective date. As CMS allows Sponsoring Organizations to complete HRAs within the 90 days preceding enrollment effective date, Humana seeks confirmation that outreach efforts conducted before the IHRA due date, and specifically those made in the 90 days prior to the enrollee's effective date, are allowed to be counted toward satisfying the outreach requirements. Additional guidance from CMS would support consistent reporting and compliance practices.

Date of last IHRA outreach attempt – Enter the date of the last IHRA outreach attempt on or before the IHRA due date. Submit in CCYY/MM/DD format (e.g., 2025/01/01). Enter NA if no outreach attempts were made.

> **Humana Comment:** Similar to our comments on the number of IHRA outreach attempts, Humana requests further clarification concerning the phrase "before the IHRA due date" to confirm that it includes the period of time preceding the enrollment effective date. As CMS allows Sponsoring Organizations to complete HRAs within the 90 days preceding enrollment effective date, Humana seeks confirmation that outreach efforts conducted before the IHRA due date, and specifically those made in the 90 days prior to the enrollee's effective date, are allowed to be counted toward satisfying the outreach requirements. Additional guidance from CMS would support consistent reporting and compliance practices.

SNPCC-Impact Analysis Document

Field H - For D-SNP AIP enrollees, was a single integrated HRA Tool used to conduct the HRA? Enter: Y for Yes; N for No

> **Humana Comment:** Humana shares CMS's objective of utilizing the impact analysis table to ensure adherence to the use of a single integrated HRA tool for D-SNP AIP enrollees. Humana recommends that CMS include "N/A" as a selectable option in the relevant field. Given that the lookback period for the impact analysis is 26 weeks, and the implementation of the rule will occur on January 1, 2027, it is possible that some D-SNP AIP enrollees may not have completed an integrated HRA within the specified lookback period, even if an impact analysis table is requested after the implementation date. Including "N/A" would accommodate these scenarios and enhance the accuracy and completeness of the data collected.

Field L - If enrollee was not involved in ICP creation, did Sponsor document attempts to contact enrollee? Enter: Y for Yes; N for No; NA if an ICP was not created.

> **Humana Comment:** Humana supports CMS's emphasis on ensuring appropriate outreach to enrollees for the creation of ICPs. To further clarify reporting requirements, Humana requests that CMS consider adding the phrase "or if the ICP was not yet due" to the NA notation. This addition would help clarify how to appropriately populate NA, particularly in situations where a member is newly enrolled, outreach is in progress, but the ICP is not yet due.

For example, this scenario may occur when an enrollee has completed an HRA and the Sponsoring Organization is conducting outreach to develop the ICP within the required 90 days following the HRA or the effective date of enrollment, whichever is later. Providing clear guidance in these scenarios would promote greater consistency and accuracy in reporting.

Additionally, Humana requests clarification from CMS regarding the inclusion and exclusion criteria for ICP reporting. Specifically, guidance is sought on whether reporting should be limited to newly created ICPs, or, if enrollees with existing ICPs should also be included when their ICP is updated in accordance with the Model of Care and outreach is performed. For example, if an enrollee has been continuously enrolled for more than 365 days and an update to their care plan is required, it is important to understand whether outreach related to these updates should be captured in the applicable data element, or if reporting is intended only for initial ICP creation.

Further clarification on these reporting parameters would help ensure consistency and accuracy, particularly in cases where outreach is conducted for required ICP updates, as outlined in the Model of Care, rather than solely for initial care plan development.

If enrollee experienced a change in health status during the IA request period, was the ICP updated?

Humana Comment: Humana appreciates CMS's efforts to refine the language to focus on enrollees who experience a change in health status. Humana requests clarification regarding the reporting requirements for enrollees for whom outreach is unsuccessful or who decline participation, but for whom a care plan is developed based on encounter data or other available information. Specifically, should these enrollees be included in the relevant data element for ICP updates?

Additionally, Humana notes that CMS retains the field, "If enrollee experienced a hospitalization, was transitional care offered to the enrollee post-discharge?" However, there does not appear to be a comparable field addressing enrollees who experience other types of changes in health status. Humana would appreciate further guidance on how to report these scenarios, particularly for enrollees whose change in health status does not involve hospitalization but still necessitates an update or creation of a care plan when outreach efforts are unsuccessful or the enrollee declines participation.

Was the ICT involved in creating the initial ICP? Enter: Y for Yes; N for No; NA if an ICT was not created.

Humana Comment: Humana supports CMS's emphasis on ICT involvement in the creation of the initial ICP for enrollees and recognizes the importance of a person-centered care plan in addressing identified enrollee needs. Humana understands the process for populating the relevant reporting field when an enrollee has an initial ICP. However, Humana requests that CMS provide additional clarification regarding the distinction between entering "N" for No and "NA" in instances where an ICT was not established.

CMS has previously communicated that 100% of enrollees are required to have an ICT. In situations where an ICT was not created, Humana's interpretation is that the appropriate response for this impact analysis field would be "N" for No. However, this interpretation does

not fully align with the current language provided for the use of "NA." Humana requests that CMS clarify the specific circumstances under which a Sponsoring Organization should select "N" for No, as opposed to "NA," to ensure consistent and accurate reporting.

Further clarification on this distinction will assist Sponsoring Organizations maintain compliance with CMS requirements and reinforce the objective of ensuring that an enrollee's ICT is engaged in the development of the initial ICP.

For D-SNP enrollees, if a Medicaid specific service or need was identified, was the provision of the service or need arranged and/or coordinated? Enter: Y for Yes; use Y if a Medicaid-specific need was arranged for; N for No

Humana Comment: Humana shares CMS's commitment to supporting dual eligible enrollees and ensuring that Sponsoring Organizations arrange and coordinate services for D-SNP enrollees when a need or service is identified.

Humana encourages CMS to consider this in relation to comments about SNPCC Protocols pg 13: Universe Field R. Medicaid-specific services vary state-by-state and can change year over year. Medicaid-specific needs are typically identified and addressed during the plan of care development process in collaboration with the enrollee, which is qualitative in nature, and primarily conducted through direct conversations with the enrollee (rather than through quantitative measures). Requiring this as a "Yes or No" element on the impact analysis introduces potential for reporting challenges and inconsistency across Sponsor Organizations and may place additional cost and administrative burden on Sponsor Organizations.

In addition, if CMS elects to maintain this field, selecting "No" to this field when an enrollee does not have an identified service or need may create ambiguity, as "No" is also used when a Sponsoring Organization fails to coordinate an identified need or service. The addition of an "N/A" option would allow for more accurate reporting by clearly differentiating between these scenarios, thereby supporting data integrity and providing a more precise reflection of enrollee needs and organizational performance. Humana recommends that CMS add "N/A" as a selectable option in the relevant data field. While Humana understands the process for documenting when services or needs have been coordinated, the inclusion of an "N/A" option would provide clarity in cases where no service or need has been identified for an enrollee, and therefore, coordination is not required.

For D-SNP enrollees, was assistance provided to the enrollee when filing for Medicaid-related appeals and/ or grievances? Enter: Y for Yes; use Y if coordination or assistance was provided; N for No

Humana Comment: Humana recognizes the critical importance of assisting enrollees in filing Medicaid appeals and grievances, as this process provides a formal mechanism to address and resolve concerns related to healthcare coverage, benefits, or services received. Ensuring that enrollees have appropriate support throughout the appeals and grievance process is essential for protecting their rights, promoting transparency, and facilitating equitable access to care.

To further improve the accuracy and clarity of data reporting, Humana recommends that CMS include "N/A" as a selectable option in the relevant data field. While Humana currently documents instances when assistance is provided to enrollees for Medicaid-related appeals and

grievances, the addition of an "N/A" option would allow for the precise identification of situations where enrollees did not have a need to file an appeal or grievance. This distinction is significant because, under the current reporting structure, answering "No" may indicate either that the enrollee did not require assistance, or that the Sponsoring Organization failed to provide assistance when it was necessary. These scenarios are fundamentally different and conflating them can lead to inaccurate reporting and misinterpretation of organizational performance.

Additionally, Humana recommends that CMS clarify this reporting requirement to apply exclusively to D-SNP AIPs. Currently, there are significant operational challenges in accessing Medicaid MCO or Fee-for-Service Medicaid information for coordination-only D-SNP enrollees, primarily due to the lack of universal access to enrollee-level Medicaid plan data. Humana fully supports providing assistance when the D-SNP is an AIP and remains committed to supporting enrollees to the best of our ability in coordination-only plans, particularly when assistance is requested for filing Medicaid appeals or grievances. However, refining the audit element to focus on integrated plans would better support the objective of comprehensive care integration and enable more effective oversight.

For coordination only D-SNP enrollees, was the State and/or applicable entity notified of the admission to a facility? Enter: Y for Yes; use Y if State was notified of facility admission; N for No

Humana Comment: Humana appreciates CMS's ongoing efforts to streamline regulatory requirements within the SNP impact analysis. However, Humana is concerned that the proposed D-SNP coordination audit element and its associated impact analysis may result in duplicative reporting, as similar data is already collected through the Medicare Part C Technical Specifications – specifically under Section X: D-SNP Transmission of Admission Notifications. To help minimize the financial and administrative burden on Sponsoring Organizations, Humana requests that this impact analysis element be removed.

Moreover, the audit element and impact analysis focuses on data notifications, an area in which SNP care coordination staff who work directly with D-SNP enrollees may not have direct visibility into the success of data transmissions and cannot influence performance reporting transactions related to this metric. CMS already reviews whether Sponsoring Organizations have developed and implemented care transition protocols to ensure continuity of care, as specified in the Model of Care (MOC) under care management audit element 2.8. The impact analysis also contains specific fields addressing mitigation strategies for any issues identified with care transition protocols.

If CMS elects to retain this audit element and impact analysis, Humana recommends the inclusion of "N/A" as a selectable option in the relevant data field. While Humana documents instances in which the state is notified of a facility admission, the availability of an "N/A" option would allow accurate reporting in cases where an enrollee has not experienced a facility admission or where state guidance does not require notification, such as when an enrollee does not meet the high-risk population definition. Currently, selecting "No" in such scenarios may be misinterpreted as a failure to report, rather than an indication that reporting was not required. The addition of an "N/A" option would help ensure clarity and precision in reporting.

Humana also requests additional clarification from CMS regarding the scope of facility admissions included in this impact analysis. Specifically, it would be helpful to confirm whether only skilled nursing facility admissions are in scope, as the current language references "admission to a facility." Clarification that other types of admissions, such as hospitalizations, are excluded would support accurate and consistent reporting in alignment with CMS's intent. Further guidance on other exclusions, including instances where notifications are required only for individuals or entities designated by the state Medicaid agency or when an enrollee does not meet the high-risk definition, would also be appreciated.

Program Audit Data Request – SNPCC – Supplemental Questionnaire

CMS is proposing to add a new 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?

Humana Comment: Sponsor Organizations may need additional clarity on the degree of information expected in response to this question. There may be wide variation among Sponsor Organizations about what types of information is shared via portals. For example, as worded, if a response simply indicated "yes, a member portal is used to share information and the portal is available to all enrollees who chose to use it," would that be considered fully responsive to the question?

It is not clear what is intended by "how do you determine which enrollees have access?" Humana requests additional clarification from CMS regarding whether CMS expects organizations to describe eligibility verification requirements—such as active enrollment status or completion of registration processes—or whether the focus should be on the methods used to notify enrollees, including the provision of instructions on how to access and use member portals. Additionally, some Sponsoring Organizations may use delegated entities who offer their own portals separate from the Sponsor's portal. Further guidance from CMS on the intent of this question would assist Organizations in aligning questionnaire responses with CMS expectations and promote best practices.

CMS is proposing to modify Question #8 – Describe the outreach policy pertaining to HRA administration and ICP development. Describe the process for enrollees who are unable to be reached or who decline to participate.

Humana Comment: Humana requests clarification from CMS regarding the language added to the supplemental questionnaire for question 8, specifically the phrase "or who decline to participate." In certain cases, enrollees may ask the Sponsoring Organization not to contact them, which is managed through established "Do Not Contact" processes. As other regulations prohibit us from outreaching enrollees on a "Do Not Contact" list, we do not consider those the same as an enrollee who explicitly declines participation in HRA completion or care plan development. Humana seeks guidance on whether CMS expects Sponsoring Organizations to describe these "Do Not Contact" procedures alongside instances where enrollees explicitly declines participation within the supplemental questionnaire. Clear guidance from CMS would help ensure that responses accurately reflect both scenarios and align with CMS's intent.

We hope that you consider our comments as constructive feedback aimed at ensuring that together we continue to advance our shared goals of improving the delivery of coverage and services in a sustainable, affordable manner to beneficiaries, focused on improving their total health care experience.

If you have any questions, please do not hesitate to reach out to me at mhoak@humana.com and 571-466-6673.

Sincerely,

Michael Hoak
Vice President, Public Policy

CMS 10717 Comments from Independence Blue Cross

1. Is there still a requirement to have an annual CPE audit by an independent auditor? While we understand there was not a specific change to this in the Compliance Program chapters, with the changes to the CPE audit protocols, we would appreciate guidance as to the expectations for plans completing these audits.
2. With the change limiting the COA universe to activities in scope for a program audit, can we confirm that we would exclude activities such as audits/monitoring of enrollment processes, since they are not part of a program audit?
3. For the COA universe, should we exclude activities that started before the audit period and that are still in process (since neither the start date nor the completion date would fall within the audit period)?
4. Are all FWA activities excluded from the COA universes?
5. CPE Program Audit Protocol and Data Request, Universe Table 1 Layout:
    a. For Column H Completion Date, can we use the date when an audit was presented to a committee?
    b. For Column I Number of Deficiencies: can CMS confirm that we are counting the number of deficiencies, and not the number of impacted cases?
6. ODAG Program Audit Protocol and Data Request, Data Analyzed During Audit:
    a. In the Table 1 record layout, per the instructions (“The MA organization’s refusal, pre- or post-service or in connection with an initial organization decision made concurrently with an enrollee’s receipt of services, to provide or pay for services, in whole or in part, including the type or level of services, that the enrollee believes should be furnished or arranged for by the MA organization”):
        i. Does this mean that we are including concurrent and post service cases?
        ii. Is a drop in level of care considered a denial? For example, request is for continued stay at acute rehab which was denied but approved for Skilled level.
        iii. Are we submitting a universe using one Time zone?
    b. In the Table 5 Reopened Part Determinations (RCD) Record Layout, per the instructions (“Include only reopening that were initiated by Sponsoring organization or an FDR on behalf of the Sponsoring organization. Do not include re-openings that were requested by the enrollee or a provider”):
        i. Column L Date the reopening was initiated: Is there is a typo in the description? Currently it says, “Enter the date the reopening was initiated by the Sponsor of their FDR.” Does CMS mean to say,

"Enter the date the reopening was initiated by the Sponsor or their FDR"?

7. ODAG CR and PDAG PCR Impact: CMS only provided the PDF documents. Will CMS be releasing the excel format?
8. Is there a Label for Concurrent cases to separate by Expedited and Standard?
9. If the audit is based on an Initial Determination, then would the below be classified as concurrent or extensions for terminations of post-acute care (SNF, CORF, Home Health)?
    a. Documentation of all communications sent and received during the post-acute stay with the facility or provider.
    b. Documentation of any medical documentation considered during the termination by the Sponsoring organization showing the enrollee no longer meets the level of care necessary for the facility/service.
    c. Documentation of any decisions related to terminating the care.
    d. Documentation of notification of the decision to terminate services including Notice of Medicare Non-Coverage (NOMNC) and if applicable Detailed Explanation of Non-Coverage (DENC).
    e. Documentation of any appeals related to the termination, including appeals to the QIO, and any applicable decisions.
10. CMS has indicated intent to stop collecting most ODAG universes once other data is available from the Service Level Data of Initial Determinations and Appeals.
    a. Which ODAG universes are no longer going to be collected?
    b. While referenced, Service Level Data is not spelled out — we are hoping to have an understanding of what CMS is defining as Service Level Data.
11. Timeliness Mitigation Analysis has been introduced - when does CMS expect that these are needed? Is there an example they can provide?

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Submitted via www.regulations.gov

Re: Medicare Program; CMS-10717 CMS Program Audit Proposed Updates CY 2027

Dear Secretary Kennedy and Administrator Oz:

Jefferson Health Plans (JHP) appreciates the opportunity to provide feedback on the proposed CY 2027 Medicare Advantage Program Audit Updates. JHP is solely owned by Thomas Jefferson University, and affiliated with Jefferson Health, a 32-hospital integrated delivery and finance system with campuses in Eastern Pennsylvania and New Jersey. Built on a foundation spanning nearly 40 years, JHP is committed to providing members with quality, affordable health coverage. We offer Medicare Advantage-Prescription Drug PPO, HMO, and D-SNP plans in select counties in Pennsylvania and New Jersey and Individual and Family PPO and HMO plans in select counties in Pennsylvania. We also offer Medicaid and CHIP plans statewide in Pennsylvania under the Health Partners Plans brand. We are nationally recognized for our innovations in managed care, including NCQA accreditation for health equity and quality standards, and are committed to building healthier lives and stronger communities through a whole-person approach to health.

General Questions and Comments

Alignment of Annual Reporting and Audit Universes
JHP encourages CMS to consider streamlining annual reporting requirements and associated file layouts so they are more closely aligned with audit universes. This alignment would significantly reduce administrative burden and allow plans to refocus staff and system resources toward activities that directly enhance member care.

Clarification on Expanded Review Periods
The proposal includes multiple caveats stating that "CMS reserves the right to expand the review period." To support audit readiness and operational planning, we request that CMS:

- Define the circumstances under which this option would be exercised.
- Clarify the potential length of such an expanded review period.
- Indicate when and how notification to plans would be provided.

- Specify expected turnaround times if additional materials are requested.

Clear parameters will help ensure plans can comply efficiently and consistently.

Desk Review Expectations
CMS introduces the possibility of conducting desk reviews. JHP requests additional detail on:

- Whether a desk review would follow the same timelines and protocols as a traditional program audit.
- The amount of advance notice plans will receive.
- Expectations regarding documentation submission (e.g., file formats, secure transfer methods).
- Whether entrance and exit conferences, as well as deliverable meetings, will still be required.
- Clarification if the expectation of the desk review would replace an in-person or web-based program audit.

Sampling Methodology – Standardized Ceilings
We support CMS's effort to standardize sampling language and incorporate minimum sample requirements. To ensure proportionality and consistency, we recommend establishing a maximum sample size or setting a cap based on a percentage of the universe.

ODAG / CDAG
Grievances Older Than 30 Days
CMS proposes requiring inclusion of all grievances older than 30 days as of the engagement letter that have not yet received a response. We request clarification on whether this requirement applies to:

- Cases under an approved extension, and
- Whether plans are expected to include extended cases that still fall within allowable timeframes.

SNPCC
CMS proposes to add three new compliance standards focused on D-SNP coordination requirements:

- Integrated Health Risk Assessment (HRA)
- D-SNP Medicaid coordination assistance
- Notification of hospital or skilled nursing facility admissions

We request clarification on whether these requirements apply exclusively to fully aligned (AIP) plans or whether partially aligned and unaligned D-SNPs must also populate the data fields.

Universe Table 1 – Column R
CMS adds a field asking whether Medicaid-specific needs (e.g., LTSS, behavioral health, non-Medicare covered items) were identified for D-SNP enrollees.
For plans that are not fully aligned, we request clarification on:

- How such plans should systematically generate this field, given current data limitations.
- Whether the appropriate response for non-AIP plans would always be "No."

CDAG
Coordination of Benefits (COB) Review Requirements
CMS proposes new language regarding the appropriateness of denials and expectations for reviewing coordination of benefits. JHP requests clarification on whether this review should:

- Address determinations regarding whether a drug should be covered under Part B versus Part D,
- Include other health insurance coverage coordination,
- Or encompass both scenarios.

Universe Tables – Inclusion/Exclusion of Case Types
In several tables, CMS proposes to exclude payment coverage determinations, direct member reimbursement requests, withdrawals, and exception requests. JHP requests confirmation that:

- Dismissals should be ***included***, and
- Withdrawals should be ***excluded***

This will ensure consistent application across plans.

Thank you for the opportunity to provide comments on the proposed Program Audit Updates. JHP strongly supports CMS's goals of improving transparency and member understanding of utilization management criteria. However, several elements of the proposed data structures require additional clarification to ensure accurate, consistent, and operationally feasible implementation.
JHP is respectfully providing our comments and feedback to CMS pertaining to proposed updates to the Program Audit documentation. Our organization appreciates and looks forward to continued partnership with CMS to deliver high quality health care to Medicare Advantage members.

Sincerely,

Krista Hoglund

Krista Hoglund, ASA, MAAA, MBA
EVP, President Jefferson Health Plans

February 20, 2026

Re: Proposed Medicare Part C and Part D Program Audit and Industry-Wide Part C Timeliness Monitoring Project (TMP) Protocols

Submitted: Electronically to http://www.regulations.gov.

Kaiser Permanente appreciates the opportunity to submit comments regarding the proposed Medicare Part C and Part D Program Audit and Industry-Wide Part C Timeliness Monitoring Project (TMP) Protocols and other supporting data collection instruments (CMS-10717; OMB control number: 0938-1395). Overall, we are supportive of the direction of the proposed changes and commend CMS for its commitment to transparency around audit processes.

Compliance Program Effectiveness (CPE)

We appreciate CMS's efforts to refine the audit protocols by integrating the CPE review with the other audited sections, rather than maintaining a standalone review. We support this approach, as it promotes a more integrated evaluation of how compliance controls operate across functional areas. This structure also reinforces the expectation that compliance is embedded throughout the organization and reflected in day-to-day operations, not solely in program documentation.

As CMS implements a revised approach, we have the following clarifying questions about the updated structure and expectations to ensure consistent interpretation and application.

- **Fraud, Waste, and Abuse (FWA):** Please confirm whether, under the proposed revisions, FWA cases and related activities are intended to be excluded from Compliance Oversight Activities (COA) data submissions.
- **Description of Corrective Action Required:** We note the updated protocols introduce a new field requiring a narrative description of the corrective action for each finding. While we understand the intent to capture more detail, in practice this change would significantly increase the administrative burden, as systematic methods to extract this information consistently are limited and it would require manual entry. We respectfully suggest that CMS consider reverting to the prior approach, which used a simple "Corrective Action Required?" yes/no field. This approach efficiently captures the necessary compliance information while minimizing operational complexity. CMS can always request additional details on corrective actions as needed during follow-up ensuring oversight without creating unnecessary manual work.
- **Organizational Overview deck:** We appreciate CMS' efforts to reduce the number of CPE supplemental documents and make the Organizational Overview deck optional. While we find the deck extremely helpful to orient auditors, we would like clarification on whether plans are permitted to modify the template based on information and context that we have found useful for auditors.
- **COA review period:** We note the revised protocols extend the COA data collection period from 26 weeks to 1 year. While we understand the intent to capture a broader range of data, the longer lookback significantly increases the administrative burden for plans, with

limited incremental value for evaluating compliance trends. We also note that other audited sections, such as ODAG and CDAG, use much shorter lookback periods (e.g., 2 weeks).

ODAG comments and questions

- **Transition to Service Level Data Reports:** We appreciate CMS' continued efforts to streamline reporting requirements and reduce duplicative data collection through the development of the quarterly service-level reporting data, which is intended to replace 3 existing program audit tables. This represents a meaningful step toward improving efficiency and reducing administrative burden for plans once the new reporting framework is finalized and implemented.

  However, we recommend CMS reconsider the proposed expansion of the inclusion language for the 3 existing audit tables that will be retired once service-level reporting takes effect.

  While CMS notes that it is not revising these tables to avoid imposing additional burden on plans during implementation of the forthcoming reporting table, expanding the inclusion criteria is effectively a significant revision. Changes to inclusion language expand the scope of what must be reported and therefore require significant system modifications. This creates administrative burden and implementation effort for plans, even if the table structure itself is unchanged.

  The newly included areas—such as withdrawals, retrospective reviews, and concurrent care—do not represent new regulatory requirements or significant known gaps that would necessitate immediate interim expansion of audit tables. As such, it is unclear what compliance or oversight benefit is achieved by expanding the scope of audit reporting, particularly given CMS's stated intent to retire these tables once the new service-level reporting becomes effective.

  Given the significant effort plans will already need to devote to implementing the new service-level reporting data, we encourage CMS to retain the current inclusion language for the 3 audit tables until the Service Level Data Pilot has successfully concluded and supersedes ODAG data for Tables 1-3 at the start of the 2028 audit cycle. Implementing changes before this transition would necessitate multiple system updates, thereby increasing operational burdens and duplicating efforts across various data collections. This approach would better align with CMS's stated goal of minimizing burden and avoiding duplicative, short-lived system investments.

- **UM Focused Audits:** We request CMS clarify its intent regarding assessing compliance with coverage and UM requirements finalized in CMS-4201-F. Specifically, CMS previously conducted UM Focused Audits that included universe table submissions such as Universe Table 7: Termination of Home Health Agencies, Skilled Nursing Facilities, and Comprehensive Outpatient Rehabilitation Facilities (TERM) Services. It is unclear whether CMS intends to continue these UM Focused audits as a separate audit activity, or whether CMS intends to assess UM compliance through existing ODAG audit protocols and universe tables. In our view, CMS can effectively evaluate compliance with UM requirements through existing ODAG program audit protocols and related universe tables, making a separate UM-focused audit process unnecessary.

- **Reopening Data:** We note CMS removed the reopening exclusion language from several existing tables, while also introducing a new standalone table specifically intended to capture reopening activity. As proposed, this appears duplicative and increases reporting burden for plans. CMS should either include reopening data in existing tables or move forward with the new standalone reopening table.

- **Timeliness Testing 1.1 – 1.6 and Timeliness Mitigation Analysis:** We request CMS clarify whether mitigating information will be requested for all ODAG cases that are untimely or only for late cases reflected in the new quarterly service-level reporting data. As currently written, the proposed audit protocols reference mitigating information in the context of quarterly service-level reporting, which suggests the request may be limited to service-level reporting data.

- **Burden Estimates:** According to the "Summary of validation activity burden changes" found on page 13 of the supporting statement, CMS is either reducing or refraining from making modifications to the ODAG universes, resulting in fewer hours allocated for certain data collection and pre-fieldwork activities. However, we think the estimated hours may be underestimated. Updates to the inclusion language in the universe table record layouts were not fully accounted for, as these changes will require significant system updates to generate additional data as well as additional pre-fieldwork review.

  Additionally, CMS decreased the number of hours that Sponsoring organizations will spend reviewing information gathered and submitted before fieldwork, from 60 hours to 20 hours. The universe submission burden was also reduced from 150 hours to 100 over a span of 2-3 years. This adjustment is a result of the shift to service level reporting and CMS's expectation that Sponsoring organizations now use more advanced systems. While data collection will use service level reporting for three tables, it is still classified as pre-fieldwork data collection for audits. We believe the service level data collection process should be included, so the reduction in hours would not be applicable.

CDAG comments and questions

- **NDC Field:** CMS clarifies that, in certain instances, entry of the NDC may not be necessary and can be left blank. We recommend CMS adding an option for "None" which can help prevent errors from incomplete data when validating other fields.

- **PBP Field:** CMS updated the PBP field so that tables 1-5 now include the PBP effective date on the date of service, and table 6 includes the PBP effective on the date the grievance was received. We are requesting CMS to allow more flexibility in producing PBP data. In some cases, populating the PBP on the data universes requires an additional step as it is often stored separately within membership-specific systems. Historically, CMS permitted plans to use current PBP details, and we ask CMS to maintain this flexibility, particularly given the limited timeframes to produce the universe files.

  Alternatively, we ask CMS to permit blanks or offer guidance when cases are dismissed because due to lack of coverage—for example, when a member does not have a PBP

assigned at KP, lacks current coverage, or has changed coverage since the grievance was issued.

- **Universe Table 3- Payment Coverage Determinations and Redeterminations (PYMT_D) Record Layout:** The updated guidance specifies that separate line items should be reported when multiple notifications are sent; each notification is to be listed individually. Additionally, the instructions note that any request denied in whole or in part should be marked as denied. In instances where a request is partially approved and two letters—one for approval and one for denial—are issued, please confirm whether these should be reported as separate line items given that two notifications have been sent.

- **Universe Table 6- Part D Standard and Expedited Grievances (GRV_D) Record Layout:** ODAG protocols specify entering "None" for "Date written notification provided to enrollee" and "Time written notification provided to enrollee" if no written notification was given or no determination made. CDAG protocols only mention entering "None" if no notification was provided. We are seeking CMS clarification on whether CDAG data entry should match the ODAG approach, if the above inclusion language is added to the final protocols.

- **Audit Field Work Phase – Sample Selection.** The updated sample selection section now asks for supporting documentation "regarding timeliness." We request that CMS offer examples of the types of documentation that may be needed.

Comments/questions applicable to both ODAG and CDAG

- **Scope of Universe Request:** Currently, CMS requests plans submit data from the 2-week period preceding, and including, the date of the engagement letter. CMS proposes to change this to plans providing data from the timeframe CMS requests in the audit engagement letter. We request CMS reconsider this shift and clarify the proposed change to the lookback period methodology. Selecting an unspecified period reduces transparency and predictability for plans and creates uncertainty regarding system preparedness. We recommend CMS retain the current lookback methodology tied to the engagement letter date, or alternatively provide clear guardrails on how the 2-week period will be selected to ensure consistency, fairness, and transparency across audits.

  CMS has also created a shorter review period for Table 3 - PYMT_C. We are supportive of this change due to the volume of claims data.

- **Field Length:** CMS removed field length specifications from the audit tables. We request CMS clarify whether field length requirements have been eliminated. This information is necessary for plans to appropriately configure system fields and avoid submission errors.

- **Field Work Sample Selection:** We note CMS' proposal to allow portions of audit fieldwork to occur via desk review rather than live webinar, with advanced notice provided to plans. While we appreciate the flexibility this may offer, desk review requires plans to prepare case files in a format suitable for review, which can be substantially more labor-intensive than participating in a live webinar. We request CMS clarify the amount of advance notice plans will receive. Based on operational experience, we recommend that, at minimum, seven to ten business days be allowed to ensure files are complete, accurate, and structured appropriately for CMS review.

- **Open (and overdue) cases in Grievance tables:** We request CMS reconsider the proposed requirement to include grievances that are open and past the 30-day due date. Historically, universe reporting has been based on closed cases, which allows for complete and stable reporting of disposition, resolution dates, and final timeliness determinations. Expanding the universe to include open and late grievances represents a significant shift in reporting expectations and would require substantial programming updates for audit tables. Additionally, we request CMS clarify whether the sponsoring organization should exclude grievances while waiting for authorized representative documentation.

- **New fields added to Grievance tables:** For coverage requests (initial determination or reconsideration) that are made after a grievance is received, please clarify whether this applies only to coverage requests related to the specific issues addressed in the grievance, or whether it also includes any coverage request submitted with the grievance. Additionally, please clarify if the coverage request needs to be initiated during the member's initial call, as well as after the coverage request has been reviewed.

- **Special Circumstances Noted in Supporting Statement:** CMS has indicated that, in specific situations, clarification or validation of submitted data may be requested within 30 days, or limited scope audits may be initiated requiring expedited responses to data requests. Will these clarification requests or limited scope audits resemble data integrity testing, and what should we anticipate in terms of their format? Does the 30-day period refer to the time following data submission during which such inquiries may be made, or is it the timeframe allotted to the Plan for providing clarification or validation upon receipt of an inquiry?

We appreciate CMS's consideration of these comments and the opportunity to provide feedback. Please contact Sahar Brown (Director, Medicare Compliance) at Sahar.Brown@kp.org with any questions or concerns.

Lumeris and Essence Healthcare appreciate the opportunity to provide feedback on the proposed 2027 Program Audit Protocols. Below are the comments and questions from our key stakeholders within the organization.

Implementation

- Given the addition of the service-level data collection, new provider directory data requirements, and overall administrative burden to MA plans, we strongly encourage CMS to allow plans sufficient time to implement these new audit protocols, especially given the volume of work that will be required for universe configuration. We would recommend that CMS provide a minimum full year before implementing protocols in the following CY (i.e., if finalized in fall of 2026, provide 2027 as time for plans to implement before applying in CY 2028).

Coverage Determinations, Appeals, and Grievances (CDAG)

- We strongly encourage CMS to specify the minimum reopening sample volumes and decision paths for dismissal and COB reviews to ensure uniform application across plans.

Organization Determinations, Appeals, and Grievances (ODAG)

- CMS should provide transition guidance on when they will rely on service level data versus plan submitted audit universes, including data quality standards, associated timelines, and the potential need for sponsor-driven reconciliation when results differ.
- We request that CMS clarify sample selection and timeliness methodologies for desk reviews, including how the Timeliness Mitigation Tool may affect potential findings.
- CMS should create a detailed definition and scope for the new Reopened Determinations universe, including required elements, data sources, and minimum sample size expectations.
    - We also request that CMS explicitly state if the universe only includes reopenings at the plan level or those remanded to the plan by the IRE for reopening.
- We request that CMS provide clarification on whether plans should all concurrent decisions (approvals and denials) or just denials on the audit universes. For example, if a plan reviews inpatient admissions on a routine cadence (i.e., daily), does the plan need to report each of these?
    - Additionally, there is currently no option for requestor to indicate the plan initiated the concurrent review. If CMS expects plans to report daily review of inpatient admissions or similar concurrent reviews, we request guidance from CMS on how to populate that field when there is no external requestor.
- We noted that CMS changed the criteria around dismissals to no longer state that withdrawals should be excluded. We also noted that this differs from what is required in CDAG. Could CMS clarify whether plans should include withdrawn Part C cases on the relevant universes?

Formulary Administration (FA)

- We ask that CMS confirm that formulary processing accuracy will be validated with the previously submitted and accepted PDE records rather than an audit table of PDE records.
- We also ask that CMS clarify eligibility rejection reporting, particularly data elements and scenarios, to ensure sponsors are consistently interpreting these reports.

Compliance Program Effectiveness (CPE)

- Given the significant changes to the CPE portion of the audit, we ask that CMS provide specifics on evaluation criteria for appropriate oversight within the new integrated approach.
- We also seek clarity on what specific supplementary evidence CMS may expect to ensure information is ready when it is not being requested as part of the initial audit process.
- CMS should provide further clarity on the new corrective action fields in the COA universe and how those will be evaluated during the audit. For example, if an issue is identified during the audit, but corrected as indicated on the COA universe, will CMS see the potential audit finding as mitigated and not cite an audit condition?

Validation Audits

- We ask that CMS provide additional details on the transition from a *Work Plan* to a *Validation Report* to provide clarity on if the separate *Work Plan* requirement is being entirely removed and, if so, how CMS will review the proposed methodology prior to field work.
- CMS should also address the following questions related to validation audits:
    - Are independent validation auditors required to use only the CMS provided case tables or can they append additional documentation?
    - Are there minimum narrative requirements for sample case summaries?
    - What are the acceptable thresholds for universe integrity and when will resubmission be required?
    - How will CMS treat new findings identified by an independent validation auditor?
        - Will plans be required to submit a new CAP?
        - Will this trigger additional CMS oversight or expanded validation?
    - Should the validation report explicitly match the sampling requirements described in the program audit protocols? We recommend that CMS provide a crosswalk for clarity.

PUBLIC SUBMISSION

As of: 2/18/26, 2:41 PM
Received: February 18, 2026
Status: Draft
Category: Health Care Industry - PI015
Tracking No. mls-2zq0-bba0
Comments Due: February 20, 2026
Submission Type: Web

Docket: CMS-2025-1856
Medicare Part C and Part D Program Audit and Industry-Wide Part C Timeliness Monitoring Project (TMP) Protocols (CMS-10717)

Comment On: CMS-2025-1856-0001
Medicare Part C and Part D Program Audit and Industry-Wide Part C Timeliness Monitoring Project (TMP) Protocols (CMS-10717)

Document: CMS-2025-1856-DRAFT-0017
Comment on CMS-2025-1856-0001

Submitter Information

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General Comment

Hello,

The comments below are related to the SNPCC Program audit protocol.

1. Program Audit Data Request section, Compliance Standards 3.2 and 3.3, Page 9:

Please consider making these Compliance Standards non applicable to HIDE and FIDE plans.

2. Universe Table 1,Column ID L, Page 12:

The description incorrectly mentions Column ID I, when it should be Column K due to the new fields included in the table.

3. Universe Table 1, Column ID R, Page 13:

Please consider making this requirement non applicable to HIDE and FIDE plans.

4. Audit Field Work Phase, Sample Selection Section, Page 14:

We believe that a one-hour preparation period is insufficient for live reviews of SNP Care Coordination samples. SNP care coordination activities rely on documentation generated across multiple functional areas, internal teams, and external partners. Even when all responsible parties are available for the live review, additional time is required to identify, retrieve, and assess enrollee-specific documentation responsive to the applicable audit elements.

Enrollees included in SNPCC samples often present with multiple chronic conditions and complex care histories, including recent transitions of care. As a result, case files may consist of extensive medical records, care management notes from multiple staff and delegated entities, provider outreach and follow-up documentation, and beneficiary communications maintained across multiple systems of record. Reviewing this documentation to

determine applicability to audit criteria and to ensure completeness and accuracy is a time-intensive process.

Additionally, the development of complete and accurate case files requires collaboration from subject matter experts and operational staff who may not participate directly in the live review but whose review and validation of evidence are essential. These individuals must be provided sufficient time to review documentation and provide informed input.

We remain fully committed to timely collaboration with CMS and will continue to optimize internal processes; however, due to these structural dependencies, a one hour turnaround may not be attainable without compromising accuracy or compliance.

Finally, we respectfully request that CMS establish a fixed deadline for desk review submission of SNPCC case files. Given the level of coordination and documentation review required, a standardized deadline would support audit readiness, promote consistency, and help ensure timely and complete submissions.

2027 Proposed Audit Protocols (CMS-10717) - Comments from Point32Health

ODAG Protocols

1. **ODAG Table 1:** Please confirm whether Reopenings should be included in ODAG Table 1. The 2027 draft protocols removed Reopenings as an exclusion, where the prior Protocols included the following: "Exclude all requests processed as.... reopenings." The Plan believes that the exclusion for Reopenings should be added back into ODAG Table 1 instructions as the new ODAG Table 5 includes Reopenings. Including Reopenings in both ODAG Table 1 and ODAG Table 5 would be duplicative.

2. **ODAG Protocols, Audit Elements 1.7 and 1.8:** Part C & D Guidance, Section 50.12.2 (Forwarding Case Files – Timeframes), provides that a plan must forward upheld expedited decisions to the IRE no later than 24 hours after the decision. The current ODAG Protocols, Audit Elements 1.7 and 1.8, similarly test whether the plan forwarded its upheld decision to the IRE within 24 hours of affirmation. This aligns with 42 C.F.R. § 422.590(e)(5), which requires that, if an MA organization affirms, in whole or in part, its adverse expedited organization determination, it must submit the written explanation and case file to the independent review entity within 24 hours of affirmation.

   We note that the explicit reference to the 24-hour forwarding requirement does not appear in the draft Protocol language. Please confirm whether the timeliness standard for forwarding upheld expedited determinations to the IRE remains 24 hours from affirmation.

3. **ODAG Universe Table 2: Standard and Expedited Pre-service Reconsiderations (RECON):** Column H (Date the request was received), and ODAG Universe Table 3: Payment Organization Determinations and Reconsiderations (PYMT_C), Column H (Date the request was received), instruct plans to enter the date the request was received. Both tables further state that, if the Sponsoring organization obtained information establishing good cause after the "60-day filing timeframe," the date reported should reflect when the information establishing good cause was received.

   However, Part C & D Guidance, Section 50.2.1 (Guidelines for Accepting Level 1 Appeal Requests), provides that standard and expedited level 1 appeal requests must be filed within 65 calendar days from the date of the notice of the initial determination.
   Clarification is requested to reconcile the reference to a "60-day filing timeframe" in the draft protocol fields with the 65-calendar-day filing timeframe established in the Part C & D Guidance and 42 CFR 422.582(b).

4. **ODAG Universe Table 3: Payment Organization Determinations and Reconsiderations (PYMT_C):** In the February 27, 2023, document titled "Questions Received Following the Final MAPD Program Audit Protocol Training Sessions," CMS clarified in Q&A #15 that "sponsoring organizations would not include drugs processed at the point of sale in the PYMT_C universe." Please confirm whether this guidance remains CMS' current position and whether Part B point-of-sale (POS) pharmacy claims continue to be excluded from the scope of ODAG Universe Table 3.

5. **ODAG Universe Table 3: Payment Organization Determinations and Reconsiderations (PYMT_C):** Record Layout for ODAG Universe Table 4: Part C Standard and Expedited Grievances (GRV_C) states that Sponsoring organizations determined to be an applicable integrated plan, as defined by 42 C.F.R. § 422.561, should populate the universe with grievances related to Medicare coverage only.

   However, ODAG Universe Table 3: Payment Organization Determinations and Reconsiderations (PYMT_C) Record Layout does not include similar exclusion language for applicable integrated plans. Please confirm whether Sponsoring organizations that meet the definition of an applicable integrated plan should likewise populate Universe Table 3 with records related to Medicare services only, or whether a different approach is intended for this table.

6. **ODAG Universe Table 4: Part C Standard and Expedited Grievances (GRV_C):** Please confirm that CMS has removed the timeliness test for Part C Expedited Grievances from ODAG Table 4. Currently, CDAG Audit Element Timeliness Compliance Standard 1.15 measures the timeliness of Part D Expedited Grievances, but the ODAG Protocol does not include a similar Timeliness Compliance Standard related to Part C Expedited Grievances.

7. **ODAG Universe Table 4: Part C Standard and Expedited Grievances (GRV_C):** Column V (Was the grievance withdrawn or dismissed?) instructs plans to report "NA" when the grievance was processed and not withdrawn or dismissed. By contrast, CDAG Universe Table 6: Part D Standard and Expedited Grievances (GRV_D) Record Layout, Column U (Was the grievance withdrawn or dismissed?) instructs plans to report "P" when the grievance was processed and not withdrawn or dismissed.
   Given the differing response conventions ("NA" versus "P") for substantively similar fields, clarification is requested as to whether CMS intends these fields to operate differently for Part C and Part D grievances. If not, alignment of the response instructions across ODAG Table 4 and CDAG Table 6 may promote consistency in reporting and reduce potential confusion during data submission and audit review.

8. **Under Draft ODAG Table 4: Standard and Expedited Grievances (GRV_C):** Column X (Date coverage request was initiated) instructs plans to enter "NA" if no coverage request was initiated.

   By contrast, CDAG Table 6: Standard and Expedited Grievances (Part D), Column W (Date coverage request was initiated) instructs plans to enter "None" if no coverage request was initiated.

   Given the differing response conventions ("NA" versus "None") for substantively similar fields, clarification is requested as to whether CMS intends these fields to operate differently for Part C and Part D grievances. If not, alignment of the response instructions across ODAG Table 4 and CDAG Table 6 may promote consistency in reporting and reduce potential confusion during data submission and audit review.

9. **ODAG Universe Table 5: Reopened Part C Determinations (RCD):** Column L – Date the Reopening Was Initiated, instructs plans to "Enter the date the reopening was initiated by the Sponsor of their FDR." Clarification is requested as to whether CMS intended to state, "by the Sponsor or their FDR," rather than "of their FDR," to accurately reflect that the reopening may be initiated by either the Sponsor or their FDR and to ensure the appropriate date is reported.

10. **ODAG Universe Table 5: Reopened Part C Determinations (RCD)** instructs plans to include all organization or reconsidered determinations (for both coverage and payment) that the Sponsoring organization reopened and revised during the universe request period. The instructions further indicate that the date the Sponsoring organization initiated the re-opening (Column ID L) must fall within the universe request period.

    a) Clarification is requested as to whether reopenings initiated within the universe request period but not yet finalized should be excluded from the universe, given that the inclusion criteria reference reopenings that were "reopened and revised" during the period and the record layout requires a final disposition.

    b) Clarification is requested as to whether any reopening that did not result in a revision to the original disposition of the organization determination be excluded. The universe criteria states that organization determinations that were "reopened and revised" should be included in the universe. However, Field N, Reopened Disposition, contains a value of "Denied", which appears should be utilized when a reopening is denied and does not result in any changes to the disposition or values in the organization determination.

11. **ODAG Universe Table 5: Reopened Part C Determinations (RCD) Record Layout,** Column N (Reopened Disposition) instructs plans to enter the final disposition following the reopening review as:
    - ANR (Approved without revision from the original approval)
    - AR (Approved with revision from the original approval)
    - Denied

    a) Clarification is requested regarding CMS' intended application of the ANR category. Specifically, please provide examples of scenarios that would be appropriately classified as ANR.
    b) Additionally, please confirm whether a reopening that results in a payment rate change, but does not alter the underlying approval of coverage, should be reported as ANR or AR for purposes of Column N. For example, if a payment organization determination (claim) was originally paid, but was then reopened and either the payment amount to the provider or the member's cost share was revised, would this be considered an "ANR" or "AR".
    c) Requesting that CMS confirm if a Payment Organization Determination (claim) is denied in part and approved in part, which response should be utilized. The Plan believes that "AR" should be utilized if there was any change at all, but requests that CMS confirm.

d) Requesting that CMS confirm if a Payment Organization Determination (claim) has multiple lines that are reopened that the Payment Organization Determination Reopening Claim would only appear on the Reopening universe on one line. In other words, Plans would not include each line item that is reopened and would include all lines that are reopened on one line.
e) Requesting that CMS confirm that the Reopening universe should only include reopened Payment Organization Determinations from non-contracted providers to align with ODAG Tables 3 and the current Part C Reporting requirement, both of which excludes Payment ODs from Non-Contracted Providers.
    - Example: Plan identifies a configuration error that impacted Payment ODs (claims). Plan identifies error, fixes configuration, and reopens and reprocesses all impacted Payment ODs (claims) submitted both by contracted and non-contracted providers. However, only reopenings for Payment ODs (claims) submitted by non-contracted providers would be included in this universe.

12. **General**: We appreciate the opportunity to comment on the draft 2027 Program Audit Protocols and the quarterly data collection for initial Part C determinations and Reopenings. While we support CMS's goals, we are concerned that these changes will increase administrative burden and duplicate existing reporting processes.

    a) **Increased Burden** - The expanded universe requirements and new quarterly submissions will require plans to maintain audit-level data year-round. This necessitates additional data extraction, reconciliation, quality checks, staffing, and vendor oversight. These activities represent a substantial operational lift without reducing other CMS ongoing reporting obligations.

    b) Duplication With Existing Reporting and Data Validation (DV) - Many of the proposed data elements overlap with current Part C & D Reporting Requirements and DV. Plans would need to build and maintain parallel data pipelines for reporting, DV, audits, and quarterly submissions—often for the same underlying events but in different formats and timeframes. This redundancy increases workload and the risk of technical inconsistencies.

    c) Limited Oversight Value Relative to Cost - Given the robust reporting and DV processes already in place, the incremental oversight benefit of quarterly, audit-level data is unclear. The proposed approach may disproportionately burden smaller plans and divert resources from beneficiary-facing activities.

    d) Recommendations - We respectfully request that CMS
        - Align data definitions, layouts, and submission processes across audits, reporting, and DV.
        - Allow reuse of DV-validated data structures for audit and quarterly submissions.
        - Reevaluate whether quarterly frequency is necessary, and if so, eliminate the annual Reporting and DV requirements.
        - Consider a unified technical submission pathway to reduce duplication

CDAG Protocols

13. **CDAG Universe Table 3: Payment Coverage Determinations and Redeterminations (PYMT_D), Column J** (Date the request was received), and CDAG Universe Table 4: Standard and Expedited Redeterminations (RD), Column J (Date the request was received), instruct plans to enter the date the request was received. Both tables further state that, if the Sponsoring organization obtained information establishing good cause after the "60-day filing timeframe," the reported date should reflect when the information establishing good cause was received.
    However, Part C & D Guidance, Section 50.2.1 (Guidelines for Accepting Level 1 Appeal Requests), and 42 C.F.R. § 422.582(b) provide that a request for reconsideration must be filed within 65 calendar days from the date of the notice of the initial determination.
    Clarification is requested to reconcile the reference to a "60-day filing timeframe" in the draft protocol fields with the 65-calendar-day filing timeframe established in the Part C & D Guidance and 42 CFR 423.582(b).

14. **Draft CDAG Table 6: Standard and Expedited Grievances (Part D), Column U** (Was the grievance withdrawn or dismissed?) instructs plans to report "P" when the grievance was processed and not withdrawn or dismissed.

    By contrast, Draft ODAG Table 4: Standard and Expedited Grievances (Part C), Column V (Was the grievance withdrawn or dismissed?) instructs plans to report "NA" when the grievance was processed and not withdrawn or dismissed.

    Given the differing response conventions ("P" versus "NA") for substantively similar fields, clarification is requested as to whether CMS intends these fields to operate differently for Part C and Part D grievances. If not, alignment of the response instructions across ODAG Table 4 and CDAG Table 6 may promote consistency in reporting and reduce potential confusion during data submission and audit review.

15. **Under Draft CDAG Table 6: Standard and Expedited Grievances (Part D), Column W** (Date coverage request was initiated) instructs plans to enter "None" if no coverage request was initiated.

    By contrast, ODAG Table 4: Standard and Expedited Grievances (Part C), Column X (Date coverage request was initiated) instructs plans to enter "NA" if no coverage request was initiated.

    Given the differing response conventions ("None" versus "NA") for substantively similar fields, clarification is requested as to whether CMS intends these fields to operate differently for Part C and Part D grievances. If not, alignment of the response instructions across ODAG Table 4 and CDAG Table 6 may promote consistency in reporting and reduce potential confusion during data submission and audit review.

ODAG & CDAG Protocols

16. Regarding **ODAG Universe Table 4: Part C Standard and Expedited Grievances (GRV_C)** Record Layout and **CDAG Universe Table 6: Part D Standard and Expedited Grievances (GRV_D)** Record Layout, the following feedback is provided:

    We appreciate CMS's focus on timely grievance resolution. Our organization already maintains strong oversight of grievance timeliness, including routine monitoring of aging grievances and targeted efforts to ensure they are resolved within the required 30-day timeframe. We have full visibility into grievances approaching or exceeding 30 days and actively manage them to prevent delays.

    However, the proposal to add to Program Audit universes all grievances older than 30 days creates an additional reporting requirement that does not exist today. Although plans already track these cases internally, we are not currently required to extract, format, and submit them as a distinct dataset for audit purposes. Building and maintaining this new audit-specific universe would require additional data processing, reconciliation, and manual review beyond the oversight processes already in place.

    We respectfully request that CMS consider aligning this requirement with existing grievance reporting structures to avoid duplicative administrative burden while maintaining strong oversight.

SNPCC Protocols

17. **SNPCC Audit Field Work Phase - Supporting Documentation Submissions – (Page 14 of the SNPCC protocols**): CMS added a new standalone requirement for timeliness documentation. Because this requirement is separate from Policies and Procedures and the Model of Care (MOC), clarification is requested regarding the specific type of documentation CMS expects to be submitted.

    Please confirm whether CMS anticipates submission of internal operational workflows, timeliness-tracking methodologies (such as system logic or reporting validation processes), case-level audit tools, or another form of documentation to demonstrate compliance with SNPCC timeliness requirements.

PUBLIC SUBMISSION

As of: 2/19/26, 9:57 AM
Received: February 18, 2026
Status: Draft
Category: Government - Federal
Tracking No. mls-hjiu-0glr
Comments Due: February 20, 2026
Submission Type: API

Docket: CMS-2025-1856
Medicare Part C and Part D Program Audit and Industry-Wide Part C Timeliness Monitoring Project (TMP) Protocols (CMS-10717)

Comment On: CMS-2025-1856-0001
Medicare Part C and Part D Program Audit and Industry-Wide Part C Timeliness Monitoring Project (TMP) Protocols (CMS-10717)

Document: CMS-2025-1856-DRAFT-0019
Comment on CMS-2025-1856-0001

Submitter Information

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General Comment

I hope all is well on your end. We have the following question regarding reporting ODAG concurrent reviews.

We are requesting clarification on concurrent reviews for reporting purposes/ODAG audit protocol. For example, we approve a skilled nursing facility stay for a certain number of days, the case is reviewed throughout the stay, with determinations made up to the 100-benefit day limit. Since concurrent reviews have multiple decisions within a single case, does CMS intend for us to report all decisions within the continuum in the Service Level Data Collection for Initial Determinations in the proposed ODAG Audit Protocols? If so, based on the example case below, how would CMS expect to see this type of case in the universe.

Example case:
1.1.26 – Initial standard request received for skilled nursing stay
1.1.26 – Request approved for 14 days – authorization #123456 (through 1.14.26)
1.12.26 – Case notes reviewed, approved for additional 14 days – authorization #123456 (through 1.28.26)
1.26.26 – Case notes reviewed, additional days denied beyond 1.28.26

Proposed ODAG Protocols
Column H: Initial request was received 1.1.26. There are also two additional request dates of 1.12.26 and 1.26.26 and we are looking for clarification on how those would be captured in this file layout, or do we only need to capture the initial
Column M: Request determination. The first decision was on 1.1.26 and approved. The second decision was on 1.12.26 and approved. However, the 1.26.26 review is denied.

We have three determinations in this one case. We are questioning how and if we should report each determination in the universe in a single or multiple rows.

Submitted by SME 562.334.7980 pacific time

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February 20, 2026

VIA ELECTRONIC SUBMISSION TO www.regulations.gov

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4212-P
P.O. Box 8016
Baltimore, MD 21244-8016

Re: CMS-10717: Medicare Part C and Part D Program Audit and Industry-Wide Part C Timeliness Monitoring Project (TMP) Protocols

To Whom It May Concern,

The Cigna Group welcomes the opportunity to respond to the Medicare Part C and Part D Program Audit and Industry-Wide Part C Timeliness Monitoring Project (TMP) Protocols issued by the Centers for Medicare & Medicaid Services (CMS) and the Department of Health and Human Services (HHS).

The Cigna Group is a global health company committed to improving health and vitality. Across all segments we serve, The Cigna Group is focused on working to deliver healthcare that is affordable, predictable, and simple so people can live healthier, more vibrant lives.

Our Cigna Healthcare and Evernorth Health Services divisions are providers of medical, pharmacy, dental, behavioral health, and related products and services, with over 186 million customer and patient relationships in the more than 30 countries and jurisdictions in which we operate. In the United States, Cigna Healthcare provides medical coverage to approximately 16 million Americans in the commercial group health plan market, predominantly in the self-insured segment. For 2026, we are providing individual market coverage in 362 counties across 11 states, both on-and off-Exchange, insuring over 365,000 individual market customers through the end of 2025.

Our health services business, Evernorth Health Services, includes a broad range of coordinated and point solution health services and capabilities in pharmacy benefits, home delivery pharmacy, specialty pharmacy, distribution, and care delivery and management solutions, which are provided to health plans, employers, government organizations, and health care providers. To that end, Evernorth provides health services that support Medicare Advantage (Part C) and Part D plans, focusing on pharmacy benefits, behavioral health, and care management.

With that context in mind, The Cigna Group offers the following comments on the Medicare Part C and Part D Program Audit Protocols. Our comments are predominantly operational in nature, with more significant comments related to changes to program audit review.

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Universe Table 6: Part D Standard and Expedited Grievances (GRV_D) Record Layout
CMS Proposal: CMS proposes to include in the audit universe grievances that are older than 30 days at the time the engagement letter is issued and that have not yet received a response.

Cigna Comment: Cigna requests clarification on whether open grievance cases that have been formally extended and remain within the applicable 14-day extension period at the time of the engagement letter would be included in the audit universe.

In addition, we request clarification on how CMS intends to treat open, in-progress cases during the universe integrity review. Because these cases are still under active review, certain data elements included in the universe—such as grievance category or status—may differ from information ultimately reflected in case documentation. Additional guidance on CMS' expectations for these scenarios would help ensure consistent and accurate reporting.

CMS Proposal: CMS proposes to require plans to report grievances involving multiple issues as a single line item when the plan received a single notification.

Cigna Comment: Cigna notes that the Medicare Part D Reporting Requirements: Technical Specifications Document for Contract Year 2026 instructs plan sponsors that "[i]f an enrollee files a grievance about multiple issues during a call or in writing, report as separate grievances." However, Table 6 audit protocols require these grievances to be consolidated and reported as a single line item in the audit universe. This inconsistency requires sponsors to manually combine multiple grievances into one record solely for audit purposes, increasing administrative burden and the risk of reporting discrepancies. During an audit, it would be more efficient and consistent for plans to align the universe with the Part D Reporting Technical Specifications by reporting grievances individually. **Cigna recommends that CMS consider allowing plans to report grievances separately in the audit universe and instead include an indicator to identify cases involving multiple issues, rather than requiring manual consolidation.**

CMS Proposal: CMS proposes to require plans to indicate whether a coverage request was initiated following receipt of a grievance, as well as the date the coverage request was initiated.

Cigna Comment: Cigna has concerns regarding the operational feasibility of this requirement. Grievance systems and coverage request systems are typically separate and not operationally linked. As a result, capturing and reporting this information within a single audit universe may be challenging and would likely require system modifications. Implementing this requirement by the 2027 audit season may be burdensome for plans. **Cigna urges CMS to consider delaying implementation to allow sufficient time for plans to design, test, and deploy necessary system changes.**

CMS Proposal: CMS proposes to include all grievances that were withdrawn or dismissed during the universe request period.

Cigna Comment: Cigna requests confirmation that "dismissed" grievances are limited to cases dismissed due to failure to return requested Authority of Representation documentation, and do not include other dismissal scenarios. Clear clarification would help ensure consistent interpretation and reporting across plans.

Coverage Determinations, Appeals, and Grievances (CDAG) and Organization Determinations, Appeals, and Grievances (ODAG) Program Audit Protocols on Page 3, Purpose Section
CMS Proposal: CMS proposes the following revised language: "At a minimum, CMS will evaluate cases against the criteria listed below but reserves the right to modify its scope as requirements are added or revised."

Cigna Comment: We appreciate CMS's intent to maintain flexibility in the audit process. However, the proposed language introduces a degree of ambiguity regarding the specific requirements that may be subject to review. Previously, the protocol clarified that CMS "may review factors not specifically addressed below if it is determined that there are other related CDAG/ODAG requirements not being met," which provided greater transparency and predictability. To preserve clarity and ensure appropriate scope alignment, **we recommend retaining language that limits any scope modifications to CDAG/ODAG-related requirements when there is an indication that such requirements may not have been met.**

ODAG Program Audit Protocols on Page 5, Timeliness Item 1.4
CMS proposal: CMS proposes the following: "Conduct timeliness test at the universe level on expedited reconsideration requests to determine whether the Sponsoring organization provided notification of its overturned decision to the enrollee or forwarded the upheld decision to the independent review entity (IRE) not later than the following:

- For a service or item, within 72 hours (17 days with extension) after receipt of the request.
- For a Part B drug, within 72 hours after receipt of the request.

Cigna Comment: We note that the proposed language does not include the applicable timeframe for forwarding upheld, adverse, plan-level reconsideration decisions to the IRE. To ensure consistency with existing regulatory requirements, **we recommend explicitly incorporating the timeframe specified at 42 CFR §422.590(e)(5), which requires forwarding such decisions to the IRE within 24 hours of affirming the upheld, adverse reconsideration decision.**

ODAG Program Audit Protocols on page 27; Audit Field Work Phase – Sample Selection Purpose Section
CMS Proposal: CMS proposes to allow all or part of the audit review to be conducted via desk review. This language suggests a shift from webinar reviews to desk reviews that spans multiple protocols including but not limited to ODAG.

Cigna Comment: Based on our extensive experience participating in CMS program audits, including live webinar-based reviews, we have significant concerns with the proposed approach to conduct part or all of the audit through desk review. Live walkthroughs provide critical plan sponsor context that supports accurate interpretation of case files and enables real-time clarification of processes and decision-making. Without this interaction, auditors may be required to review documentation in isolation, which could result in increased follow-up questions, iterative information requests, and a prolonged audit timeline. In many instances, a case packet alone may not fully capture the sequence of events or considerations that informed the final determination. **Cigna strongly recommends that CMS reconsider a shift away from live sample reviews and retain webinar-based sessions with plan sponsors and their delegated entities, which allow plans to clearly explain their processes and highlight associated best practices.**

ODAG Program Audit Protocols on Page 13, Table with Column Defining the Scope of Universe Request
CMS Proposal: CMS proposes to revise the universe submission requirements by removing the explicit reference to the calendar timeframe from which data should be pulled and instead requiring plans to "submit a 12-week period as requested by CMS." This proposed language appears across multiple audit protocols, including ODAG.

Cigna Comment: Cigna notes that the current audit protocols instruct plans to submit "the 12-week period preceding, and including, the date of the audit engagement letter," which clearly limits sample selection to the current plan year. The proposed revision, while likely not intended to broaden audit scope, removes this guardrail and could be interpreted to allow requests for data from prior plan years. This lack of clarity may create unnecessary administrative burden and uncertainty for plans. **Cigna recommends that CMS maintain the existing calendar-based limitation or explicitly clarify that universe submissions are restricted to the current plan year and a defined, contemporaneous timeframe.**

CDAG and ODAG Program Audit Protocols on Page 7, Processing of Coverage Requests and Page 6 in Formulary Administration
CMS Proposal: Across all universes, CMS has updated the language to reflect a minimum sample size for Formulary Administration, CDAG, and ODAG.

Cigna Comment: Cigna recommends CMS consider establishing a maximum sample size, rather than a minimum. The absence of a defined upper limit may create unnecessary operational strain on sponsors and

delegated entities, as audit activities could expand without a clearly defined endpoint. This may divert resources away from higher-risk areas that would benefit most from focused oversight. A maximum-based approach would support efficient deployment of audit resources while continuing to meet CMS' oversight objectives. In contrast, a fixed minimum sample size may result in oversampling, particularly in smaller or lower-risk universes, without a corresponding increase in audit effectiveness. Allowing CMS discretion to select samples up to a defined maximum would preserve flexibility while better aligning sample size with universe characteristics, operational risk, and historical performance. This approach would also help reduce unnecessary administrative burden and enable both CMS and plan sponsors to focus resources on areas presenting the greatest compliance risk, while fully supporting CMS' audit goals.

* * *

Thank you for your consideration of these comments. The Cigna Group would welcome the opportunity to discuss these issues with you in more detail at your convenience.

Respectfully,

Courtney Lawrence
Senior Vice President, Head of Government Affairs and Global Public Policy
The Cigna Group

February 20, 2026

Centers for Medicare & Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Attention: CMS-10913
OMB Control Number: 0938–1395
7500 Security Boulevard
Baltimore, Maryland 21244–1850.

Submitted Electronically: www.regulations.gov

Re: *Medicare Part C and Part D Program Audit and Industry-Wide Part C Timeliness Monitoring Project (TMP) Protocols (Document Identifier CMS-10717)*

Dear Sir/Madam:

UnitedHealthcare (UHC) is pleased to respond to the CMS*'s* request for comments regarding the *Medicare Part C and Part D Program Audit and Industry-Wide Part C Timeliness Monitoring Project (TMP) Protocols* published in the Federal Register on December 22, 2025 (90 FR 59834).

UnitedHealthcare offers a full range of health benefits, enabling affordable coverage, simplifying the health care experience, and delivering access to high-quality care. UnitedHealthcare is the health benefits business of UnitedHealth Group, a health care and well-being company working to help build a modern, high-performing health system through improved access, affordability, outcomes, and experiences. We are committed to a future where every person has access to high-quality, affordable health care and a modern, high-performing health system that reduces disparities, improves outcomes, and lessens the burden of disease.

We offer the following technical comments for CMS's consideration:

Coverage Determinations, Appeals, and Grievances (CDAG)

Universe Table 2: Standard and Expedited Coverage Determination Exception Requests (CDER) - Record Layout
Currently, the CDER record layout instructions under "Enter any request denied in whole or in part as Denied…" are a standalone instruction. In CMS's proposed guidance, this instruction is a sub-bullet under the 'If a request has multiple exception types…" UHC requests confirmation whether this change indicates that this instruction only applies to a request that has multiple exceptions. If this request to enter denials is still intended to apply more broadly, UHC requests further instructions on how to report a scenario with a non-exception denial and an exception

approval since the instruction also state “Requests for a single drug involving multiple UM criteria and exception types must be entered as a single line item in Universe Table 2 only.” As an example, we request confirmation whether a prior authorization required (non-exception) denial with Safety Edit exception approval should be reported as a Request Determination of “denied” for the prior authorization review but reflect an “Exception Type” of “Safety Edit Exception.”

Formulary Administration (FA)

Universe Table 1: Rejected Claims Formulary Administration (RCFA) Record Layout Universe Table 2: Rejected Claims Transition (RCT) Record Layout
UHC requests that CMS consider the significant data, operational, and privacy risks associated with the proposed shift in the universe generation pull.

CMS proposes updating the FA universe requirements, with new directions for populating the RCFA and RCT record layouts for “eligibility rejections.” Currently, claims that are submitted without sufficient information to match an individual enrollee are considered PBM transactions and do not become Sponsor claims until after the match to an enrollee occurs. This proposed change would fundamentally modify the FA universe generation to a PBM-level pull, even when claims are not yet attributable to a specific MA or Part D enrollee. Populating universes in this manner would necessitate significant redesigning for longstanding universe generation logic, which may impact reliability. We anticipate that these changes in guidance may also lead to situations where a PBM may be unclear of whether a claim belongs to a particular health plan member, and there may be potential inadvertent exposure of Personal Health Information (PHI) to other Sponsors.

CMS modified several fields to specify that they should be populated “as submitted by the pharmacy.” UHC seeks further clarification regarding CMS’s expectations for Sponsors to use pharmacy submitted information, even if they do not match the Sponsor’s official enrollee record. Information submitted by a pharmacy may be internal or chain-specific formatting convention instead of the Sponsor assigned identifier. If this is CMS’s intent, CMS should update the definition so it no longer implies that the value must be the Sponsor’s enrollee identifier. UHC requests further direction regarding this data to ensure consistency and avoid discrepancies that may be interpreted as Sponsor data quality errors during the audit.

If data accuracy discrepancies occur due to pharmacy-submitted data (e.g., misspelled name, incomplete or truncated information, incorrect date of birth), UHC requests further information regarding how CMS plans to evaluate accuracy during an audit.

Organization Determinations, Appeals, and Grievances (ODAG)

Quarterly Data: Service Level Data Collection for Initial Determinations and Appeals (CMS-10905)
With the new Service Level Data Collection for Initial Determinations and Appeals, UHC requests clarification on the time frame for the lookback period if the most recently submitted quarterly report does not align with the audit notification date. For example, if CMS issues an audit notice in April, the Q1 report will not yet be submitted since it is due May 25. In this

circumstance, the most recent available submission would be the prior year's Q4 report that was submitted by February 22, which contains universe data for the period of October 1 through December 31. UHC requests that CMS clarify whether plans should expect CMS to request universes based on the most recently submitted quarterly report (e.g., Q4), or whether CMS will require universes that align with the audit notice date, even if they fall outside a submitted reporting period. For universes that require resubmission during fieldwork, CMS should clarify whether it expects the resubmitted universe to align with the timeframe of the originally requested data, or if the resubmission should reflect the most current quarter available at the time of correction. Additionally, if CMS utilizes the quarterly reported data to identify samples (e.g, denied claims reflected in Table 3 universes), CMS should specify whether they will select cases associated with contracted providers or if they intend to limit case file review to non-contracted providers only, similar to the current process.

UHC recommends that CMS refrain from using the quarterly reports as the source documentation for CMS or TMP audit case selection. As currently structured, the quarterly reports do not contain the level of detail necessary to accurately measure timeliness. If CMS intends to leverage the Pilot files for audit oversight in lieu of or in addition to current reporting structures, UHC recommends enhancing the Pilot file layout to include the following data elements to support accurate timeliness assessment and CMS audit sampling methodology:

- Standardized date and timestamp formats (CCYY/MM/DD and HH:MM:SS) to align with the current audit protocols. Time is not required for standard Non Part B drug cases or claims.
- Time-of-day fields for both request receipt and determination issuance (particularly critical for expedited requests and Part B drug decisions)
- Separate timestamp fields for oral notifications and written notifications
- Designated indicators for: Timeframe extensions (Y/N), and expedited-to-standard downgrades (Y/N)
- Waiver of Liability (WOL) date and IRE forwarding date for applicable payment reconsiderations
- First Tier, Downstream, and Related Entities (FDR) field
- Authorized Representative (AOR) date

<u>ODAG Program Audit Protocol and Data Request, Compliance Standards</u>
Currently, Part D protocols for Universe Table 4: Standard and Expedited Redeterminations (RD) Record Layout contains language that says to exclude appeals of dismissals or requests to vacate dismissals. However, ODAG protocols do not include this language. UHC requests that CMS add language to exclude appeals of dismissals or requests to vacate dismissals in ODAG to be consistent with the regulations.

UHC requests information on how long Sponsors will have to prepare and submit files for a desk review and if Sponsors will have the option of requesting a live review or desk review.

The audit element titled *Processing of Coverage Requests 2.7* includes both Universe Table 3 (*Payment Organization Determinations*) and Universe Table 5 (*Reopening Determinations*) as data requests. UHC requests confirmation that Table 3 should be included as data for this item since the method of evaluation references reopenings, not payment organization determinations: "For each sampled case, review case file to ensure reopened and revised

decisions were appropriate and for proper notification to the enrollee that explains the rationale for the reopening and revision, and any appeal rights. When applicable, review reopened case to ensure coverage was not denied inappropriately when prior approval or concurrent approval was given on the service."

In the audit element titled *Classification of Requests 3.1*, UHC recommends that CMS add the missing bullet point in front of the text stating, "The enrollee's right to request a reconsideration of the dismissal" to ensure clarity.

ODAG Program Audit Protocol and Data Request, Audit Field Work Phase, Timeliness Mitigation Analysis

UHC requests further clarity on the threshold triggering a timeliness mitigation analysis. UHC recommends that CMS set a statistically valid percentage standard that triggers a review instead of just one untimely case triggering an analysis for the entire universe.

In the Timeliness Audit Elements 1.3, 1.4, and 1.6: UHC requests confirmation regarding the wording stating, "noncompliance for any initial determinations that appear untimely." We believe the current proposed wording may be a typographical error, and that it should instead state, "noncompliance for any reconsideration that appears untimely."

In Timeliness Audit Element 1.7, UHC requests clarification whether the 24-hour timeliness standard for expedited cases will be incorporated into Element 1.7 or whether CMS intends to create a separate Element 1.8 to measure expedited timeliness.

ODAG Program Audit Protocol and Data Request, Universe Table 1: Standard and Expedited Organization Determination (OD) Record Layout

In the guidance for Universe Table 1, the proposed language states that all initial organizational determinations reported should include, "Failure of the MA organization to approve, furnish, arrange for, or provide payment for health care services in a timely manner, or to provide the enrollee with timely notice of an adverse determination, such that a delay would adversely affect the health of the enrollee." UHC requests clarification regarding CMS's intent with this statement or examples of cases that should be included based on this language. UHC also recommends that reopens and withdraws be added back in with the exclusions list for the record layout as inclusion in the universe would be duplicative of Table 5.

ODAG Program Audit Protocol and Data Request, Universe Table 2: Standard and Expedited Reconsiderations (RECON) Record Layout

UHC requests CMS further refine the proposed language in Column R (*Date oral notification provided to enrollee*) to be more precise. Instead of the current proposed language, "Enter None for dismissed requests or if no oral notification was provided," UHC recommends adding language similar to the CDAG protocols which states, "Enter None for standard cases, dismissed cases, if no oral notification was provided, or if oral notice was not successful."

UHC also recommends that CMS reinstate withdraws within the exclusion logic for the T02 universe. Removing withdraws from the exclusion criteria may result in inappropriate inclusion of cases that are not statistically valid for audit sampling.

ODAG Program Audit Protocol and Data Request, Universe Table 3: Payment Organization Determinations and Reconsiderations (PYMT_C) Record Layout
UHC recommends that CMS add reopens and retrospective reviews back in with the exclusions list for the record layout, as inclusion in the universe would be duplicative of Table 5.

ODAG Program Audit Protocol and Data Request, Universe Table 4: Part C Standard and Expedited Grievances
UHC requests additional guidance regarding whether there is a character limit for the Grievance field description. Clear direction on this requirement will help ensure accurate, complete, and compliant documentation across all submissions.

ODAG Program Audit Protocol and Data Request, Universe Table 5: Reopened Part C Determinations (RCD)
UHC requests confirmation whether CMS will require submission of Table 5 since reopenings are already captured within the quarterly report, making Table 5 duplicative.

If the submission of Table 5 is required, UHC requests further guidance on how Sponsors should distinguish between the reopening categories, given the updated requirements. For example, if a provider submits new and material evidence that results in a change to the outcome, UHC recommends this reopening would be excluded from reporting because the Sponsor did not initiate it. Clarification is appreciated to ensure consistent categorization.

CMS states that Column N (*Reopened disposition*) should reflect the final disposition following the reopening review, using the codes “ANR” for approved without revision, “AR” for approved with revision, or “Denied”. UHC requests that CMS provide definitions of each disposition type within the context of reopenings to ensure consistency.

Special Needs Plans Care Coordination (SNPCC)

SNPCC Program Audit Protocol and Data Request, Compliance Standards
With the addition of D-SNP-specific questions, UHC recommends that CMS designate the specific plan types (e.g., Applicable Integrated Plan (AIP), Coordinated D-SNP, and Coordination Only (CO) D-SNP) to align with each question. If this is CMS’s intention, we request a description of the selection methodology and confirmation whether assignments will be mutually exclusive (i.e., question mapped to one plan type) or overlapping across plan types. Ensuring plans have clear understanding of the specific questions and answers for each plan type furthers audit reliability as well as reducing potential plan confusion during an audit.

For Compliance Standards 1.1-1.2, UHC recommends that CMS set a statistically valid percentage standard benchmark that would trigger a review instead of just one untimely case triggering an analysis for the entire unaffected claim universe to ensure that review is necessary.

Applicability Across D-SNP Types – Medicaid Coordination Requirement
In the proposed protocol, CMS states, “Review documentation for each D-SNP sample to ensure the Sponsor offered to coordinate and provide Medicaid assistance where applicable for the dually eligible enrollees.” UHC seeks confirmation whether this requirement applies uniformly across all D-SNP types (e.g., AIP and Coordinated D-SNPs). If expectations differ by

plan type, UHC requests information regarding the criteria and examples that distinguish applicability.

SNPCC Sample Delivery Timing

In prior protocols, a four-day advance time was used, but the proposed guidance instead includes a one-hour notice for selected samples. UHC believes that replacing the much shorter time frame places a burden on Sponsoring organizations, and it will not allow adequate time to gather the extensive amount of information to demonstrate compliance with SNPCC audit standards.

UHC also recommends that CMS provide a minimum and maximum range for sample selection (e.g., per protocol area and per plan type). If larger samples are selected (e.g., 30 cases), UHC recommends extending the fieldwork timeframe proportionally, and providing a scaling table or rule of thumb to outline of the adjustment approach.

SNPCC Program Audit Protocol and Data Request, Audit Engagement and Universe Phase, Universe Table 1

UHC seeks confirmation whether the Initial HRA will ever be calculated using Column I (Most Recent Plan Change Effective Date) instead of Column H (SNP Enrollment Effective Date). Further, UHC requests clarification whether the Initial HRA timeliness should be driven by the re-enrollment date in Column J (Most Recent Plan Change Effective Date for Non- Continuous Enrollment), or if it should remain based on Column H. Several scenarios indicate that the logic in Column H may already capture the intended requirements, which may eliminate the need for Column J.

Thank you for your thoughtful consideration of our comments. Should you have any questions, please do not hesitate to contact me.

Sincerely,

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CMS 10717 | Comments from UPMC Health Plan

Comment 1:

In the draft 2027 Audit Protocols, for the Special Needs Plans Care Coordination (SNPCC) audit, under the Audit Field Work Phase, Sample Selection, CMS revised this language: *If the audit fieldwork is done live via webinar, the Sponsoring organization will receive notice of the selected samples 1 hour in advance of the live review. CMS may conduct all or part of the review via desk review. If desk review is conducted, the Sponsoring organization will receive samples with enough advanced notice to prepare and submit full or partial case files.*

This is a significant change from the current process where CMS provides the cases on the Thursday before the audit. Within one hour, it would be difficult to pull and organize the data for 30 samples, which includes the following data:

- Completed enrollee Health Risk Assessment(s).
- Copy of the enrollee's Individualized Care Plan (ICP).
- Care and case management documentation associated with the ICP (including claims, encounters, and Prescription Drug Events) submitted for the enrollee since the last HRA was completed. Specific documentation will be selected by the audit team based on the content of the ICP.
- Membership of the ICT with evidence of appropriate credentials.
- Information on the Sponsoring organization's process to confirm MOC training for network providers and ICT members and evidence of the Sponsoring organization's confirmation.
- Meeting minutes
- Case files
- Telephone scripts
- Attendance records
- Policies and procedures
- Documentation regarding timeliness

The credential information is a big lift to collect for all members mentioned on the ICT for the selected members.

Comment 2:

In the draft 2027 Audit Protocols, for the Special Needs Plans Care Coordination (SNPCC) audit, for Universe Table 1: Special Needs Plans Enrollees (SNPE) Record Layout, CMS is adding a field for "Was there a hospital or SNF admission?". Can CMS provide additional

information as to how they expect plans to get the data to populate this field? Is the expectation that it's based on claims data or some other data source outlined by CMS?