

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

CMS received 24 public submissions, which included 155 comments on the December 27, 2019, (CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests proposed information collection. We then combined the 155 comments into 74 unique comments and provided responses in the document below. Comments are categorized in the following order: those that are general in nature, those that pertain to the Pre-Audit Issue Summary (PAIS), those pertaining to more than one program area and, finally, those that apply to the individual program areas.

GENERAL COMMENTS

Comment 1: Two commenters expressed support of CMS' on-going effort to make the program audits meaningful and to reduce regulatory burdens for sponsoring organizations. Another commenter welcomed the updates made to the CMS Program Audit Protocols applicable to 2021 audits as it has removed redundancy and therefore increases efficiency, however noted that some of the proposed changes in CMS-10717 OMB 0938-NEW would require substantial changes to systems. The commenter also requested for CMS to consider using the July, 2019 version (announced via 84 FR 41991) of the protocols for the 2020 Program Audit year and consolidating the November, 2019 (announced via 84 FR 66912) and December, 2019 (announced via 84 FR 71427) changes for implementation for 2021 Program Audits. Another commenter expressed appreciation for CMS' efforts to reduce burden by eliminating numerous fields across the universes and enhance data consistency by standardizing field names and formats. The commenter noted that sponsoring organizations need sufficient time to modify universe queries to test and validate the changes and that sponsoring organizations will likely have less than a month to implement these changes as CMS intends to start issuing audit notices in March. The commenter recommended that CMS defer sending audit notices out until April, 2020 to afford sponsoring organizations sufficient time to thoroughly test and validate all of the proposed universe changes.

Response 1: We appreciate the commenters support. CMS has aimed to eliminate redundancy in data collection and streamline the audit process. With respect to 2021 protocols, the commenter is referring to CMS-10717 OMB 0938-NEW which is outside the scope of this request. For additional information pertaining to universe periods beginning in audit year 2021, please refer to the instructions in 84 FR 66912. With respect to the subject collection request, CMS acknowledges that sponsoring organizations need sufficient lead time to operationalize changes to program audit data collection and submissions. As such, CMS has minimized updates in the interest of limiting programming updates and providing sponsoring organizations with as much time as possible to prepare for 2020 audits. At this time, CMS believes it would be more burdensome for all sponsoring organizations to revert back to a prior version of the protocols (OMB No: 0938-1000 (Expires: 04/30/2020) CMS-10191), and notes the prior versions do not account for regulatory updates that have since been finalized. CMS notes that the timing of sending routine program audit engagement letters to sponsoring organizations is outside of the scope of this collection request, however CMS will take this request into consideration.

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: A commenter recommended that CMS provide the universes in an Excel format as well as the current PDF format.

Response 2: All of the information requested by CMS is detailed in the individual record layouts within the data collection documents. Sponsoring organizations are responsible for submitting universes to CMS inclusive of all of the information contained in each record layout, and as specified in the instructions of the data collection documents. Because the instructions in the data collection documents allow for universes to be submitted in formats other than Excel, CMS does not believe a standard template is needed.

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

Comment 3: A commenter asked if the audit submission checklist will be included with the audit protocols again and stated they found the document helpful for tracking due dates.

Response 3: We appreciate the commenter's feedback on the usefulness of Audit Submission Checklist. As the commenter noted, this document serves as a comprehensive reference tool to guide sponsoring organizations on submission deadlines connected to a program audit, as outlined in the individual protocols. 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, a blank Audit Submission Checklist template 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 3: No changes were made to the protocols in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 4: Two commenters asked CMS to clarify language in its 2020 Program Audit Process Overview document.

Response 4: Because this document does not collect information from the sponsoring organization undergoing a program audit, it has not been included in this collection request, and the comments received are outside of the scope of this collection request. For questions related to the program audit process, please contact the program audit mailbox at part_c_part_d_audit@cms.hhs.gov.

CMS Action 4: 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 5: One commenter referred to the draft 2020 MMP Program Audit Protocols that are undergoing public comment. The commenter asked whether CMS also intends to share 2021 MMP Program Audit Protocols for public comment.

Response 5: Although this comment is beyond the scope of this collection request, CMS intends to share draft 2021 MMP Program Audit Protocols in a manner similar to the way in which the 2020 MMP Program Audit Protocols were circulated for comment.

CMS Action 5: 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.

PRE-AUDIT ISSUE SUMMARY (PAIS)

Comment 6: One commenter requested that CMS clarify whether MMP-SARAG and MMP-CCQIPE issues should be included or excluded from the PAIS.

Response 6: In instances where a sponsoring organization's 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 6: No changes were made to the protocols in response to this comment. No changes were made to the burden estimate in response to this comment.

MULTIPLE PROGRAM AREAS

Comment 7: Five commenters recommended that CMS delay transition from the Cardholder ID to the Medicare Beneficiary Identifier (MBI). Commenters stated the change provides limited time for sponsoring organizations to ensure operational readiness and would affect the reporting burden on sponsoring organizations because programming changes would be required.

Response 7: Starting January 1, 2020, all Medicare Advantage (MA) and Prescription Drug Plans (PDPs) were required to use the Medicare Beneficiary Identifier (MBI) for Medicare transactions. Since the transition period has ended, the MBI must be submitted for CMS Program Audits.

CMS Action 7: 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 8: One commenter asked which MBI should be used to populate each universe, the MBI received with the request or the current or most recent MBI.

Response 8: Sponsoring organizations should include the MBI received with the request.

CMS Action 8: 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 9: A commenter asked if "0000000000" could be populated for compound claims in situations other than when the compound claim does not include any Part D drug products.

Response 9: Per the existing NDC field description, for multi-ingredient compound claims the field should be populated with the NDC of the most expensive drug (or as submitted on the associated PDE).

CMS Action 9: No changes were made to the protocols in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 10: A commenter asked how to populate the NDC field if the pharmacy or delegate submits it as blank.

Response 10: Per the Data Request record layouts, when a blank field is submitted by the pharmacy or delegate, the sponsoring organization should populate the field as submitted.

CMS Action 10: 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 11: 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 11: 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 11: 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 12: A commenter asked which protocols will be used for the 2021 Timeliness Monitoring Project (TMP).

Response 12: The universe record layouts from the 2020 program audit protocols, finalized in this collection request, will be used for TMP in 2021. We also note that 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 12: 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 13: A commenter noted the December 30, 2019, revisions to the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance changed the criteria to meet the verbal notification requirements (*i.e.* from a documented good faith attempt to leaving a voicemail or speaking directly with the enrollee or representative). The commenter stated that the adjudication timeframe for expedited cases can be as little as 24 hours and that the notification requirements may not be met with the new criteria if the phone number cannot be reached. The commenter noted they have drafted comments to CMS to address this policy issue. For program audit purposes, two commenters asked how to populate the "Date oral notification provided to enrollee" and "Time oral notification provided to enrollee" fields when a good faith attempt is completed, or when the outreach is successful with a voicemail or directly speaking with the enrollee or representative. One of these commenters asked if voicemails asking an enrollee to contact the sponsoring organization would be considered a successful verbal notice. A commenter also asked how timeliness will be calculated in light of good faith effort language being removed from the CDAG and ODAG record layouts.

Response 13: Policy questions should be directed to the CMS policy mailbox <https://appeals.lmi.org>. Please see section 10.5.3 of the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance (effective January 1, 2020) for more information on when notification is

considered delivered. In assessing notification for CMS Program Audit timeliness purposes, CMS does not deviate from the notification timeframes identified in 42 CFR Parts 422 and 423 Subpart M.

CMS Action 13: 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.

COMPLIANCE PROGRAM EFFECTIVENESS (CPE)

Comment 14: Several commenters asked that CMS clarify sponsoring organizations' responsibilities in verifying individuals against the OIG and GSA exclusions databases given that CMS has removed this reference from the CPE Organizational Structure PPT. One commenter asked whether there is still a regulatory requirement to review the exclusion databases and asked why CMS decided not to include the OIG/GSA exclusion process in the CMS Program Audit. This commenter requested that CMS not remove the requirement even though it will not be reviewed during the CMS Program Audit.

Response 14: Although CMS will no longer evaluate sponsoring organizations' processes for screening individuals against the OIG/GSA exclusion lists as part of its Medicare Part C and Part D program audit beginning in audit year 2020, CMS clarifies that it is not removing requirements under which this audit test was previously conducted. Rather, CMS' compliance standards related to GSA/OIG exclusion list screening were removed from the 2020 program audit protocols to avoid overlap with other oversight activities currently conducted within CMS.

CMS Action 14: 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 15: Two commenters requested that CMS provide additional detail outlining the way in which it will assess the adequacy of call routing including consideration of input collected from the new question in the CPE Compliance Officer Questionnaire: "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." The commenter requested that CMS provide additional information as to what kind of oversight would be acceptable if call routing and classification does not prioritize high enough on a sponsoring organization's risk assessment and therefore did not result in auditing and/or monitoring from its compliance department.

Response 15: With the removal of the CDAG and ODAG call log universes, proper routing and follow up of calls will now be assessed through the CPE review, as facilitated by the question referenced in the commenter's remarks. The CMS audit team will ask follow up questions during the interview, as necessary, to determine whether sponsoring organizations have measures that prevent, detect, and correct non-compliance related to defining and processing requests according to program requirements. CMS defers to sponsoring organizations to determine which risks they consider when establishing and implementing a system for routine monitoring and identification of compliance risks and will ask questions during the interview to get a better understanding of the considerations made by the sponsoring organization.

CMS Action 15: 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 16: One commenter expressed support for the proposed 26-week universe timeframe for Compliance Oversight Activities for audit year 2021 with the note that CMS may expand this, if needed, to obtain a universe of sufficient size.

Response 16: The commenter is referring to CMS-10717 OMB 0938-NEW which is outside the scope of this request. If approved by OMB, this collection request (CMS-10191) would be implemented for audit year 2020 and CMS-10717 would replace 10191 beginning in audit year 2021. For additional information pertaining to universe periods beginning in audit year 2021, please refer to CMS-10717.

CMS Action 16: No changes were made to the protocols in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 17: One commenter requested that CMS clarify whether the tracer presentations alone or the tracer presentations and supporting documentation must be submitted on the date of the entrance conference. The commenter also asked whether the sponsoring organization would have the choice of uploading documentation in support of the tracer summary to HPMS at the time the tracer summary is due or to present the supporting documentation to CMS during the onsite CMS audit.

Response 17: The tracer presentations are due on the day of the entrance conference so that auditors may begin their desk review of tracer presentations before arriving onsite. While some sponsoring organizations choose to submit supporting documentation to CMS as part of their tracer presentation submission in an effort to reduce the number of questions asked by auditors during the onsite review, other sponsoring organizations wait to share supporting documentation with auditors while they are onsite conducting tracer presentation reviews. Should CMS need to collect supporting documentation from a sponsoring organization as a result of the tracer presentation review, sponsoring organizations will have two business days after the tracer review is concluded to provide the supporting documentation through HPMS.

CMS Action 17: No changes were made to the protocols in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 18: Two commenters referred to the removal of the "Contract Effective Date" within CPE Table 1. One commenter asked whether sponsoring organizations could remove this column when submitting their universes or if they should populate it with NR for not required. Another commenter requested that we retain the column indicating that sponsoring organizations do not have enough time to make these programming changes. That commenter further noted that this data indirectly assists sponsoring organizations in tracking new contracts for the pre-delegation process and assists CMS auditors in the tracer selection and review process.

Response 18: We appreciate the commenters input however, we do not believe that this data is necessary for CMS Program Audit purposes. In the interest of streamlining and consolidating audit collection instruments we are finalizing our edit to remove the "Contract Effective Date" column from Table 1: First-Tier Entity Auditing and Monitoring (FTEAM) Record Layout. As a result, this data will no longer be collected.

CMS Action 18: 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 19: One commenter referred to the following language that CMS added to the description field for the Column titled "Compliance or FWA" in CPE Tables 1, 3 and 4: "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." The commenter stated that sponsoring organizations do not have enough time to make all of the changes set forth in this collection request and

recommended that CMS allow sponsoring organizations to indicate both Compliance and FWA by using a slash between them (*e.g.*, Compliance/FWA).

Response 19: The additional language to which the commenter refers was added in response to input received during the 60 day comment period. However, CMS would also accept an entry of "Compliance/FWA" in this field in instances where issues are related to both compliance and FWA.

CMS Action 19: No changes were made to the protocols in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 20: One commenter requested that CMS clarify whether sponsoring organizations may continue to exclude employees who do not support the Medicare Parts C and/or D line of business from the CPE Table 2: Employees and Compliance Team (ECT) Record Layout. The commenter further noted that to expand the data collection beyond employees that support the Medicare Parts C and/or D line of business would significantly increase burden.

Response 20: We clarify that our intent in removing the phrase "or do not work on the Medicare Parts C and/or D line of business" from the exclusion criteria 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 20: No changes were made to the protocols in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 21: One commenter stated that it would be helpful to allow the sponsoring organization the ability to specify the type of auditor/monitor (*e.g.*, external auditor or monitor) within the Auditor Type field of the Table 3: Internal Auditing (IA) Record Layout and the Monitor Type field of the Table 4: Internal Monitoring (IM) Record Layout.

Response 21: We do not believe that additional clarification is necessary given that the Auditor Type and Monitor Type description columns currently allow for the identification of external auditors or monitors.

CMS Action 21: No changes were made to the protocols 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 22: One commenter asked whether sponsoring organizations are required to populate Prescription Drug Event (PDE) data in the FA universe, stating that organizations already supply that data to CMS twice monthly.

Response 22: As part of the process of undergoing a program audit, sponsoring organizations are required to submit all final action PDEs accepted by CMS with dates for service in September through December of the contract year immediately prior to the audit year, as this information is necessary for sampling purposes.

CMS Action 22: No changes were made to the protocols in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 23: One commenter compared the FA protocol that has been in place for audit years 2017 through 2019 to the FA protocol included in this collection request and noted that the description of sample case selection no longer specifies the number of non-protected class verses protected class drug claims that will be pulled from the rejected claims universes. The commenter was concerned about the possibility of the audit capturing an unbalanced number of protected class verses non-protected class claims and also lead to more conditions requiring immediate corrective action, or ICARs, to the extent that more protected class cases lead to findings.

Response 23: Based on CMS' prior audit experience, we have not had a situation where more protected class samples were disproportionately selected. It is possible that we may have more non-protected class samples than protected class due to limited sample selections based on the universe. Despite the possibility that the number of samples selected from protected class versus non-protected class claims may not be equal, we do not believe that this would impact the identification of potential non-compliance issues. Lastly, when a potential issue is identified and an impact analysis is requested, all impacted drugs, regardless of protected class versus non-protected class status, must be included. A thorough analysis of the total dataset including the root cause is paramount for condition classification of a non-compliance issue.

CMS Action 23: No changes were made to the protocols in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 24: One commenter asked whether, in cases that the pharmacy submits a value greater than 11 characters in the NDC field, it would be acceptable for sponsoring organizations to populate the NDC field of FA universes with ""valueXeeded."

Response 24: As reflected in the 60-day collection request, we maintain that in instances where the pharmacy submits a value greater than 11 characters in the NDC field, sponsoring organizations should populate the NDC field of FA universes with ""valueXeeded."

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

Comment 25: One commenter noted that the NDC field description was updated to remove the Uniform Product Code (UPC) or Health Related Item Code (HRI). The commenter asked whether, for instances that the pharmacy submits the UPC or HRI, the sponsoring organization should include it in its universe submission.

Response 25: Yes; sponsoring organizations should include the value as submitted by the pharmacy.

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

PART D COVERAGE DETERMINATIONS, APPEALS, AND GRIEVANCES (CDAG)

Comment 26: One commenter agreed with all of the updates CMS made to the majority of the CDAG record layouts.

Response 26: CMS appreciates the feedback. We attempted to provide clarification and remove data fields where possible as part of an on-going effort to reduce burden for sponsoring organizations.

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

Comment 27: One commenter stated that the requirement to provide an explanation of why the initial coverage determination was denied was new for the CDAG "Issue Description" field and stated that sponsoring organizations will have to develop a process for tracking the information. The commenter also stated that because of the timing of the 2020 audits this would likely be problematic.

Response 27: We are not sure why the commenter believes that this is a new requirement. The "Issue Description" field has not been changed and previously read "Provide a description of the issue and, for denials, an explanation of why the decision was denied."

CMS Action 27: No changes were made to the protocols in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 28: A commenter asked if CMS could remove the "Enrollment effective date" field from the CDAG record layouts.

Response 28: CMS acknowledges that sponsoring organizations need sufficient lead time to operationalize changes to program audit data collection and submissions. In the interest of limiting programming updates and providing sponsoring organizations with as much time as possible to prepare for 2020 audits, CMS will not be removing the "Enrollment effective date" field from the CDAG record layouts.

CMS Action 28: No changes were made to the protocols in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 29: Several commenters asked what sponsoring organizations should enter in the date and time written notice was provided to the enrollee fields for cases where an appeal is auto-forwarded to the Independent Review Entity (IRE).

Response 29: Sponsoring organizations would enter NA if no written notification of the decision was provided to the enrollee. These fields should not be populated with the date the sponsoring organization sends an auto-forward notice to the enrollee.

CMS Action 29: 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 30: Several commenters asked how to populate the "NDC" field for appeals of at-risk determinations when there is no specific drug under appeal.

Response 30: To accommodate at-risk redeterminations, CMS has added clarification within the NDC field description for CDAG Tables 6 and 8 to indicate that when less than 11 characters or a blank field is submitted by the pharmacy or delegate, or NDC is not applicable (e.g., for at-risk redeterminations), the sponsoring organization is instructed to populate the field as submitted.

CMS Action 30: CMS added "or NDC is not applicable (e.g., for at-risk redeterminations)" to the NDC field description for CDAG Tables 6 and 8 such that it now reads: "When less than 11 characters or a blank field is submitted by the pharmacy or delegate, or NDC is not applicable (e.g., for at-risk redeterminations), populate the field as submitted." No changes were made to the burden estimate in response to these comments.

Comment 31: Several commenters noted there was a change to the "NDC" field description and NA can no longer be entered. Commenters noted when coverage determinations are requested by a provider or enrollee, the NDC is not always provided; commenters requested for CMS to add an NA option to the CDAG NDC field. One commenter asked what a sponsoring organization should do if they do not have access to the information. One commenter requested for the NDC field description updates to be deferred because sponsoring organizations will need to make changes to systems logic to accommodate the proposed change. Two commenters expressed appreciation for CMS' effort to drive consistency across the FA and CDAG audit protocols by standardizing the field description. Another commenter recommended a change to the NDC field description in the CDAG Data Request to allow sponsoring organizations to enter "0000000000" if the NDC is unknown.

Response 31: During the 60-day comment period, CMS received a request to standardize the "NDC" field description since the CDAG field description differed from the one found in the FA protocol. CMS agreed with the commenter's suggestion and standardized the "NDC" field in the CDAG and FA protocols. At this time, CMS believes it will be more burdensome for all sponsoring organizations to revert back to the prior version of the NDC field description as it was made consistent with the FA protocol and several commenters expressed appreciation for the consistency. In addition, we maintain that allowing for the submission of a blank in the NDC field description accommodates instances where the NDC is not available. Therefore, we do not believe that it is necessary to add the option of "NA" within the NDC field description. We decline to adopt the commenter's suggestion to enter "0000000000" if the NDC is unknown because, per the existing field description, this entry is for cases where compound claims do not include any Part D drug products.

CMS Action 31: No changes were made to the protocols in response to this comment. No changes were made to the burden estimate in response to these comments.

Comment 32: A commenter asked if the NDC being requested should come from the rejected claim that generated the prior authorization (PA) request or from the paid claim on the authorization.

Response 32: When the PA request has an associated rejected claim, sponsoring organizations should provide the NDC from the rejected claim that generated the PA request.

CMS Action 32: No changes were made to the protocols in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 33: A commenter asked if it would be acceptable to populate the "NDC" field with the Generic Product Identifier (GPI).

Response 33: Sponsoring organizations are instructed to populate the "NDC" field with the 11-Digit National Drug Code as stated in the "NDC" field description.

CMS Action 33: No changes were made to the protocols in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 34: A commenter noted that CMS updated the NDC field description and removed "withdrawn" from the Request Disposition field description and asked for clarification because within the NDC field description there is no reference to "withdrawn".

Response 34: CMS believes that the commenter may be referring to two separate updates that were made to the CDAG Data Request and summarized in the crosswalk as a single line item. First, CMS

updated the NDC field for consistency with the FA Data Request. Second, CMS also removed "withdrawn" from the "Request Disposition" field description. Although grouped together in the crosswalk, these changes were unrelated to one another.

CMS Action 34: 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 35: Two commenters asked CMS to clarify under what circumstances the safety edit exception option should be used. Another commenter asked if the new addition of "safety edit exception" to the "Exception Type" field could only be used if a sponsoring organization has a hard edit on the morphine milligram equivalents (MME). A couple of commenters asked if the addition of "safety edit exception" to the Exception Type field could be deferred until 2021 and if CMS could allow sponsoring organizations to report opioid exceptions in one of the existing values. Several commenters also asked if "safety edit exception" should be added to the "Exception Type" field for Tables 6 and 8. Two commenters noted that a Formulary UM Exception Type is unavailable when the exception is due to a safety edit.

Response 35: Sponsoring organizations may enter "Safety edit exception" in the "Exception Type" field for any type of safety edit. In the previous comment period, a commenter requested for CMS to update the description for the Exception Type field to account for opioid requests. As the commenter noted, there was previously no entry available for opioid requests in the CDAG Data Request. CMS believes this addition is necessary and will not be removing the safety edit exception language. CMS did not previously receive a comment requesting for the "safety edit exception" language to be added to Tables 6 and 8, however CMS agrees with the commenters and has added the "safety edit exception" language to Tables 6 and 8. The commenters correctly noted that a Formulary UM Exception Type is unavailable when the exception is due to a safety edit. For these cases, sponsoring organizations may enter NA if the request was not a formulary UM exception, as noted in the protocol.

CMS Action 35: CMS added "safety edit exception" to the "Exception Type" field description for CDAG Tables 6 and 8. No changes were made to the burden estimate in response to these comments.

Comment 36: A commenter requested that CMS use numerical values in the "Issue Description" and "Was the coverage determination request denied for lack of medical necessity?" field descriptions for CDAG Tables 6 through 8.

Response 36: 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 36: No changes were made to the protocols in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 37: A commenter disagreed with CMS' addition of "Enter NP if the payment has not been issued at the time of the universe submission" to the "Date reimbursement provided" field for CDAG Tables 3 and 10 because there is not much time to reprogram to identify cases that would need NP.

Response 37: In the previous comment period, it was noted that there was 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. In the prior version of the protocol, there was no option to enter if the payment had not been issued at the time of the universe submission. As such, CMS updated the "Date reimbursement provided" field description to include

"Enter NP if the payment has not been issued at the time of the universe submission." CMS believes this field description required clarification and will not be removing the NP addition.

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

Comment 38: A commenter asked how to populate the "Date prescriber supporting statement received" and "Time prescriber supporting statement received" fields for a couple of different scenarios. First, how to populate the fields if a physician supporting statement is provided with the initial request and no additional information is requested from the physician. Second, how to complete the fields if the sponsoring organization completes outreach to the physician and doesn't receive enough information to complete the coverage determination. Third, how to populate the fields if a case is initiated by an enrollee with all the information needed to make a decision about an exception request and no supporting statement is requested.

Response 38: For the first scenario, the fields would be populated with the date and time the initial request was received. For the second scenario, we point the commenter to the table instructions in the CDAG Data Request to "submit cases based on the date the sponsoring organization's decision was rendered or should have been rendered (the date the request was initiated may fall outside of the review period)." If this instruction applies to the request, the sponsoring organization can enter NA for the "Date prescriber supporting statement received" and "Time prescriber supporting statement received" fields for the second scenario. For the third scenario, the applicable regulations at 42 CFR § 423.578 require a prescribing physician or other prescribers oral or written supporting statement for exceptions requests.

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

Comment 39: A commenter asked if CMS could add language to the CDAG protocol to exclude preclusion list determinations.

Response 39: 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 Data Request record layout instructions. 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 39: 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 40: A commenter asked if sponsoring organizations should include requests that are pending an Appointment of Representative (AOR) form.

Response 40: Sponsoring organizations may exclude cases where a decision has been made but the decision has not been issued while it awaits the appropriate representative documentation.

CMS Action 40: 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 41: A commenter requested that CMS add the following language to the Responding to Universe Requests section of the CDAG Data Request instructions, "(e.g. sponsoring organizations will

not be allowed to resubmit universes after auditors have shared timeliness test results with the sponsoring organization)."

Response 41: 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 41: 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 42: A commenter asked if CMS could add NA as an option for the "Was this request processed as an exception?" and "Was the coverage determination request denied for lack of medical necessity?" fields for reimbursement requests.

Response 42: 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 42: 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 43: For the "Date reimbursement provided" field, a commenter asked if the date, NRD and NP options are for approved requests only.

Response 43: Sponsoring organizations should populate the "Date reimbursement provided" field based on the status of the reimbursement at the time of universe submission. Sponsoring organizations would enter either the date the check or reimbursement was provided to the enrollee, NRD if the request was approved but no reimbursement was due to the enrollee, NP if the payment has not been issued at the time of the universe submission, or NA if the request was not approved.

CMS Action 43: 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.

PART C ORGANIZATION DETERMINATIONS, APPEALS, AND GRIEVANCES (ODAG)

Comment 44: Two commenters asked for clarification regarding requests that do not require a prior authorization (PA). Specifically, they asked if an enrollee/provider submits a request for a service that does not require a PA, must these be included in the ODAG Record Layouts.

Response 44: Sponsoring organizations must include all requests for services made by, or on behalf of, an enrollee. If an enrollee (or provider acting on behalf of an enrollee) requests a PA where one is not needed, they are requesting the sponsoring organization make and issue a decision. These are organization determinations that must be included in the appropriate record layout.

CMS Action 44: 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 45: Several commenters requested the appropriate response for Table 7, Field Name 'Date the Reconsideration request was paid' if the reconsideration was denied.

Response 45: CMS appreciates this being brought to our attention. Sponsoring organizations should enter “NA” if the request was denied.

CMS Action 45: CMS added “denied or” to the description in Table 7, Field Name ‘Date the Reconsideration request was paid.’ It now reads, “Date the reconsideration request was paid. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Sponsoring organizations should answer NA for denied or untimely cases that are still open.” No changes were made to the burden estimate in response to these comments.

Comment 46: One commenter asked if the reduced list of documentation identified in Timeliness - Organization Determinations, Appeals, and Grievances (TODAG) section 2.1 also applied to Appropriateness of Clinical Decision-Making & Compliance with Organization Determinations and Appeals Processing Requirements section 2.1 or if leaving the complete list was intentional.

Response 46: This was intentional. This information was removed from TODAG because it was not pertinent to the TODAG review.

CMS Action 46: 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 47: One commenter asked if the following language on page 8 of the ODAG Process and Data Request instructions applied to Tables 4, 5, 6, and 7 since regulations no longer require enrollee notification of upheld reconsiderations “Documentation showing denial notification to the enrollee and/or their representative and provider/physician, if applicable”.

Response 47: The list of documentation on page 8 of the ODAG Process and Data Request instructions are provided to prepare sponsoring organizations for program audits. CMS will not deviate from the regulations found in 42 CFR § 422.590 and will not require sponsoring organizations to show enrollee notification when it is not required. Since Table 4 is comprised of both organization determinations and/or reconsiderations, sponsoring organizations should populate the date of the appropriate notification depending on the type of case (for example, the denial notice for organization determinations or NA for reconsiderations).

CMS Action 47: We updated Table 4, Column O to add, “Answer NA for reconsideration requests.” No changes were made to the burden estimate in response to this comment.

Comment 48: Two commenters requested clarification that CMS will no longer test dismissal timeliness in 2020.

Response 48: Dismissal timeliness will no longer be assessed during CMS Program Audits.

CMS Action 48: 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 49: One commenter asked if the following exclusion language applies to pre-service concurrent reviews for outpatient requests such as PT/OT, outpatient therapy, and home health, “exclude requests for extensions of previously approved services, concurrent review for inpatient hospital and SNF services, post-service reviews, and notifications of admissions.”

Response 49: CMS is not certain how the commenter defines "pre-service concurrent reviews for outpatient requests." If the pre-service concurrent review is a submission to the sponsoring organization for a determination on outpatient service, it must be included in the applicable universe(s).

CMS Action 49: 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 50: One commenter asked if NA is an acceptable response if a diagnosis/diagnoses ICD-10 code or description of diagnosis is unavailable.

Response 50: If a diagnosis is not submitted along with the request, sponsoring organizations may populate this field with NA.

CMS Action 50: 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 51: One commenter asked if compliance standard 3.1.1 under Appropriateness of Clinical Decision-Making & Compliance with Organization Determinations and Appeals Processing Requirements applies only to overturned reconsiderations since 5 organization determination approvals have been removed from sampling.

Response 51: This is correct. Please be aware that the initial denial is within scope of the reconsideration approval review.

CMS Action 51: 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 52: One commenter asked CMS to define lack of medical necessity when a sponsoring organization with a valid step therapy program for certain classes of Part B drugs denies a request for an HMO or PPO member (provider is in-network) because (1) the requested drug is not an approved one in a step therapy class, and (2) the member has not taken the requested drug in the 365-day lookback period.

Response 52: For program audit purposes, CMS does not explicitly define lack of medical necessity. Therefore, CMS will accept a sponsoring organization's determination on how cases like these are defined.

CMS Action 52: 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 53: Several commenters asked if CMS would hold sponsoring organizations accountable to the new Part B drug timeframes that went into effect January 1, 2020. This same commenter recommended CMS add the regulations specific to Part B timeframes to the timeliness tests chart on page 4 of the ODAG Protocol and Data Request document.

Response 53: 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, then the request must be included in the applicable ODAG universe.

CMS Action 53: 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 54: One commenter believes knowing if an expedited requested was processed by the plan under the standard timeframes is not pertinent to timeliness and asked CMS to delete the respective fields from the record layouts.

Response 54: Thank you for the recommendation. This field is used for separate compliance measures.

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: One commenter asked CMS to delete “if no written notification was provided” from the description in field N of Table 7 as written notification of upheld reconsideration decisions is no longer required.

Response 55: CMS clarified the instructions for the field, "Date written notification provided to enrollee" in response to the 60 day comments. The current instructions request the date the enrollee was notified if the decision was favorable. Sponsoring organizations may enter 'NA' if the request was denied, or no written notification was sent.

CMS Action 55: 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 56: One commenter requested CMS allow for numerical values to represent specific requests such as ‘1’ for Grievances, ‘2’ for pre-service organizations determinations, etc.

Response 56: 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 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: One commenter asked CMS to confirm that extensions of previously approved services must now be included in the ODAG record layouts.

Response 57: Per the Table instructions, sponsoring organizations must include requests for extensions of previously approved services. Sponsoring organizations may exclude requests for concurrent review for inpatient hospital and SNF services, post-service reviews, and notifications of admissions.

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: One commenter asked for clarification on description field for Table 1 (SOD), Column ID J. They asked if sponsoring organizations are required to enter both the NDC and the ICD-10 for drug requests or if the ICD-10 code alone would suffice.

Response 58: We thank the commenter for identifying this oversight. In the event ICD-10 codes are unavailable, the sponsoring organization should provide a description of the diagnosis, or, for drugs,

provide the 11-digit NDC. CMS has updated the instructions to remove "as well as the ICD-10 code related to the request."

CMS Action 58: We removed "as well as the ICD-10 code related to the request" from the Diagnosis field description in Tables 1 through 10. No changes were made to the burden estimate in response to this comment.

Comment 59: One commenter asked for guidance on the appropriate person to populate for Column G when there is both a requesting provider who is performing the service and an ordering provider.

Response 59: For Column G, sponsoring organizations must indicate who requested the service, *i.e.* the ordering provider.

CMS Action 59: 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 60: One commenter asked that CMS not remove the field "Level of Service" in Tables 1 through 10 from the 2020 protocols because it will increase the difficulty of identifying specific requests for sampling during an independent validation audit and sponsoring organizations may not have time to implement this change prior to the start of 2020 program audits.

Response 60: We appreciate and understand the commenters concern regarding the removal of this column. However, we believe there is sufficient data collected in the remaining fields to select appropriate samples.

CMS Action 60: 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 61: One commenter disagreed with CMS' decision to add "if the decision was favorable" to the description field in Table 5, 6, and 7 since it would impact timeliness measurements between favorable and unfavorable decisions. This commenter noted this change did not apply to the 2021 audit protocols as well as the 2020 MMP protocols.

Response 61: We disagree with the commenter. Regulations effective in 2019 no longer require notification to enrollees/providers of upheld decisions. Rather, sponsoring organizations are required to forward upheld decisions to the IRE within the specific timeframes that are appropriate for each case. CMS accounted for this change in 2019 and updated the field descriptions to accurately reflect how timeliness is assessed by CMS.

CMS Action 61: 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 62: One commenter requested clarification regarding the instructions for Table 13: Dismissals. The instructions state to submit cases based on the dismissal date or based on the date the IRE requested information from the sponsoring organization for a case that was appealed to the IRE. The commenter asked if a case should be included twice if it was both dismissed in the universe period and the IRE requested information on the same case within the universe period.

Response 62: In these instances, sponsoring organizations may enter just the case that was dismissed.

CMS Action 62: 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 63: Several commenters asked if the dismissal exclusion language is being removed from Tables 5, 6, and 12 since the following exclusion language was removed, “Requests that require an AOR (or other conforming instrument) but the AOR has not been received as of the date of the universe submission; and extensions of previously approved services.”

Response 63: Dismissals should not be included within Tables 5 and 6. Cases dismissed for lack of a valid AOR should be included in Table 13: Dismissals.

CMS Action 63: 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 64: One commenter asked for the appropriate response in Table 5, Column ID R, Field name “Was the organization determination denied for lack of medical necessity?” if the initial request was approved since the description was updated to read, “Yes (Y)/No (N) indicator of whether the initial request was denied for lack of medical necessity. Answer No if the initial request was denied because it was untimely.”

Response 64: If the initial request was approved, CMS does not suspect there would be an appeal.

CMS Action 64: 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 65: One commenter asked for the appropriate response in Table 6, Column ID S, Field name “Was the organization determination denied for lack of medical necessity?” if the initial request denied timely since the description was updated to read, “Yes (Y)/No (N) indicator of whether the initial request was denied for lack of medical necessity. Answer No if the initial request was denied because it was untimely.”

Response 65: For program audit purposes, CMS does not explicitly define lack of medical necessity. Sponsoring organizations should, therefore, answer Yes or No depending on whether or not they decided the request was denied for lack of medical necessity.

CMS Action 65: 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.

SPECIAL NEEDS PLAN MODEL OF CARE (SNP-MOC)

Comment 66: One commenter stated that they believe that the questions included in the SNP questionnaire overlap with data that is available in the sponsoring organizations' MOC(s). The commenter asked whether organizations should simply cut/paste information from the MOC into the SNP questionnaire.

Response 66: We thank the commenter for raising this concern and agree that is important to reduce any overlap in reporting, when possible. We have removed this overlap as described in the CMS Action below.

CMS Action 66: We have removed questions 3, 7, 9, 10, 11 and 14 from the SNP Questionnaire. We revised the language in question # 12 to read: “Describe the outreach policy pertaining to HRA

administration and ICP development. Describe the process for enrollees that cannot or do not want to be contacted”. We renumbered the remaining questions accordingly. No changes were made to the burden estimate in response to this comment.

Comment 67: One commenter indicated that the questions included in the SNP questionnaire are slightly different from the standards and guidelines in the CMS Model of Care Scoring Guidelines used in the National Committee for Quality Assurance (NCQA) reviews. The commenter asked for a crosswalk of guidance between the questions in the SNP questionnaire and the Scoring Guidelines.

Response 67: It appears that the commenter is suggesting that CMS Program Audits would be evaluating and scoring the MOC in a manner that is duplicative of NCQA’s role in scoring MOCs. However, we clarify that MOC scoring is under the purview of NCQA, and program audits evaluate sponsoring organizations’ implementation of the MOC that was approved by CMS. Therefore, the SNP questionnaire is considered separate from NCQA requirements.

CMS Action 67: No changes were made to the protocols in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 68: One commenter requested clarification regarding the SNP universe time period for audit year 2020. The commenter asked whether there was a separate HRA-specific universe to capture only those persons enrolled at least 90 days up to 13 continuous months. The commenter further noted that members who enrolled 13 months ago, may have had an HRA up to 3 months prior which would extend the review timeframe to 16 months. The commenter asked whether CMS would narrow the universe to beneficiaries with HRA information that falls within the 13-month timeframe. The commenter also requested guidance on the universe periods for audit year 2021.

Response 68: We clarify that for audit year 2020, the universe is to capture individuals who have been enrolled at least 13 continuous months. Individuals with continuous enrollment less than 13 months will not be included in the universe submission. Further, CMS clarifies that even if an HRA was conducted within 90 days prior to enrollment, and the enrollee was only enrolled for ten months as of the engagement letter, CMS would not expect to see this enrollee in the universe as the enrollee does not meet the instructions for the universe that specify to include individuals who have been enrolled at least 13 continuous months. Therefore, this would not expand the universe request timeframe to 16 months. Finally, with respect to the audit year 2021 universes, the commenter is referring to CMS-10717 OMB 0938-NEW which is outside the scope of this request. If approved by OMB, this collection request (CMS-10191) would be implemented for audit year 2020 and CMS-10717 would replace 10191 beginning in audit year 2021. For additional information pertaining to universe periods beginning in audit year 2021, please refer to CMS-10717.

CMS Action 68: No changes were made to the protocols in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 69: One commenter requested clarification regarding any off-cycle, red-lined edits to the MOC and modifications to the HRA tool, expressing concerns about uploading documents that may not have been reviewed by NCQA and asking for guidance on how to best reflect ongoing work on the HRA tool that is not finalized in a revised MOC. The commenter stated that sponsoring organizations do not have an avenue for informing CMS about operational changes that occur during the off-cycle except for individual communication to their CMS Contract Manager. The commenter asked whether this type of communication would be considered sufficient.

Response 69: We are not able to address this comment as it is beyond the scope of this collection request in that it is seeking policy clarification.

CMS Action 69: No changes were made to the protocols in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 70: One commenter asked whether documentation that the HRA had been completed but is not yet available would be sufficient for providing to the auditors. The commenter outlined a scenario under which an enrollee that has only been enrolled for 90 days, the HRA may have been mailed by the enrollee but not yet received by the organization.

Response 70: Because the universe is limited to individuals that have been continuously enrolled for at least 13 continuous months, the enrollment referred to in this example would not be included in the universe.

CMS Action 70: No changes were made to the protocols in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 71: One commenter asked whether a comprehensive HRA done by a designee of the state, within 90 days prior to the effective date of enrollment, would meet the HRA standard.

Response 71: We are not able to address this comment as it is beyond the scope of this collection request in that it is seeking policy clarification.

CMS Action 71: No changes were made to the protocols in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 72: One commenter requested clarification regarding the timely versus untimely completion of the initial HRA and reassessment HRA and the documentation requirements associated with the assessments. The commenter provided several scenarios to illustrate the question.

Response 72: We are not able to address this comment as it is beyond the scope of this collection request in that it is seeking policy clarification.

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

Comment 73: One commenter requested that as auditors are reviewing the sample of 30 beneficiaries, they should take into consideration all documentation included in the member's record that may demonstrate the sponsoring organization's due diligence in trying to achieve compliance. The commenter believes that CMS should attribute partial credit to the organization based on documentation of the level of effort expended in attempting to achieve compliance.

Response 73: We thank the commenter for their suggestion and clarify that CMS does consider mitigating factors when it is determined that a requirement is not met.

CMS Action 73: No changes were made to the protocols in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 74: One commenter asked, about a 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 74: 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 74: No changes were made to the protocols in response to this comment. No changes were made to the burden estimate in response to this comment.