Responses to Comments Received
Federal Register Notice on (CMS-10191)
Medicare Parts C and D Program Audit Protocols and Data Requests

CMS received 35 public submissions, which included 250 comments on the August 16, 2019 (CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests proposed information collection. We then combined the 250 comments into 109 unique comments and provided responses in the document below. Comments are categorized first, by those that are general in nature, next, those that pertain to more than one program area and, finally, those that apply to each individual program area.

GENERAL COMMENTS

Comment 1: A couple of commenters asked if there is a standard Excel template, inclusive of column headers, for populating data universe submissions to ensure that all related information is provided.

Response 1: All of the information requested by CMS is detailed in the individual record layouts and data collection documents. CMS believes that the field names and descriptions contained in each record layout provide the clarification requested by the commenter. Sponsoring organizations are responsible for submitting universes to CMS inclusive of all of the information contained in each record layout and allows formats other than Excel, as specified in the data collection documents. For these reasons, CMS does not believe a standard template is needed.

CMS Action 1: No changes were made to the protocols in response to these comments. No changes were made to the burden estimate in response to these comments.

Comment 2: Several commenters noted that the collection request does not include protocols for Medicare-Medicaid Plan Service Authorization Requests, Appeals and Grievances (MMP-SARAG) and Medicare-Medicaid Plan Care Coordination and Quality Improvement Program Effectiveness (MMP-CCQIPE) and asked whether these would be released at a later time or if the audit protocols that were in place in 2019 for MMP would remain unchanged in 2020. One commenter asked whether, consistent with the approach in the Part D Coverage Determinations, Appeals and Grievances (CDAG) and Part C Organization Determinations Appeals and Grievances (ODAG) data requests, Table 12 MMP Call Logs would be removed from the MMP-SARAG data request in 2020. Commenters further requested that CMS streamline the submission requirements across the ODAG and MMP-SARAG data requests.

Response 2: MMPs are demonstration programs. Section 3021 of the Affordable Care Act grants the Secretary of Health and Human Services the authority to waive requirements of Titles XI, Titles XVIII, and sections 1902(a)(1), 1902(a)(13), and 1902(m)(2)(A)(iii) as necessary to conduct these demonstrations. The provision also exempts the testing, evaluation, and expansion of demonstrations from Chapter 35 of title 44, the Paperwork Reduction Act (PRA), which requires federal agencies to receive OMB approval for each collection of information request. Therefore, the MMP-SARAG and MMP-CCQIPE protocols are not included in this collection request. However, sponsoring organizations offering MMP plans are required to submit program audit data in accordance with the MMP-SARAG and MMP-CCQIPE data requests.

We agree with the commenters' suggestion of streamlining submission requirements not only across ODAG and MMP-SARAG but also across Special Needs Plan Model of Care (SNP-MOC) and MMP-CCQIPE. Therefore, to the greatest extent possible, CMS plans to align the ODAG and MMP-SARAG data collection instruments as well as the SNP-MOC and MMP-CCQIPE data collection instruments.

The MMP audit protocols that were in place during audit year 2019 will be revised for audit year 2020 and will be made available for public comment.

CMS Action 2: No changes were made to the documents in this collection request in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 3: Several commenters expressed their support of CMS' efforts to streamline and consolidate the collection instruments by removing unnecessary or duplicative data requests. Commenters referred to the removal of the following collection instruments: Medication Therapy Management (MTM) Program Data Request, MTM impact analysis template, the Compliance Program Effectiveness (CPE) Self-Assessment questionnaire, and Part D Coverage Determinations, Appeals, and Grievances (CDAG) and Part C Organization Determinations, Appeals, and Grievances (ODAG) questionnaires. Commenters encouraged CMS to continue to identify additional ways to streamline the audit documents and process.

Response 3: We appreciate the commenter's support and agree that removal of these documents eliminates redundancy in data collection and streamlines the audit process. We have also made additional changes to this package based on comments, for example removal of certain data fields that are no longer necessary, and created consistency in submission terminology across program areas.

CMS Action 3: The specific documents to which commenters refer had already been removed from this collection request. However, we refer readers to the crosswalk summary for a complete listing of changes made to the remaining documents included in this collection request. No changes were made to the burden estimate in response to this comment.

Comment 4: One commenter expressed appreciation for the details included in Supporting Statement A outlining CMS' timeline for this collection request as well as a forthcoming, new collection request under a separate Office of Management and Budget (OMB) number that will reflect recent regulatory changes and further streamlining revisions. This commenter recommended that CMS release the final program audit documents as soon as possible to allow sponsoring organizations sufficient time to prepare for upcoming audit years.

Response 4: As the commenter correctly noted, this collection request is intended to be effective for audit year 2020. We also share the commenter's interest in allowing sponsoring organizations as much time as possible to prepare for upcoming audit years. Changes to the 2020 audit materials are technical, align with the clarifications provided in audit year 2019 and reduce overall burden. We intend to finalize this collection request as soon as possible prior to the start of the 2020 audit season.

CMS Action 4: No changes were made to the documents in this collection request in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 5: One commenter stated that they appreciate CMS' effort to provide clarifying resource documents to the data collection instruments such as Frequently Asked Questions (FAQs) and the annual audit memo, but asked that we take into account the effort required in reviewing and reconciling these resources to one another and asked that CMS ensure consistency among these resources.

Response 5: We appreciate the commenter's concern. To minimize disruption, all materials that have been included in prior program audit collection requests have remained unchanged and in effect until the expiration date identified in the PRA Disclosure Statement. While the data collection instruments are not updated annually, we release an annual HPMS memo that summarizes any minor changes to the upcoming year's audit processes. For example, prior to audit year 2019, we clarified that several data collection elements would become optional in audit year 2019. CMS will minimize the use of any audit-

related resources shared outside of the PRA process. In accordance with PRA requirements, any such resources will focus on minor audit process clarifications and will not result in collection burden.

CMS Action 5: No changes were made to the documents in this collection request in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 6: One commenter requested clarification as to which version of the protocols would be used for the Timeliness Monitoring Project (TMP) audits in 2020.

Response 6: As indicated in the HPMS memo dated October 8, 2019, the universe record layouts from the 2019 program audit protocols will be used for the TMP. Those protocol are available as a zip file named "2017_Medicare_Parts_C_and_D_Program_Audit_Protocols_and_Data_Requests.zip" and can be located in the Downloads section at the bottom of the page using this link: https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/ProgramAudits.html

CMS Action 6: No changes were made to the documents in this collection request in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 7: One commenter asked CMS to confirm that 2020 will be the final year for the collection of Part D TMP data and whether the collection of Part C TMP data will continue in 2021.

Response 7: As the commenter correctly noted, CMS announced in the Calendar Year (CY) 2020 Final Call Letter that it will stop collection of Part D TMP data after the 2019 data are collected in 2020. Beginning in 2021, the annual industry-wide timeliness monitoring effort will be limited to Part C organizations.

CMS Action 7: No changes were made to the documents in this collection request in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 8: Several commenters indicated that the Audit Submission Checklist is helpful to sponsoring organizations in tracking due dates for submitting program area record layouts and audit deliverables. The commenters noted that this document is not included in the collection request but requested that CMS continue to provide this resource to plans.

Response 8: We appreciate the commenters' feedback on the usefulness of Audit Submission Checklist. As the commenters noted, this document serves as a reference tool to guide sponsoring organizations on submission deadlines connected to a program audit. Because this document does not collect information from the sponsoring organization undergoing a program audit, we have not included it in this collection request. However, it will continue to be made available on CMS' program audit website at: https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/ProgramAudits.html

CMS Action 8: No changes were made to the documents in this collection request in response to these comments. No changes were made to the burden estimate in response to these comments.

ALL PROGRAM AREAS

Comment 9: A commenter requested that CMS update the example dates provided in the CDAG protocol for the date fields.

Response 9: CMS agrees with the commenter's suggestion and has updated the example dates provided in the date fields for all of the program area protocols.

CMS Action 9: CMS updated the example dates provided in the date fields for all of the program area protocols. Additionally, CMS updated the date format in all program area Impact Analyses (IAs) from MM/DD/YY to CCYY/MM/DD to better align with the protocols. No changes were made to the burden estimate in response to this comment.

Comment 10: Several commenters asked about the language in the CDAG protocol stating a universe could be submitted in CSV format because the crosswalk document stated that CMS cannot accept CSV files. Commenters requested that CMS clarify whether data may be submitted in Comma Separated Values (CSV) format.

Response 10: In the 60 day package, we inadvertently failed to remove the reference to CSV files in the CDAG protocol. However, because HPMS cannot accept files that are submitted in CSV format, we agrees that the Comma Separated Values (.csv) file format should be removed from the record layout instructions section of all program area data requests. All program area data universes must be submitted in the Microsoft Excel (.xlsx) file format with a header row or Text (.txt) file format without a header row.

CMS Action 10: CMS has removed the Comma Separated Values (.csv) file format from the record layout instructions section. No changes were made to the burden estimate in response to these comments.

MULTIPLE PROGRAM AREAS

Comment 11: A commenter noted that the NDC Field description for CDAG differs from the one found in the FA protocol and requested that CMS consider standardizing the description for this field across all universe tables for CDAG and FA.

Response 11: CMS agrees with the commenter's suggestion and has standardized the NDC field in the CDAG and FA protocols.

CMS Action 11: CMS updated the NDC field name and description in the CDAG and FA protocols. No changes were made to the burden estimate in response to this comment.

Comment 12: Two commenters asked if sponsoring organizations should enter valueXeeded for the NDC field if the pharmacy submits a value greater than 11 characters.

Response 12: Yes, sponsoring organizations should enter "valueXeeded" when a pharmacy submits an NDC greater than 11 characters. CMS has added this instruction to the NDC field description of the FA and CDAG protocols.

CMS Action 12: CMS added the following language to the NDC field description in the FA and CDAG protocols, "If the pharmacy submits a value greater than 11 characters, enter ‘valueXeeded’ in the field." No changes were made to the burden estimate in response to these comments.

Comment 13: A commenter asked what should be populated in the NDC field for multi-ingredient compound claims with no Part D covered drug. The commenter noted that the previous protocol indicated to enter 00000000000 and asked for the same instruction to be added for this data collection.

Response 13: CMS agrees and has added the following language to the NDC field description in the FA and CDAG protocols, "When compound claims do not include any Part D drug products, populate the field with '00000000000' consistent with the NDC 11 format."

CMS Action 13: CMS added the requested language to the NDC field description in the FA and CDAG protocols. No changes were made to the burden estimate in response to this comment.

Comment 14: A number of commenters requested clarification on Appointment of Representative (AOR) documentation. Particularly, commenters requested guidance on the following exclusion language that was added to the CDAG and ODAG record layouts, "Exclude requests that require an AOR (or other conforming instrument) but the AOR has not been received as of the date of the universe submission." One commenter suggested this language should also be applied to Waiver of Liabilities (WOL). For ODAG, one commenter requested confirmation on whether or not cases dismissed for no AOR should be included in ODAG Table 13: Dismissals. Similarly, for CDAG commenters asked whether a request should be included or excluded in the record layouts if the case is dismissed for an appointment of representative (AOR) not received prior to the universe submission. One commenter asked for additional information on what could be interpreted as "other conforming instrument" and another commenter asked how a missing Appointment of Representative (AOR) would be identified. Lastly, a couple of commenters requested a "cutoff" date for requests that were received without an AOR/WOL but the documentation was received outside of the universe timeframe but prior to submission of the universes to CMS. One of these commenters requested that CMS change the exclusion language to read, "Exclude requests that require an AOR (or other conforming instrument) but the AOR has not been received as of the date of the Audit Engagement Letter".

Response 14: CMS appreciates the commenters requesting additional information regarding this exclusion language. In light of the confusion caused by the additional language, CMS has removed this language from all applicable ODAG and CDAG record layouts. Sponsoring organizations may exclude cases where a decision has been made but the decision has not been issued while it awaits the appropriate documentation. CMS confirms cases that have been dismissed for no AOR or WOL should be included in ODAG Table 13: Dismissals and requests that are dismissed for an AOR (or other conforming instrument) not received should be included in the applicable CDAG record layouts.

For more information on "other conforming instrument," sponsoring organizations should reference section 20.2 of the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance issued in February, 2019.

Finally, CMS will not hold a sponsoring organization accountable for excluding requests that were not considered valid within the universe time period if the appropriate documentation was received after the close of universe period (i.e. Date of the Engagement Letter).

CMS Action 14: CMS has removed the following language from the ODAG and CDAG Table instructions, "Exclude requests that require an AOR (or other conforming instrument) but the AOR has not been received as of the date of the universe submission". No changes were made to the burden estimate in response to these comments.

Comment 15: A number of commenters asked for clarification regarding the inclusion/exclusion status of withdrawn requests for the ODAG record layouts. For CDAG, a commenter asked whether withdrawn cases should be included in the universes for Table 14: SGD and Table 15: EGD.

Response 15: CMS appreciates the comments regarding the status of withdrawn requests. CMS has made the decision to exclude withdrawn requests from all of the ODAG Tables. Similarly, withdrawn grievances should be excluded from CDAG Tables 12 and 13 (formerly Tables 14 and 15). CMS has added exclusion language to all of the CDAG tables for withdrawn cases and has also removed "withdrawn" from the "Request Disposition" field description.

CMS Action 15: For ODAG, CMS has updated the Table instructions for each record layout, with the exception of Table 13: DIS, to exclude withdrawn requests. For CDAG, CMS added exclusion language to all of the CDAG Table instructions for withdrawn requests and also removed "withdrawn" from the "Request Disposition" field description and throughout the protocol. No changes were made to the burden estimate in response to these comments.

Comment 16: For ODAG and CDAG, a few commenters requested for CMS to provide policy clarification on the date and/or time a written notice is considered delivered by a sponsoring organization and/or provided to the enrollee. Some commenters also requested clarification on whether or not CMS assesses timeliness for favorable and adverse expedited organization determinations in the same manner.

Response 16: CMS appreciates the clarifying questions from sponsoring organizations. For more information on when a notification is considered delivered by a sponsoring organization, CMS suggests that sponsoring organizations review section 10.5.3 of the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance issued in February, 2019. In light of this information being included in the aforementioned guidance, CMS has removed the following language from all applicable ODAG and CDAG record Tables, “The term “provided” means when the letter left the sponsor’s establishment by US Mail, fax, or electronic communication. Do not enter the date when a letter is generated or printed within the sponsor’s organization.” Additionally, CMS assesses timeliness of notifications for both pre-service OD (standard and expedited) and pre-service reconsiderations (standard and expedited) according to the appropriate regulations in 42 CFR Subpart M.

CMS Action 16: CMS removed the following language from all of the applicable ODAG and CDAG Table fields, “The term “provided” means when the letter left the sponsor’s establishment by US Mail, fax, or electronic communication. Do not enter the date when a letter is generated or printed within the sponsor’s organization.” No changes were made to the burden estimate in response to these comments.

Comment 17: A few commenters requested clarifying guidance on “Good Faith Effort to Provide Verbal Notification” and how this is applied to CMS Program Audits. Particularly, commenters requested guidance on how they should populate the ODAG Tables in light of the guidance referenced in Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance issued in February, 2019. For CDAG, a commenter suggested that CMS add, "or documented good faith attempt", to the “Time oral notification provided to enrollee” field to mirror the “Date oral notification provided to enrollee” field.

Response 17: CMS has removed all references to good faith efforts from the CDAG audit protocol. Please see section 10.5.4 of the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance (issued February 2019) for more information on good faith efforts. In assessing good faith effort for CMS Program Audit timeliness purposes, CMS does not deviate from the notification timeframes identified in 42 CFR Parts 422 and 423 Subpart M when assessing notification timeliness.

CMS Action 17: CMS has removed references to good faith efforts within the descriptions of the applicable CDAG Table field descriptions. No changes were made to the burden estimate in response to these comments.

Comment 18: One commenter was concerned about CMS referencing only the CFR in the 2020 protocols and asked CMS to include references to the appropriate section of the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance as well. Another commenter requested that CMS update the 2020 data collection documents to better align with the aforementioned appeals guidance.

Response 18: We appreciate the commenter's suggestion but will not be making the first requested update. CMS does not believe that adding sub-regulatory guidance references to the protocol is necessary since such information is duplicative of the Regulatory requirement citations. CMS has taken regulatory updates into account and updated the data collection documents where applicable.

CMS Action 18: No changes were made to the protocol in response to this comment. No changes were made to the burden estimates as a result of this comment.

Comment 19: Commenters asked CMS to clarify whether the CDAG Cardholder ID field includes the Medicare Beneficiary Identifier (MBI) and several commenters requested that CMS change the name of the "Cardholder ID" field to "MBI Number" in all Tables.

Response 19: CMS agrees and has renamed the "Cardholder ID" field in the CDAG, ODAG and SNP-MOC Tables to "Enrollee ID". The updated field description indicates the Enrollee ID is the MBI. CMS notes that the Part D Formulary and Benefit Administration (FA) protocol in this data collection already has an MBI field so no updates are required.

CMS Action 19: CMS renamed the "Cardholder ID" field to "Enrollee ID" in the CDAG, ODAG and SNP-MOC Tables and updated the description to reflect the Medicare Beneficiary Identifier (MBI) as well as the respective Impact Analyses for each program area. CMS also updated the character count in the aforementioned tables from '20' to '11' characters. Additionally, "Medicare Beneficiary Identifier (MBI)" was added to the FA Impact Analysis. No changes were made to the burden estimate in response to these comments.

Comment 20: Several commenters requested for CMS to clarify whether grievances and coverage determinations expressed via live chat should be classified as written requests for CDAG and ODAG.

Response 20: Whether a live chat is deemed an oral or written request is a policy question, and should be directed to the CMS policy mailbox https://appeals.lmi.org.

CMS Action 20: No changes were made to the protocol in response to these comments. No changes were made to the burden estimates as a result of these comments.

Comment 21: For the Universe Accuracy Standard found in the CDAG and ODAG protocols, a commenter asked CMS to confirm that if the first four samples pass, that the fifth sample will be skipped and not tested.

Response 21: The commenter is correct. As stated in the protocol, the integrity of the universe will be questioned if more than one of the five sample cases observed during the audit does not match the data provided in the universe.

CMS Action 21: No changes were made to the protocol in response to this comment. No changes were made to the burden estimates as a result of this comment.

Comment 22: A commenter requested that CMS add the following language to the Responding to Universe Requests section of the CDAG protocol, "(e.g. sponsoring organizations will not be allowed to resubmit universes after auditors have shared timeliness test results with the sponsoring organization)."

Response 22: CMS thanks the commenter for this suggestion. However, the addition of this information to each of the protocols is redundant and duplicative of audit process information already shared in the Audit Process Overview document that is updated annually on our website. Please refer to https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/ProgramAudits.html for more information.

CMS Action 22: No changes were made to the protocol in response to this comment. No changes were made to the burden estimates as a result of this comment.

Comment 23: Several commenters requested clarification regarding the oversight of incoming calls. One commenter requested confirmation that call logs have been removed from the CDAG and ODAG data requests. Several commenters requested that CMS elaborate on the way in which CMS' review of the call routing process will transition to the compliance program effectiveness portion of the program audit since call logs have been removed from the CDAG and ODAG data requests. One commenter advised CMS to add a question to the CPE FDR Oversight Questionnaire that addresses call log oversight.

CMS Response 23: Call logs were removed from the CDAG and ODAG data requests. During the onsite portion of the CPE review, the Medicare Compliance Officer should be prepared to discuss the sponsoring organization's oversight of incoming calls (e.g. those calls previously collected via the Part C and Part D Call Log record layouts) to ensure that they are properly routed, classified, and processed. While some sponsoring organizations may delegate call center responsibilities, not all organizations do. Therefore, while we agree that there is value in collecting information pertaining to call routing oversight, we believe that it should be collected via the CPE Compliance Officer Questionnaire.

CMS Action 23: We have updated the CPE Compliance Officer Questionnaire with a new, question #7 that reads: "Please describe how you oversee the call routing process to ensure incoming requests are properly classified and processed in accordance with 42 CFR Parts 422 and 423 Subpart M requirements." No changes were made to the burden estimate in response to this comment.

Comment 24: One commenter, representing multiple organizations, stated that it is easier and faster to enter numeric fields than to enter text fields. The commenter asked that CMS consider whether it would be possible to convert any of the existing text fields to numeric fields.

Response 24: We understand that for some sponsoring organizations, to require submission of numeric characters instead of text may result in significant programming burden. Given the short window between approval of this package and the start of audit year 2020, we decline to adopt this proposal at this time. We will take it under consideration in a future collection request.

CMS Action 24: No changes were made to the documents in this collection request in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 25: One commenter asked whether sponsoring organizations should include, in their data submissions, cases connected to enrollments that are not yet effective. The commenter provided the following example: A member enrolls on October 1st with an effective date of January 1st and submits a request for coverage or files a grievance prior to January 1st. The commenter requested clarification as to whether the sponsoring organization should process that request and include it in the applicable universe record layout. Specifically, should the organization approve or deny the request and provide appeal rights for coverage requests or provide resolution notification for grievances? The commenter also asked whether the guidance would apply equally to CDAG, ODAG and MMP-SARAG and all tables within them.

Response 25: Sponsoring organizations can exclude requests from members whose coverage is not yet effective as of the date of the Engagement Letter from their CDAG, ODAG and/or MMP-SARAG universe submissions. However, CMS would expect to see Part D claims rejected at the point of sale due to eligibility issues in the applicable Part D Formulary and Benefit Administration universes, as those universes should not be filtered in any way.

CMS Action 25: No changes were made to the documents in this collection request in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 26: Several commenters noted that while CMS provides guidance in calculating timeliness within the CDAG and ODAG universes, the thresholds that CMS uses in determining the classification of any noncompliance, are not shared. One commenter stated that without the thresholds, sponsoring organizations are not able to ensure that their performance meets CMS standards. One commenter further suggested that CMS share detailed information that would allow sponsoring organizations to see how they compare with one another and identify the plans that did not meet the CMS timeliness threshold requirements.

Response 26: CMS appreciates the comment, but will not be sharing the thresholds used in determining the classification of timeliness conditions for CMS Program Audits, consistent with the data collection package that expires April 30, 2020. Sponsoring organizations can ensure they meet CMS timeliness expectations by referring to the requirements found in 42 CFR Parts 422 and 423 Subpart M.

We also decline the suggestion of sharing sponsoring organizations' detailed timeliness results publicly. However, the overall audit score of each CMS program audit is available on CMS' website and within the annual Part C and Part D Program Audit and Enforcement Report located at: https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/ProgramAuditResults.html

CMS Action 26: No changes were made to the documents in this collection request in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 27: A number of commenters noted that CMS did not include updated regulatory citations to address the reduction in timeframes for Part B drugs effective January 1, 2020 in this package. Two commenters asked whether sponsoring organizations should report their Part B Step Therapy organization determinations in ODAG or CDAG universes, noting that the universe compliance standards do not reflect the regulatory changes.

Response 27: CMS is not proposing to test the timeliness of Part B drug requests against the new timeliness standards effective January 1, 2020, in its 2020 Program Audits. Sponsoring organizations should continue to include Part B drug requests in the applicable universes based on how the sponsoring organization processed the requests. For instance, if the sponsoring organization processed the request as

a coverage determination then the request must be included in the applicable CDAG universe. If the sponsoring organization processed the request as an organization determination (OD), then the request must be included in the applicable ODAG universe.

CMS Action 27: No changes were made to the protocol in response to these comments. No changes were made to the burden estimate in response to these comments.

PRE-AUDIT ISSUE SUMMARY (PAIS)

Comment 28: Several commenters requested that CMS clarify whether the Medication Therapy Management (MTM) program should continue to be listed in the Pre-Audit Issue Summary (PAIS) given that the MTM protocol has been suspended as described in Supporting Statement A.

Response 28: We thank the commenter for noting this inconsistency and agree that MTM should not be included in the PAIS.

CMS Action 28: We have updated the PAIS to remove references to MTM. No changes were made to the burden estimate in response to this comment.

Comment 29: One commenter stated that MMP-SARAG and MMP-CCQIPE are listed in the PAIS that is available in HPMS.

Response 29: We clarify that the PAIS that was available in HPMS during the public comment period was reflective of audit year 2019. As noted above, MMP collection instruments are not part of this collection request. However, if the engagement letter identified MMP-SARAG and MMP-CCQIPE as program areas to be reviewed, we would consider these pre-audit issues within the scope of the CMS Program Audit and would encourage sponsoring organizations to include those issues in the PAIS.

CMS Action 29: No changes were made to the documents in this collection request in response to this comment. No changes were made to the burden estimate in response to this comment.

COMPLIANCE PROGRAM EFFECTIVENESS (CPE)

Comment 30: One commenter requested that CMS clarify question number 9 in the CPE Compliance Officer Questionnaire that asks for a description of a recent experience with a miscommunication with an employee(s) when dealing with suspected, detected or reported incidents of noncompliance or fraud, waste and abuse (FWA). The commenter asked whether the question is meant to reflect miscommunication with an employee or an instance of FWA.

Response 30: In this question, we are looking for a description of a recent experience of miscommunication with an employee(s). That miscommunication may relate to FWA, either suspected, detected or reported.

CMS Action 30: No changes were made to the documents in this collection request in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 31: In referring to question number 8 within the CPE SIU FWA Questionnaire (i.e., How are the fraud alerts issued through HPMS incorporated into FWA prevention and detection, monitoring, and audit activities), one commenter stated that because they were not aware of any fraud alerts released through HPMS in 2019, this question is now outdated.

Response 31: While there may have been fewer alerts issued in FY2019, CMS continues to issue Fraud and Educational alerts through HPMS. Therefore, this question remains relevant to our program audits.

CMS Action 31: No changes have been made to the documents in this collection request. No changes were made to the burden estimate in response to this comment.

Comment 32: One commenter stated that the question in the First-Tier, Downstream and Related Entities Oversight Questionnaire that pertains to the number of first-tier entities is duplicative of information collected in the CPE Organizational Structure power point presentation template.

Response 32: We thank the commenter and agree that, as written, the information that was to be collected via these two instruments was repetitive.

CMS Action 32: We have removed the following bullet from the CPE Organizational Structure power point presentation: "Describe the approach and mechanisms used to monitor FDRs performance against contractual and regulatory requirements." No changes were made to the burden estimate in response to this comment.

Comment 33: Several commenters asked whether a sponsoring organization may choose to either upload documentation to support the tracer summary at the time the tracer summary is due or present the supporting documentation to CMS during the CPE onsite portion of the audit.

Response 33: As indicated in the "Submit Tracer Documentation to CMS" section on page 8 of the CPE data request, as long as the sponsoring organization uploads the tracer presentation by the due date, they may either provide the supporting documentation by uploading to HPMS or providing to CMS while the audit team is onsite.

CMS Action 33: No changes have been made to the documents in this collection request. No changes were made to the burden estimate in response to this comment.

Comment 34: Commenters requested that CMS clarify our intent behind removing the phrase "or do not work on the Medicare Parts C and/or D line of business" from the exclusion criteria in Table 1. Commenters asked whether it is CMS' intent for employees not supporting Medicare contracts to be included in Table 1 and explain the way in which this information would provide value to the CMS reviewer.

Response 34: We clarify that our intent in removing the phrase "or do not work on the Medicare Parts C and/or D line of business" was to eliminate redundancy given that the inclusion criteria already clarifies that employees who work on the Medicare Parts C and/or D line of business are to be included. Sponsoring organizations are to continue to exclude current employees who do not work on the Medicare Parts C and/or D line of business.

CMS Action 34: No changes were made to the documents in this collection request in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 35: Several commenters stated that the use of "NA" is not consistent throughout the universes noting that in the CPE data request requires the slash (N/A) whereas the other universes do not have the slash (NA).

Response 35: We thank the commenters for noting this inconsistency across program area data requests and agree with the suggested clarification.

CMS Action 35: We have updated the CPE data request to align with the other program area data requests by removing the slash in "NA". No changes were made to the burden estimate in response to this comment.

Comment 36: Several commenters noted a discrepancy between the PRA crosswalk and CPE Table 1, Column: FTE Contract Effective Date. The crosswalk indicated that the column should be populated with NA whereas the CPE data request indicated that the column should be populated with NR. Some commenters asked that CMS clarify whether to populate the field with NR or NA. Other commenters stated that, because the Contract Effective Date is no longer required, this column could be removed from the CPE data request.

Response 36: We thank the commenters for identifying this discrepancy between the CPE data request and the crosswalk and for the suggested correction.

CMS Action 36: Because Column: FTE Contract Effective Date of Table 1 is no longer required, we have deleted this column from the CPE data request. No changes were made to the burden estimate in response to this comment.

Comment 37: One commenter suggested that the character limit within Table 1 FTEAM, Column: FTE Contract Effective Date, should be increased to three characters.

Response 37: As noted previously, we removed Column: FTE Contract Effective Date from Table 1.

CMS Action 37: No changes were made to the documents in this collection request in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 38: Some commenters requested that CMS clarify the CPE review period, noting that a 26 week review period was proposed in a prior collection request. One commenter stated that a 26 week review period would reduce administrative burden on providing large amounts of data while also maintaining CMS' ability to view the most recent auditing and monitoring activity related to a plan's compliance program activities.

Response 38: We decline the suggestion to shorten the audit review period to 26 weeks for audit year 2020 but will consider this update in future program audit protocols.

CMS Action 38: No changes were made to the documents in this collection request in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 39: One commenter requested that CMS provide a power point template to guide sponsoring organizations in providing appropriate information in the tracer case summaries.

Response 39: We decline the commenter's suggestion to create a CPE tracer power point template. We believe that the CPE data requests include sufficient guidance while allowing necessary flexibility regarding the required points for inclusion in the tracer.

CMS Action 39: No changes were made to the documents in this collection request in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 40: One commenter requested that CMS clarify whether the submission of redlined documents that are not yet finalized and approved by Governance would be sufficient in reference to the

following guidance within the CPE data request: "If the audit review crosses calendar years, sponsoring organizations must provide the requested documentation (e.g. standards of conduct/code of conduct documents, audit and monitoring work plans, Corporate Compliance/Medicare Compliance/Fraud Waste Abuse (FWA) plan, formal risk assessments, etc.) that covers the entire audit period."

Response 40: Except under limited circumstances, CMS will not consider redlined documents that have not been finalized by the organization's governing body by the submission deadline to be sufficient.

CMS Action 40: No changes were made to the documents in this collection request in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 41: One commenter requested clarification regarding Table 1: First-Tier Entity Auditing and Monitoring (FTEAM); Table 3: Internal Auditing; and Table 4: Internal Monitoring. Specifically, the commenter requested that CMS provide examples to clarify whether the activity start date field within these tables should reflect the date the engagement letter is sent, documents are received, when the review of the documents begin, or when the onsite begins. The commenter also requested that CMS provide examples to clarify whether the activity completion date field within these tables should reflect the day the onsite is complete, when findings are finalized or when the deficiency has been remediated.

Response 41: Consistent with Section 50.6.3 of Chapter 21 of the Medicare Managed Care Manual and Chapter 9 of the Medicare Prescription Drug Benefit Manual, the activity start and completion dates within CPE tables 1, 3 and 4 should mirror those outlined in the sponsoring organization's auditing or monitoring work plan.

CMS Action 41: No changes were made to the documents in this collection request in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 42: One commenter noted that during a 2019 program audit, CMS provided the sponsoring organization with a list of 20 employees, contractors, etc., on day one of the CPE onsite audit and the organization was required to provide samples two days later. This commenter requested that CMS elaborate on the sample selection and review process to assist organizations in preparing for the onsite visit. The commenter also suggested that CMS provide the employee sample list prior to the onsite audit.

Response 42: An Employee and Compliance Team (ECT) and First-Tier Entity (FTE) walkthrough session will be scheduled during the week of onsite field work. Twenty employee samples will be selected from the ECT universe, which will be reviewed for training and accessibility of the Policies & Procedures and Standards of Conduct. Two FTE samples will be selected from the FTEAM universe, which will be reviewed for accessibility of the Policies & Procedures and Standards of Conduct. We believe that providing the sample selections at the beginning of the onsite visit (rather than the week prior), allows the sponsoring organization to prioritize ongoing audit activities that are already underway during week two. Therefore, the sample selections will be uploaded to HPMS the morning of day one of the onsite field work. The review will take place on day three of the onsite field work.

CMS Action 42: We have updated the Tracer Evaluation section of the CPE data request, by renaming it to a more generalized Sample Evaluation section and included the Employee and Compliance Team and First Tier Entity sample selection and review process. No changes were made to the burden estimate in response to this comment.

Comment 43: One commenter requested that CMS outline any requirements for sponsoring organizations to demonstrate their training system and OIG/GSA exclusion review process.

Response 43: Beginning in audit year 2020, CMS will no longer evaluate OIG/GSA exclusion lists as part of its Medicare Part C and Part D program audit. However, employee and FTE samples (as applicable) will be evaluated live in the sponsoring organization's system during the onsite portion of the fieldwork phase of the audit. As outlined in each sponsoring organization's audit engagement letter, CMS expects audit participants to have familiarity with the organization's operations, have the ability to explain the organization's internal policies and procedures, and possess knowledge of the organization's systems and how to navigate within them. This would include providing auditors with a walkthrough of documentation in applicable systems that are used to track CPE training requirements and evaluate accessibility of policies and procedures.

CMS Action 43: We have removed the reference to the sponsor's monthly screening to identify employees and FDRs excluded by the Office of Inspector General (OIG) and General Services Administration (GSA) throughout the protocol. No changes were made to the burden estimate in response to this comment.

Comment 44: One commenter suggested that CMS separate the FWA and auditing and monitoring functions to better account for the way sponsoring organizations are structured. For example, an organization may have separate units for Special Investigations vs. Compliance. The commenter requested that CMS separate FWA from routine auditing and monitoring activities within Table 1: FTEAM; Table 3: Internal Auditing; and Table 4: Internal Monitoring.

Response 44: We appreciate that each sponsoring organization is uniquely structured. However, we decline the commenter's suggestion to separate FWA from routine auditing and monitoring activities.

CMS Action 44: No changes were made to the documents in this collection request in response to this comment. No changes were made to the burden estimate in response to this comment.
Response:

Comment 45: One commenter expressed concern about the requirement that sponsoring organizations undergo annual CPE audits, noting that CMS has cited plans for not providing evidence that it audits, or otherwise measures, the effectiveness of the compliance program at least annually and that the results are shared with the governing body. The commenter requested that CMS consider requiring a less frequent evaluation of an organization's compliance program effectiveness, noting that the time to engage with an external audit firm or the sponsoring organization's internal audit function, and to complete the audit takes a minimum of 6-9 months, leaving minimal time to take meaningful action to enhance the compliance program based on the audit results before the next annual audit, which minimizes the value of the audit. The commenter referred to the Institute of Internal Auditors' International Professional Practices Framework Standard 1,300 which specifies that an internal audit function undergo an external review every five years. The commenter concludes by urging CMS to consider ways that will make the required compliance program effectiveness audit most meaningful to drive sponsoring organization improvements.

Response 45: We consider the commenter's request to allow a less frequent compliance program effectiveness audit to be outside of the scope for PRA and, we are not able to revise the CPE audit requirements found in 42 CFR Parts 422 and 423 Subpart M as part of this PRA process. However, we did want to point the commenter to the CY2019 Final Call Letter that clarified sponsoring organizations are not required to conduct their internal CPE audit in the calendar year following the year a CMS program audit is initiated. For example, if a CMS program audit begins at any point in 2020, sponsoring organizations are not expected to conduct an internal CPE audit until 2022.

CMS Action 45: No changes were made to the documents in this collection request in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 46: One commenter identified a typo in the CPE FDR Oversight Questionnaire in the sentence that reads "your c criteria."

Response 46: We thank the commenter for identifying this typo.

CMS Action 46: We have removed the "c" from this sentence such that it now reads "Please describe your criteria..." No changes were made to the burden estimate in response to this comment.

Comment 47: One commenter suggested that CMS update page 6 of the CPE Organizational Structure power point template to reflect current years as was done on page 7.

Response 47: We thank the commenter for the suggestion and agree that all pages of the power point template should reflect the most current years.

CMS Action 47: We have updated page number 6 of the CPE Organizational Structure PPT template such that column 2 reads 2018, column 3 reads 2019, and column 4 reads 2020. No changes were made to the burden estimate in response to this comment.

Comment 48: One commenter suggested that CMS add clarifying language in the description fields of the following CPE tables: Table 1: FTEAM, Column: Compliance or FWA; Table 3: Internal Auditing, Column: Compliance or FWA; and Table 4: Internal Monitoring, Column: Compliance or FWA. Specifically, the commenter suggested the following language: "In situations where the activity can be both compliance and FWA related, sponsoring organizations should list "FWA" in the record layout and, during the universe validation process, the sponsoring organization can explain to the audit team which issues are related to both compliance and FWA."

Response 48: We agree that the commenter's suggestion adds valuable guidance to sponsoring organizations and have adopted this change.

CMS Action 48: We have inserted the following statement in the description column of Table 1: FTEAM, Column: Compliance or FWA; Table 3: Internal Auditing, Column: Compliance or FWA; and Table 4: Internal Monitoring, Column: Compliance or FWA: "In situations where the activity can be both compliance and FWA related, sponsoring organizations should list "FWA" in the record layout and, during the universe validation process, the sponsoring organization can explain to the audit team which issues are related to both compliance and FWA." No changes were made to the burden estimate in response to this comment.

Comment 49: One commenter recommended that CMS update Table 2: ECT table instructions to reflect employees who "...worked/served at the time of the audit engagement notice." In this way, the ECT universe would reflect employees that currently maintain a role that supports the Medicare Parts C and D products. This commenter further indicated that it is administratively burdensome for plans to reflect all individuals who may have worked/served at any time, that this request could be considered out of scope for CMS review, and that the information would not add value to CMS auditors.

Response 49: We decline the commenter's suggested change. Because we are interested in assessing compliance during the audit review period, we do not believe it would be appropriate to exclude ECT members that worked/served at any time during the audit review period from the data submission.

CMS Action 49: No changes were made to the documents in this collection request in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 50: One commenter requested that with in Table 2: ECT, CMS add the following clarifying phrase to the description connected to Column: Employee Type: "If an employee fills multiple roles (e.g., full-time employee and governing body member), identify all roles in this field separated by a forward slash (e.g., full-time/BOD)."

Response 50: We thank the commenter for the suggested clarification and agree that this addition would further clarify the way in which employees with multiple roles could be reflected in the data submission.

CMS Action 50: We have added the following text to Table 2, Column: Employee Type "If an employee fills multiple roles (e.g., full-time employee and governing body member), identify all roles in this field separated by a forward slash (e.g., full-time/BOD)." No changes were made to the burden estimate in response to this comment.

Comment 51: One commenter requested that within Table 3: Internal Auditing, Column: Auditor Type and within Table 4: Internal Monitoring, Column: Monitor Type, of the CPE data request, CMS add the following clarifying phrase at the end of the column description: "and indicate external auditor." In this way, the column description would read: For external audit firms/firms provide the name(s) of the audit firm/company or firm/company and indicate "external auditor."

Response 51: We disagree that this clarification is necessary given that the description column currently allows for the identification of external auditors.

CMS Action 51: No changes were made to the documents in this collection request in response to this comment. No changes were made to the burden estimate in response to this comment.

PART D FORMULARY AND BENEFIT ADMINISTRATION (FA)

Comment 52: Several commenters noted that the crosswalk indicated that the field length for the MBI field would be 15 characters, however in the FA record layouts the field length is noted as 11 characters.

Response 52: The field length of 11 for the Medicare Beneficiary Identifier (MBI) is correct in the FA protocol and was incorrectly listed as 15 characters in the crosswalk.

CMS Action 52: No changes were made to the protocol in response to these comments. No changes were made to the burden estimate in response to these comments.

Comment 53: A commenter noted that FA Tables 1, 2 and 3 include all rejected claims with dates of service and asked whether this includes only active carriers or inactive carriers as well. Another commenter asked about the inclusion criteria for the FA tables and asked if sponsoring organizations should include rejected claims from inactive carriers and also asked CMS to consider updating the dates cited parenthetically.

Response 53: Per the instructions for Table 1: RCFA, Table 2: RCT-N, and Table 3: RCT-P, sponsoring organizations are to include all rejected claims with dates of service that fall within the applicable review period. Data must not be filtered under any circumstance. As mentioned above, CMS has updated the example dates provided in the date fields for all of the program area protocols.

CMS Action 53: CMS updated the example dates provided in the date fields for all of the program area protocols. No changes were made to the burden estimate in response to this comment.

Comment 54: A commenter suggested that CMS add the following language to the FA protocol, "If the Sponsor does not have any cases responsive to a particular universe request (e.g., if there were no Rejected Claims Transition – Previous Contract Year), the sponsor must upload an Excel spreadsheet to the Health Plan Management System (HPMS) at the appropriate universe level that includes a statement explaining it does not have responsive cases for this particular universe during the requested audit period."

Response 54: CMS appreciates the comment but does not anticipate this occurring, therefore no change has been made to the FA protocol.

CMS Action 54: No changes were made to the protocol in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 55: A commenter noted that CMS removed the numeric breakdown of the number of cases and increased the targeted sample of claims from 15 to 30. The commenter also noted that CMS did not specify the numeric breakdown between protected and non-protect class drugs and recommended that CMS keep the numeric breakdown of samples to ensure there is a consistent and fair review of "like" plans. Another commenter requested that CMS include the definition for the scope of the sample selection to provide clarification on what is meant by "claims rejections relating to formulary administration."

Response 55: CMS removed the specific number of samples that will be selected for Formulary Administration from each category of protected class and non-protected class drugs. Instead, the samples selected will represent a mix of claims for protected class and non-protected class drugs. The sampling criteria could include, but is not limited to, rejections for formulary drugs, PA rejections where the PA edit is not approved, ST rejections where the ST is not approved, etc.

CMS Action 55: No changes were made to the protocol in response to these comments. No changes were made to the burden estimate in response to these comments.

Comment 56: A commenter noted that in Section II Transition CMS increased the targeted sample of claims from 15 to 30 and clarified that claims will be selected for both protected and non-protected class drugs. The commenter asked for CMS to clarify whether the 30 total claims will be selected for continuing and new enrollees or whether 30 claims will be selected for continuing members and 30 claims selected for new enrollees for a total of 60 claims.

Response 56: CMS will select a total of 30 samples. This total will represent a combination of new and continuing enrollees as well both protected class and non-protected class drugs. For continuing enrollees, the samples will consist of rejected claims related to cross-year formulary changes between the audit year and the previous contract year (e.g., formulary deletions). For new enrollees, the samples will consist of rejected claims related to formulary administration during transition (e.g., prior authorization, step therapy, non-formulary drugs, and quantity limitations).

CMS Action 56: No changes were made to the protocol in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 57: A commenter stated that they believe the information contained in the new member (Table 5: NM) and rejected claims transition -new contract year (Table 2: RCT-N) universes is adequate to test rejected claims related to cross-year formulary changes between the audit year and previous contract year, and that the rejected claims transition -previous contract year (Table 3: RCT-P) universe is duplicative and unnecessary. The commenter recommended that CMS remove the Table 3: RCT-P

universe from the protocol and use the data contained in the Table 2: RCT-N universe to test cross-year formulary changes.

Response 57: We appreciate the commenter's suggestion, but will not be making this change to the FA protocol. CMS will take this comment under consideration for potential future process improvements.

CMS Action 57: No changes were made to the protocol in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 58: A commenter noted there are inconsistencies between the data requests under Table 1 of the FA Audit Protocol relating to the rejected claims FA record layout and the FA Impact Analysis. The commenter recommend that CMS consider aligning the fields in these data collection instruments where feasible to reduce burden.

Response 58: The FA Impact Analysis is used to fully assess non-compliance with contract requirements identified on audit including the time of a rejected claim, therefore CMS requests additional data not included in the record layouts for FA universes.

CMS Action 58: No changes were made to the protocol in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 59: A commenter recommended that CMS consider adding the following language from the 2019 Program Audit FAQ document to Table 5, "Populate the New Member universe to include only enrollees for which the sponsoring organization does not utilize prior claims history".

Response 59: CMS accepts the commenter's suggestion and has added the following language to the Table 5: NM instructions, "Include eligible members (including members enrolled in employer plans and Medicare-Medicaid Plans (MMPs)) for which the Sponsoring organization does not utilize prior claims history. In some cases, the Sponsoring organization may have the full claims history for the member from the most recent PBP, and thus, the Sponsoring organization may be able to determine new versus ongoing therapy. In this example, the member should not be included in the New Member Universe since they are determined to be a continuing member."

CMS Action 59: CMS added the requested language to the FA Table 5: NM instructions. No changes were made to the burden estimate in response to this comment.

PART D COVERAGE DETERMINATIONS, APPEALS AND GRIEVANCES (CDAG)

Comment 60: Several commenters asked if CMS could update the field names in the redetermination tables to clarify that the "Was the request denied for lack of medical necessity?" field pertains to the initial coverage determination request. Another commenter requested that CMS clarify the "If denied for lack of medical necessity, was the review completed by a physician?" field to reflect whether the redetermination was reviewed by physician if the coverage determination was denied for lack of medical necessity. Another commenter suggested that CMS remove NA as an option for the "Was the request denied for lack of medical necessity?" field in Table 8: Expedited Redeterminations (ERD) since the initial determination had to be denied in order for the subsequent request to be treated as a redetermination.

Response 60: CMS agrees with the commenters' first suggestion to clarify that in Tables 6, 7 and 8 we are intending to capture whether the coverage determination request was denied for lack of medical necessity. CMS has also determined that we no longer need to collect data for the "If denied for lack of

medical necessity, was the review completed by a physician?" field since this can be determined during sample case review. CMS also agrees with the commenter that the NA option is no longer needed for the "Was the request denied for lack of medical necessity?" field in Tables 6, 7 and 8 in light of the clarification that has been made to the field name.

CMS Action 60: CMS updated the field name in CDAG Tables 6, 7 and 8 to read "Was the coverage determination request denied for lack of medical necessity?" and removed the NA option in the field description that reads, "Answer NA if the request was not denied …". CMS also removed the "If denied for lack of medical necessity, was the review completed by a physician?" field from CDAG Tables 1, 2, 4, 5, 6, 7 and 8. No changes were made to the burden estimate in response to these comments.

Comment 61: Some commenters asked whether CMS intends to renumber the CDAG universe table numbers with the removal of several tables, and a couple of commenters specifically requested for CMS to renumber the remaining tables.

Response 61: CMS accepts the commenters' suggestions and has renumbered the CDAG universe tables as follows:

Table 1: Standard Coverage Determinations (SCD) Record Layout
Table 2: Standard Coverage Determination Exception Requests (SCDER) Record Layout
Table 3: Direct Member Reimbursement Request Coverage Determinations (DMRCD) Record Layout
Table 4: Expedited Coverage Determinations (ECD) Record Layout
Table 5: Expedited Coverage Determination Exception Requests (ECDER) Record Layout
Table 6: Standard Redeterminations (SRD) Record Layout
Table 7: Direct Member Reimbursement Request Redeterminations (DMRRD) Record Layout
Table 8: Expedited Redeterminations (ERD) Record Layout
Table 9: Standard IRE, ALJ or MAC Determinations (SIAM) Record Layout
Table 10: Direct Member Reimbursements decided by review entity other than sponsor (DMRRE) Record Layout
Table 11: Expedited IRE, ALJ or MAC Determinations (EIAM) Record Layout
Table 12: Standard Grievances Part D (SGD) Record Layout
Table 13: Expedited Grievances Part D (EGD) Record Layout

CMS Action 61: CMS has renumbered the CDAG Tables sequentially. Previous CDAG Tables 11, 12, 13, 14 and 15 have been updated to Table numbers 9, 10, 11, 12 and 13 respectively. No changes were made to the burden estimate in response to these comments.

Comment 62: Several commenters noted the sample size for 5 cases selected from 13 universes appears to be incorrect and should be 65 cases instead of 75 cases. Another commenter noted the Table numbers in this section should be updated to 1-8 and 11-15.

Response 62: CMS agrees that the number of samples listed in the Select Sample Cases section (under Timeliness - Coverage Determinations, Appeals and Grievances (TCDAG)) should be 65 instead of 75. However, since CMS has renumbered the CDAG Tables, no update is required to the table number references within this section.

CMS Action 62: CMS updated the number of TCDAG samples in the Select Sample Cases section to 65. No changes were made to the burden estimate in response to these comments.

Comment 63: We received numerous comments asking for clarification regarding the addition of QL as a valid value for at-risk appeals for the Formulary UM Exception Type field of the Standard Coverage

Determination Exception Requests (SCDER) and Expedited Coverage Determination Exception Requests (ECDER) Tables. A commenter also requested a definition of at-risk appeals.

Response 63: The at-risk appeals language was added to the SCDER and ECDER Tables in error. CMS has removed "For at-risk appeals; valid value is QL" from the Formulary UM Exception Type fields. For this data collection, since at-risk determinations are not defined as coverage determinations, at-risk determination data will not be collected via the program audit universe record layouts for coverage determinations. However, if an enrollee appeals the at-risk determination (and subsequent limitation on coverage), the appeal is a redetermination and would be entered into Table 6: Standard Redeterminations (SRD) and Table 8: Expedited Redeterminations (ERD), as applicable. Questions pertaining to at-risk determination policy and/or definition should be addressed to the appropriate CMS policy mailbox. For questions related to appeals of at-risk determinations, please email https://appeals.lmi.org. For questions about Drug Management Program (DMP) policy, please email PartD_OM@cms.hhs.gov.

CMS Action 63: The Formulary UM Exception Type field description has been updated to remove "For at-risk appeals; valid value is QL". No changes were made to the burden estimate in response to these comments.

Comment 64: A commenter pointed out a difference between CMS' 2019 Program Audit Frequently Asked Questions and the protocol within this data collection pertaining to the instructions for populating the "Date reimbursement provided" field.

Response 64: We attempted to clarify this field description within the applicable CDAG Tables based on information provided in the 2019 CMS Program Audit Frequently Asked Questions; however, CMS believes that additional clarification could be provided. As such, CMS has updated the "Date reimbursement provided" field description to include NRD, NP and NA options as follows:

- Enter NRD if the request was approved but no reimbursement was due to the enrollee.
- Enter NP if the payment has not been issued at the time of the universe submission.
- Enter NA if the request was not approved.

CMS Action 64: CMS updated the description for the “Date reimbursement provided” field in the DMRCD, DMRRD, and DMRRE tables. No changes were made to the burden estimate in response to this comment.

Comment 65: A commenter asked if CMS could clarify whether the Issue Description field for all CDAG Tables (with the exception of SGD and EGD) should include or exclude cases that were rejected or denied due to the provider being on the Preclusion List. Another commenter suggested that CMS add exclusion language to the CDAG protocol for preclusion list determinations.

Response 65: Any cases that were rejected or denied as a result of the provider being on the Preclusion List must be excluded from the CDAG universe submissions since these determinations are not coverage decisions. For this reason, CMS has not added exclusion language to the CDAG protocol. However, if an enrollee contacts the sponsoring organization to find another provider that is not on the Preclusion List to furnish services, CMS would expect to see that coverage request in the applicable universe.

CMS Action 65: No changes were made to the protocol in response to these comments. No changes were made to the burden estimates as a result of these comments.

Comment 66: A couple of commenters asked if CMS could add NA as an option for the "Was this request processed as an exception?" field in Tables 3 and 7.

Response 66: CMS recognizes that some requests may not be processed as exceptions but believes that the option to enter N for No in the CDAG Tables covers this scenario.

CMS Action 66: No changes were made to the protocol in response to these comments. No changes were made to the burden estimate in response to these comments.

Comment 67: One commenter recommended that the compliance standard applicable to Table 1 under Timeliness Tests be updated to remove the word "adjudication" to match the expedited coverage determination (ECD) language.

Response 67: For consistency, CMS has updated the Table 1: SCD compliance standard to read, "No later than 72 hours. Late cases must be auto-forwarded to the IRE within 24 hours of the expiration of the timeframe."

CMS Action 67: CMS updated the Table 1 compliance standard by removing the word "adjudication". No changes were made to the burden estimate in response to this comment.

Comment 68: A commenter asked if the "Date Enrollee Notified Request Has Been Forwarded to IRE" field is still required.

Response 68: CMS agrees that this information is no longer needed and has removed the field from Tables 1-8.

CMS Action 68: CMS removed the "Date Enrollee Notified Request Has Been Forwarded to IRE" field from Tables 1-8. No changes were made to the burden estimate in response to this comment.

Comment 69: A commenter asked if the description for the Exception Type field could be updated in Table 2: Standard Coverage Determination Exception Requests (SCDER) and Table 5: Expedited Coverage Determination Exception Requests (ECDER) to account for opioid requests.

Response 69: CMS agrees with the commenter's suggestion and has added "Safety edit exception" to the description for the "Exception Type" field in Tables 2 and 5.

CMS Action 69: CMS added "Safety edit exception" to the description for the "Exception Type" field in Tables 2 and 5. No changes were made to the burden estimate in response to this comment.

Comment 70: One commenter stated that most of its delegates are not capable of adding an 11-digit National Drug Code (NDC).

Response 70: CMS is not sure what the commenter means by "not capable", however we have added the following language to the NDC field description, "When less than 11 characters or a blank field is submitted by the pharmacy or delegate, populate the field as submitted." CMS believes this update addresses the commenters concern.

CMS Action 70: CMS added "When less than 11 characters or a blank field is submitted by the pharmacy or delegate, populate the field as submitted" to the NDC field description in Tables 1-8. No changes were made to the burden estimate in response to this comment.

Comment 71: A commenter noted that in Table 1: Standard Coverage Determinations (SCD) the "Issue Description" field requires a "description of the issue and, for denials, an explanation of why the decision

was denied." The commenter asked for clarification on what "an explanation of why" means and also asked whether general descriptions of issues are permissible.

Response 71: By "an explanation of why", CMS means include in the "Issue Description" field the rationale or basis for the denial, if applicable. The commenter did not provide an example of what is meant by "general descriptions of issues". Without this context, CMS is not able to state whether such an entry would be permissible in the universe submission. CMS also notes that the field length for the "Issue Description" field is 2,000 characters.

CMS Action 71: No changes were made to the protocol in response to this comment. No changes were made to the burden estimates as a result of this comment.

Comment 72: A commenter asked how to populate the universe when an enrollee submits an expedited coverage request and the request is later switched from expedited to standard.

Response 72: We are not clear on the commenter's request for clarification since Table 1: SCD does not include a field for the date a request is changed from expedited to standard. If the request was processed as a standard coverage determination it would be included in Table 1.

CMS Action 72: No changes were made to the protocol in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 73: A commenter asked CMS to clarify the directive for the "Date forwarded to IRE" and "Time forwarded to IRE" fields because, as they currently read, only untimely decisions should have dates/times entered. The commenter also asked CMS to clarify whether untimely notifications should have dates and times entered in these fields and recommended that CMS add untimely notifications to guidance.

Response 73: CMS appreciates this request for clarification and believes these field descriptions can be simplified. CMS is updating the field descriptions for the "Date forwarded to IRE" and "Time forwarded to IRE" fields in the Tables by removing the language "For untimely decisions". CMS does not understand the commenter's request for untimely notifications to be added to guidance. CMS believes this is already addressed in the regulations at 42 CFR Part 423 Subpart M.

CMS Action 73: CMS has updated the descriptions for the "Date forwarded to IRE" and "Time forwarded to IRE" fields in the Tables to remove the language "For untimely decisions" from Tables 1-8. No changes were made to the burden estimate in response to this comment.

Comment 74: A commenter requested clarification on how to populate the "AOR Receipt Date" and "AOR Receipt Time" fields. The commenter asked whether the fields should be populated with the date/time the request was received or the date/time the sponsoring organization received the AOR since it is not a valid request until the representative form is on file, where appropriate. The commenter also asked how to populate these fields to ensure cases are timely.

Response 74: The "AOR Receipt Date" and "AOR Receipt Time" fields should be populated with the date/time the Appointment of Representative (AOR) form or other appropriate documentation is received by the sponsoring organization. The date/time the request was received is captured in separate fields within the universe submission. CMS calculates timeliness based on when a request becomes valid.

CMS Action 74: No changes were made to the protocol in response to these comments. No changes were made to the burden estimates as a result of these comments.

Comment 75: A commenter requested clarification on how to populate the "Request Disposition" field if the request was never resolved or processed. The commenter requested clarification on whether NA or IRE auto-forward should be populated in this field and stated they were unclear when NA would be appropriate.

Response 75: For the scenario presented by commenter, the "Request Disposition" field would be populated with IRE auto-forward if the sponsoring organization forwarded the case to the Independent Review Entity (IRE). If the request was never resolved/processed and the case has not been forwarded to the IRE, the sponsoring organization would enter NA in the "Request Disposition" field.

CMS Action 75: No changes were made to the protocol in response to this comment. No changes were made to the burden estimates as a result of this comment.

Comment 76: A commenter asked CMS to consider adding reopenings and withdrawals to the NA parenthetical statement for the "Date effectuated in the plan's system" and "Time effectuated in the plan's system" fields to align with guidance in the Direct Member Reimbursement Request Coverage Determinations (DMRCD) universe.

Response 76: CMS is not sure what the commenter means by suggesting an update to align with the DMRCD Record Layout since Table 3 does not contain date and time effectuated fields. We think the commenter may be referring to the following language in the "Date reimbursement provided" field for Table 3 - "Answer NA if the request was not approved." CMS notes that the descriptions for the "Date effectuated in the plan's system" and "Time effectuated in the plan's system" fields currently state "Answer NA for requests that were not approved (e.g. denials/auto-forwards)", which is the same language noted above in Table 3. Denials and auto-forwards are provided in the field descriptions as examples. If a request is not approved and was withdrawn or re-opened and denied, NA can be entered in the "Date effectuated in the plan's system" and "Time effectuated in the plan's system" fields.

CMS Action 76: No changes were made to the protocol in response to this comment. No changes were made to the burden estimates as a result of this comment.

Comment 77: A commenter asked if a reimbursement request which also requires a review for utilization management should be included in the Table 6: Standard Redeterminations (SRD) Record Layout.

Response 77: Sponsoring organizations should include cases in the Tables based on how the request was processed. For the scenario presented by the commenter, if the sponsoring organization processed the request as both a reimbursement redetermination request and pre-service redetermination request, the requests would appear in Table 7: Direct Member Reimbursement Request Redeterminations (DMRRD) and Table 6: Standard Redeterminations (SRD), respectively.

CMS Action 77: No changes were made to the protocol in response to this comment. No changes were made to the burden estimates as a result of this comment.

Comment 78: A commenter asked how sponsoring organizations should populate fields for an untimely direct member reimbursement (DMR) case where the sponsoring organization provides a Notice of Case Status letter to the enrollee notifying him/her that the case has been sent to the IRE. The commenter asked whether this means that the request has been processed and enrollee notification has been provided and noted that both fields state to use "NA" if the request was never resolved/processed.

Response 78: For the example provided, the sponsoring organization would enter IRE auto-forward in the "Request Disposition" field and would enter NA in the "Date written notification provided to enrollee field" since no written notification of the decision was provided to the enrollee. The date the request was forwarded to the IRE would be entered in the "Date forwarded to IRE" field. Since CMS has removed the "Date enrollee notified request has been forwarded to IRE" field from the CDAG Tables this information is no longer required.

CMS Action 78: No changes were made to the protocol in response to this comment. No changes were made to the burden estimates as a result of this comment.

PART C ORGANIZATION DETERMINATIONS, APPEALS AND GRIEVANCES (ODAG)

Comment 79: One commenter identified an error in the total number of cases noted under the Universe Accuracy Standard since Table 13: Dismissals will no longer be evaluated for timeliness.

Response 79: CMS appreciates this comment. We have updated the number of total cases to read "60" rather than "65."

CMS Action 79: CMS updated the number of total cases to read "60" and the number of universes tested to "12" in the Timeliness - Organization Determinations, Appeals and Grievances (TODAG) section of the ODAG protocol. No changes were made to the burden estimate in response to this comment.

Comment 80: A few commenters requested clarification on CMS Program Audit timeliness standards for post-service organization determinations. Particularly, commenters requested confirmation that direct member reimbursements (DMRs) and non-contracted provider (NCP) claims/reconsiderations will be tested against 60 days even though the prompt pay provisions state, "The contract between CMS and the MA organization must provide that the MA organization will pay 95 percent of the clean claims within 30 days of receipt if they are submitted by, or on behalf of, an enrollee of an MA private fee-for-service plan or are claims for services that are not furnished under a written agreement between the organization and the provider."

Response 80: CMS Program Audits test all post-service organization determinations (claims and payment reconsiderations) against 60 days. This standard is for CMS Program Audit purposes only. It does not relieve the sponsoring organization of its obligation to adhere to the prompt pay provisions which can be found at 42 CFR 422.520(a)(1).

CMS Action 80: No changes were made to the protocol in response to these comments. No changes were made to the burden estimate in response to these comments.

Comment 81: One commenter recommended using the disposition 'Pending' rather than 'Denied' in Table 1: SOD, Table 2: EOD, Table 3: Claims, and Table 4: DMR, to identify cases that are both untimely and not yet resolved (still outstanding) since these cases may eventually be approved therefore granting the service or payment.

Response 81: CMS disagrees with this approach. Failure to provide enrollees with timely notice of an organization determination constitutes and adverse organization determination and may be appealed as stated in 42 CFR Subpart M.

CMS Action 81: No changes were made to the protocol in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 82: Several commenters identified an error in the total number of cases selected for review during the appropriateness of clinical decision making portion of a CMS Program Audit.

Response 82: CMS has updated the total number of cases to read "35".

CMS Action 82: Updated the total number of cases to read "35" in the Appropriateness of Clinical Decision-Making & Compliance with Organization Determinations and Appeals Processing Requirements section of the protocol. No changes were made to the burden estimate in response to these comments.

Comment 83: One commenter identified the following language on page 14 was not applicable to grievances based on the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance Manual "…documentation showing when the sponsor acknowledged receipt of the grievance to the enrollee, and/or requested additional information from the enrollee and/or their representative, including the date and time…" Additionally, this commenter stated the grievance record layout has no capacity for date and time of receipt.

Response 83: CMS appreciates the commenter bringing this to our attention. We were unable to identify the language the commenter referenced in the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance Manual. However, CMS agrees that regulations do not require acknowledgement of a grievance. Therefore, language pertaining to acknowledgement of grievances has been removed from the protocol. Further, Table 11: GRV_S requests the date of receipt in Column: Date Grievance/Complaint was Received and Table 12: GRV_E requests the date in Column: Date Grievance/Complaint was Received and the time in Column: Time Grievance/Complaint was Received.

CMS Action 83: CMS removed the reference to documentation that the sponsoring organization acknowledged receipt of the grievance from the Grievances and Misclassification of Requests section of the ODAG protocol. No changes were made to the burden estimate in response to this comment.

Comment 84: A few commenters requested confirmation that dismissals would no longer be included in the timeliness portion of a CMS Program Audit.

Response 84: This is correct. Dismissal timeliness is no longer assessed as part of a CMS Program Audit.

CMS Action 84: No changes were made to the protocol in response to these comments. No changes were made to the burden estimate in response to these comments.

Comment 85: One commenter requested the option of entering HCPCs, NDCs, and/or DME numbers as a response to "Issue Description and type of service" in the applicable record layouts.

Response 85: CMS believes, based on additional feedback we have received from multiple sponsoring organizations, that allowing HCPCs, NDCs, and/or DME numbers may be more burdensome at this time. Therefore, no changes have been made.

CMS Action 85: No changes were made to the protocol in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 86: One commenter recommended removing the field "Level of Service" from all record layouts.

Response 86: CMS agrees with the commenter. The field "Level of Service" has been removed from all applicable ODAG Tables.

CMS Action 86: CMS has removed the "Level of Service" field from ODAG Tables 1 -10 and the ODAG CDM Impact Analysis and from within the "Issue Description Field" in the ODAG PMNT Impact Analysis . No changes were made to the burden estimate in response to this comment.

Comment 87: One commenter requested that CMS use numerical values in Table 13: DIS for the type of request that was received such as '1' for grievances, '2' for pre-service ODs, etc.

Response 87: CMS appreciates the suggestion. At this time, CMS believes it will be more burdensome for all sponsoring organizations to implement this change prior to the start of the 2020 audit year.

CMS Action 87: No changes were made to the protocol in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 88: One commenter requested clarification regarding the issuance of written notices between the previously released Chapter 13 of the MMCM (Issued April 12, 2012) and the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance issued in February, 2019.

Response 88: Sponsoring organizations should contact the CMS policy mailbox at https://appeals.lmi.org for clarification requests pertaining to written notice requirements in the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance issued in February, 2019.

CMS Action 88: No changes were made to the protocol in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 89: A number of commenters identified a discrepancy in Table 10: ALJMACEFF, Column: Request for Expedited Timeframe. The Field Length is identified as '1'. Since NA is an acceptable response, the value should be '2'.

Response 89: CMS appreciates this being brought to our attention. The Field Length value has been updated to reflect '2.'

CMS Action 89: CMS updated Table 10: ALJMACEFF, Column: Request for Expedited Timeframe, to state "2" for the Field Length. No changes were made to the burden estimate in response to these comments.

Comment 90: A few commenters asked how the following exclusion language applies to Table 3: Claims and Table 11: GRV_S: "Exclude requests for extensions of previously approved services, concurrent review for inpatient hospital and SNF services, post-service reviews, and notifications of admissions."

Response 90: CMS agrees this language does not apply to the Table 3: Claims and Table 11: GRV_S. This language has been removed.

CMS Action 90: CMS removed the following exclusion language from the instructions in Table 3 Claims and Table 11: GRV_S. "Exclude requests for extensions of previously approved services, concurrent review for inpatient hospital and SNF services, post-service reviews, and notifications of admissions." No changes were made to the burden estimate in response to these comments.

Comment 91: Two commenters questioned whether or not post-service reviews should still be excluded from Table 1: SOD**.**

Response 91: CMS considered this comment and removed the following exclusion language from all ODAG tables "exclude extensions of previously approved services."

CMS Action 91: Removed "Exclude extensions of previously approved services" from all ODAG Tables. No changes were made to the burden estimate in response to these comments.

Comment 92: A few commenters requested clarification on the Table 13: DIS instructions. Commenters noted that CMS now asks for all cases dismissed by a sponsoring organization. Commenters asked for confirmation on whether or not all dismissed cases should be included.

Response 92: CMS confirms the instructions for Table 13: DIS. It is expected that sponsoring organizations include all cases that were dismissed during the universe period.

CMS Action 92: No changes were made to the protocol in response to these comments. No changes were made to the burden estimate in response to these comments.

Comment 93: A few commenters asked CMS if the Table 1: SOD and Table 2: EOD should include cases that have been both approved and denied since CMS does no longer selects approvals during its Appropriateness of Clinical Decision-Making & Compliance with ODA Processing Requirements review.

Response 93: Table 1: SOD and Table 2: EOD should be populated with both approvals and denials. We confirm that approved OD cases will not be reviewed during appropriateness of clinical decision making. However, to conduct an accurate universe-level timeliness assessment, a full universe of approvals and denials is needed.

CMS Action 93: No changes were made to the protocol in response to these comments. No changes were made to the burden estimate in response to these comments.

Comment 94: A few commenters mentioned the update to regulations which no longer require a sponsoring organization to notify an enrollee of an upheld reconsideration decision. Rather, sponsoring organizations are only required to forward the case to the IRE. Commenters requested clarification on how CMS will assess timeliness with regard to the updated regulatory text found in 42 CFR §422.590.

Response 94: While enrollees no longer need to be notified of upheld decisions, sponsoring organizations are still required to send the case file to the IRE within the same timeframes as notifying the enrollee of an overturned decision. For CMS Program Audits, the notification timeliness test ensures enrollees were notified of overturned decisions and whether or not the sponsoring organization forwarded upheld decision to the IRE within the appropriate timeframes.

CMS Action 94: No changes were made to the protocol in response to these comments. No changes were made to the burden estimate in response to these comments.

Comment 95: Several commenters requested updates to the reconsideration tables (Table 5: SREC, Table 6: EREC, and Table 7: PREC) to more clearly define notice requirements. Specifically, commenters requested changes to the column descriptions that would indicate when sponsoring organizations are required to notify enrollees. Commenters also requested the removal of Column: If request denied or untimely, date enrollee notified request has been forwarded to IRE from Table 4: DMR, Table 5: SREC, Table 6: EREC from the record layouts since sponsoring organizations are no longer required to notify

enrollees their cases have been forwarded to the IRE when reconsidered decisions uphold the initial denial.

Response 95: CMS agrees and updated Tables 4, 5, 6 and 7 to align notice requirements with updated regulations.

CMS Action 95: Within Table 4, CMS has removed Column: If request denied or untimely, date enrollee notified request has been forwarded to IRE.

Within Table 5, CMS has removed Column: Date oral notification provided to enrollee and Column: If request denied or untimely, date enrollee notified request has been forwarded to IRE. CMS revised Column: Date written notification provided to enrollee/provider to read: Date written notification provided to enrollee if the decision was favorable, or if applicable, the non-contract provider. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Otherwise answer NA if denied or no written notification was provided.

Within Table 6, CMS has removed Column: If request denied or untimely, date enrollee notified request has been forwarded to IRE. CMS has revised the description in Column: Date oral notification provided to enrollee to read: Date oral notification provided to enrollee, if decision was favorable. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Otherwise, answer NA if no oral notification was provided.
CMS has revised the description in Column: Time oral notification provided to enrollee to read: Time oral notification provided to enrollee, if decision was favorable. Submit in HH:MM:SS military time format (e.g., 23:59:59). Otherwise, answer NA if no oral notification was provided.
CMS has revised the description in Column: Date written notification provided to enrollee to read: Date written notification provided to enrollee, if the decision was favorable. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Answer NA if denied or no written notification was provided.
CMS has revised the description in Column: Time written notification provided to enrollee to read: Time written notification provided to enrollee, if decision was favorable. Submit in HH:MM:SS military time format (e.g., 23:59:59). Answer NA if denied or no written notification was provided.

Within Table 7, CMS updated the Field Name for Column: Date the reconsideration request was paid or denied to read “Date the reconsideration request was paid” and CMS revised the description for this field by removing the phrase: "or the date the denied claim was upheld, which may be the IRE auto-forward date". CMS has revised the description in Column: Date written notification provided to provider to read: Answer NA if no written notification was provided.

CMS removed Column “If request denied or untimely, date enrollee notified request has been forwarded to IRE” from the ODAG CDM Impact Analysis. No changes were made to the burden estimate in response to these comments.

Comment 96: One commenter asked CMS why the following compliance standard was removed and, requested that it be added back in, “Did the enrollee get a clinically equivalent or alternate service, if applicable?”

Response 96: CMS removed this compliance standard as it is no longer assessed for CMS Program Audits.

CMS Action 96: No changes were made to the protocol in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 97: One commenter wanted to ensure CMS accounted for the additional timeframes allotted to overturned reconsideration cases made after the adjudication timeframe but within 24 hours of the expiration of the timeframe. This commenter requested that language be added to indicate cases such as these will not be marked untimely if the decision is made within 24 hours of the expiration of the timeframe.

Response 97: CMS disagrees with the proposed update. Fully favorable reconsideration cases that miss the adjudication timeframe are considered late per the applicable regulations. In these instances, guidance allows a sponsoring organizations to notify the enrollee of the overturned decision in lieu of forwarding the case to the IRE so long as this is completed within 24 hours of the expiration of the timeframe. For CMS Program Audits, a sponsoring organization will not be cited for failing to forward cases such as these to the IRE. However, the case will still be marked as untimely for notification of an overturned decision.

CMS Action 97: No changes were made to the protocol in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 98: Two commenters requested clarification and updates to the "Was the request denied for lack of medical necessity" field in the reconsideration record layouts (Table 5: SREC, Table 6: EREC, Table 7: PREC). One commenter questioned why dismissed cases would be referenced in the field description as an option, since, if the case was dismissed it would not be included in the reconsideration tables. Another commenter requested an update to the ODAG tables to mirror the field names in CDAG. This commenter requested an update to the field description to read, "Answer NA if the initial request was not denied for medical necessity."

Response 98: CMS appreciates the comments. We agree with both commenters and, as a result, have updated Table 1: SOD, Table 2: EOD, Table 3: Claims, Table 5: SREC, Table 6: EREC and Table 7: PREC. CMS has modified the Table 1: SOD, Table 2: EOD, and Table 3: Claims by removing the field, "If request denied for lack of medical necessity, was the review completed by a physician or other appropriate healthcare professional?" Additionally, CMS has modified Table 5: SREC, Table 6: EREC, and Table 7: PREC by removing the following two fields: "If denied for lack of medical necessity, was the review completed by a physician or other appropriate health care professional?" and "If the request was denied for lack of medical necessity, was the reconsideration completed by a physician other than the person involved in making the initial OD?" Additionally, CMS has updated Table 5: SREC, Table 6: EREC, and Table 7: PREC to mirror CDAG. CMS has updated the field description to read, "Was the organization determination denied for lack of medical necessity? Yes (Y)/No (N) indicator of whether the initial request was denied for lack of medical necessity."

CMS Action 98: Removed the field "If denied for lack of medical necessity, was the review completed by a physician or other appropriate health care professional?" from the Table 1: SOD, Table 2: EOD, Table 3: Claims, and Table 7: PREC. CMS removed the column, "If denied for lack of medical necessity, was the review completed by a physician or other appropriate health care professional?" and "If the request was denied for lack of medical necessity, was the reconsideration completed by a physician other than the person involved in making the initial OD?" from the Table 5: SREC and Table 6: EREC. CMS updated the field description for "Was the request denied for lack of medical necessity?" to read "Was the organization determination denied for lack of medical necessity? Yes (Y)/No (N) indicator of whether the initial request was denied for lack of medical necessity" for Table 5: SREC, Table 6: EREC, and Table 7: PREC. No changes were made to the burden estimate in response to these comments.

Comment 99: One commenter requested the removal of the following language from the timeliness test portion of the ODAG protocol as it general does not apply:

- Notices, letters, call logs or other documentation showing the sponsor requested additional information (if applicable) from the requesting provider/physician, including date, time, and type of communication. If the request was made via phone call, copy of the call log detailing what was communicated to the physician/provider.
- All supplemental information submitted by the requesting provider/physician or enrollee, including documentation showing when information was received by the sponsor.
- Documentation of case review steps including name and title of final reviewer; rationale for denial; any reference to CMS guidance, Federal Regulations, clinical criteria, peer reviewed literature (where allowed), and sponsor documents (e.g., Evidence of Coverage (EOC)); or any other documentation used when considering the request.

Response 99: CMS agrees and has removed this language from the ODAG protocol.

CMS Action 99: CMS removed the following language from the timeliness portion of the ODAG protocol:

- Notices, letters, call logs or other documentation showing the sponsor requested additional information (if applicable) from the requesting provider/physician, including date, time, and type of communication. If the request was made via phone call, copy of the call log detailing what was communicated to the physician/provider.
- All supplemental information submitted by the requesting provider/physician or enrollee, including documentation showing when information was received by the sponsor.
- Documentation of case review steps including name and title of final reviewer; rationale for denial; any reference to CMS guidance, Federal Regulations, clinical criteria, peer reviewed literature (where allowed), and sponsor documents (e.g., Evidence of Coverage (EOC)); or any other documentation used when considering the request.

No changes were made to the burden estimate in response to this comment.

Comment 100: One commenter requested that CMS clarify whether sponsoring organizations should exclude requests that do not require prior authorization from Tables 1: SOD and Table 2: EOD. The commenter also asked why Sponsor (S) and Contracted Provider (CP) are not included as options in the Field Description column when they are included in Column: Subsequent expedited request of Table 2 which appears to be seeking the same data.

Response 100: Sponsoring organizations should continue to exclude requests that do not require prior authorization from Tables 1: SOD and Table 2: EOD. We believe the commenter was seeking clarification regarding the absence of options for Sponsor (S) and Contracted Provider (CP) within Column: Request for expedited timeframe of Table 1: SOD. We gave further consideration to this comment and have decided to remove this Column from both Table 1: SOD and Table 2 EOD. Subsequent requests to expedite a case that are processed as such will be in Table 2: EOD.

CMS Action 100: We have updated the exclusion criteria in ODAG Tables 1 and 2 to clarify that requests that do not require prior authorization should be excluded. We have also removed Column: Request for expedited timeframe from Table 1: SOD and Column: Subsequent expedited request from Table 2: EOD. No changes were made to the burden estimate in response to this comment.

SPECIAL NEEDS PLAN MODEL OF CARE (SNP-MOC)

Comment 101: Two commenters noted that SNP-MOC Protocol Table 1 is referred to as SNPE in the table of contents but referred to as PE on page 5.

Response 101: CMS corrected the reference on page 5 of the SNP-MOC protocol.

CMS Action 101: CMS has updated the reference on page 5 of the SNP-MOC protocol to read "Special Needs Plan Enrollees (SNPE) Record Layout (Table 1)". No changes were made to the burden estimate in response to these comments.

Comment 102: Two commenters asked CMS to consider removing the following fields from the Table 1: Special Needs Plan Enrollees (SNPE) Record Layout as they provide little visibility to the model of care process conducted by sponsoring organizations: Column: Cumulative Dollar Amount of Parts C & D Claims Paid, Column: Cumulative Dollar Amount of Parts C & D Claims Denied, Column: Cumulative # of Parts C & D Claims Paid, and Column: Cumulative # of Parts C & D Claims Denied.

Response 102: We appreciate the commenters' suggestions, however CMS requires these fields for sampling purposes. CMS will consider the necessity of these fields for future protocols.

CMS Action 102: No changes were made to the protocol in response to these comments. No changes were made to the burden estimates as a result of these comments.

Comment 103: A commenter noted that CMS removed the option to submit universes in delimited .txt file format with no header row and asked if this was an intentional omission.

Response 103: CMS agrees that an update to the SNP-MOC protocol is required and has added text files as a permissible universe file format.

CMS Action 103: CMS updated the language within the Universe Prep and Submission section of the SNP-MOC protocol to read, "Sponsoring organizations should submit each universe in the Microsoft Excel (.xlsx) file format with a header row (or Text (.txt) file format without a header row) following the record layouts shown in Appendix A, Tables 1 and 2." CMS also added the following language to Appendix A, "(or Text (.txt) file format without a header row)". No changes were made to the burden estimate in response to this comment.

Comment 104: One commenter asked, for the scenario where an enrollee has a legal mono-name, whether it would be permissible to enter the mono-name as both the First Name and Last Name in the SNP Record Layouts.

Response 104: Yes, it is permissible to enter a legal mono-name in both the First Name and Last Name fields of the Record Layout.

CMS Action 104: No changes were made to the protocol in response to this comment. No changes were made to the burden estimates as a result of this comment.

Comment 105: A commenter requested clarification on SNP-MOC compliance standard 2.5.1. The commenter asked if the intent was to change the protocol standard question to assess this requirement for the ICP and not HRA. The commenter also requested clarification on the intent of adding "CMS Requirements" to this protocol standard question since MOCs align to CMS requirements found in Chapter 5 of the Medicare Managed Care Manual.

Response 105: CMS' intention was to update compliance standard question 2.5.1 to assess the requirement for both the ICP and the HRA. CMS has updated compliance standard question 2.5.1 to read, "Did the personnel who reviewed, analyzed, developed and implemented the HRA and ICP possess appropriate professional knowledge and credentials, as defined in the MOC". For consistency with other

compliance standards, CMS has also removed the phrase "and CMS requirements" from compliance standard 2.5.1 and has added the following language to the Apply Compliance Standard Section of the SNP-MOC protocol, "CMS will defer to regulatory requirements in absence of an applicable clause in the MOC."

CMS Action 105: CMS reworded compliance standard question 2.5.1 and added clarifying language to the Apply Compliance Standard Section of the SNP-MOC protocol. No changes were made to the burden estimate in response to this comment.

Comment 106: A commenter suggested that CMS remove SNP-MOC compliance standard 2.5.2 (Did the personnel who reviewed the ICP possess professional knowledge and credentials, as defined in the MOC) because it is redundant of compliance standard 2.5.1 (Did the personnel who reviewed, analyzed, developed and implemented the ICP possess appropriate professional knowledge and credentials, as defined in the MOC?).

Response 106: CMS agrees with the commenter's suggestion and has removed compliance standard 2.5.2 from the SNP-MOC protocol.

CMS Action 106: CMS removed the compliance standard that read, “Did the personnel who reviewed the ICP possess professional knowledge and credentials, as defined in the MOC” from the SNP-MOC protocol and renumbered the following two compliance standards accordingly. No changes were made to the burden estimate in response to this comment.

Comment 107: A commenter suggested that CMS revise the SNP-MOC compliance standard that reads: ‘Have appropriate staff (employed, contracted, or non-contracted) trained on the SNP plan model of care to coordinate and/or deliver all services and benefits?’ to read, "Have all members of the sponsoring organization’s staff (employed, contracted, or non-contracted) that serve on the ICT received training on the SNP plan model of care to coordinate and/or deliver all services and benefits?"

Response 107: CMS accepts the commenter's suggestion.

CMS Action 107: We have updated the compliance standard to read, "Have all members of the sponsoring organization’s staff (employed, contracted, or non-contracted) that serve on the ICT received training on the SNP plan model of care to coordinate and/or deliver all services and benefits?" No changes were made to the burden estimate in response to this comment.

Comment 108: A commenter noted that the crosswalk indicated the example dates in the Review Period section of the SNP-MOC protocol were updated, however they still appeared to be the same.

Response 108: CMS has updated the Review Period within the Audit Purpose and General Guidelines section of the SNP-MOC protocol to read, "(for example, for an engagement letter sent on March 9, 2020, the universe review period would be February 1, 2019 through March 9, 2020).”

CMS Action 108: CMS has updated the Review Period example dates in the SNP-MOC protocol. No changes were made to the burden estimate in response to this comment.

Comment 109: One commenter inquired as to whether a SNP questionnaire would be included in this collection request.

CMS Response 109: In audit year 2019, our process was to collect oral responses to questions related to the sponsoring organization's SNP. However, some sponsoring organizations preferred to provide this information in written format. Therefore, we have added the SNP questionnaire to this PRA package.

CMS Action 109: We have included the SNP questionnaire in this collection request. No changes were made to the burden estimate in response to this comment.