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

CMS received 13 public submissions, which included 138 comments on the December 12, 2016 (CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests proposed information collection. We then combined the 138 comments into 92 unique comments and provided responses in the document below. Comments are separated first by protocol area, and then by element or section of the protocol. Additionally, some general comments received are addressed in the first part of the document.

GENERAL AUDIT QUESTIONS

Self-Disclosed vs. Self-identified:

Comment 1: One commenter had questions regarding what should be included in Pre-Audit Issue Summary. The commenter noted that in CY2017 CMS has removed self-identified issues from items that need to be reported. The commenter went on to state: "As a plan, there are times that we work through inquiries with our CMS Account Manager that require research and potentially a corrective action plan for resolution. We recommend if issues were worked through with our regional account manager that they be included in the Pre-Audit Issue Summary as CMS would have been aware of these prior to the audit engagement notice being received."

Response 1: As we stated in response to the 60 day comments, for 2017, we are eliminating the reporting of self-identified issues and only asking sponsors to include issues that have been previously disclosed to CMS that may impact the sponsor's audit universes. Issues that are detected and disclosed by the sponsor discussed and then worked on with your account manager are issues that should be included in the Pre-Audit Issue Summary in 2017. Issues that are detected by CMS, and result in CMS inquiries or research follow-up from sponsors, are not considered "disclosed" issues for inclusion on the Pre-Audit Issue Summary. For those disclosed issues that were promptly identified and corrected, CMS may consider that disclosure as a reason to downgrade the classification of that condition from an ICAR to a CAR when on audit. This modified approach will also ensure CMS appropriately recognizes organizations that are transparent with CMS when discovering issues of non-compliance.

CMS Action 1: No changes were made to the Pre-Audit Issue Summary template or protocols in response to this comment. No changes were made to the burden estimates in response to this comment.

Comment 2: Commenters noted that Sponsors will be asked to provide a list of all disclosed issues of non-compliance that are relevant to the program areas being audited and may be detected during the audit on the PAIS. Issues identified by CMS through on-going monitoring or other account management/oversight activities during the plan year are not considered disclosed.

Commenters stated that this proposal will substantially change when disclosure is required to CMS. The proposal to include only CMS disclosed items on the PAIS provides an incentive to disclose all noncompliance events to CMS, regardless of size or significance. Commenters suggested Regional Offices may want different levels of disclosure and often react differently to self-disclosed items, with some issuing NONCs more liberally than others for similarly disclosed events.

Commenters went on to state that if this change were to be finalized, plans would be penalized for not disclosing all items, even if the impact was only one member. CMS has always been silent on specific criteria that Plans must follow to determine which issues should be disclosed to CMS. Plans have been allowed latitude to determine its own criteria, in accordance with its compliance program, plan size, and relationship with its CMS Regional Office Account Manager. The CMS audit protocols should not be policy vehicle to substantially change the disclosure criteria established in Section 50.7.3 in Chapter 9/21.

Response 2: Nothing in the audit protocol supersedes or changes a sponsor's obligations under Section 50.7.3 in Chapter's 9 and 21. The instructions in the audit protocol package are specific to completing the Pre-Audit Issue Summary. The instruction to include "disclosed" issues on the PAIS document has not changed in 2017. We are only asking you to limit what you include on the PAIS document by not including "self-identified" issues that have not been disclosed to CMS. The self-identification and prompt correction of non-compliance can still be reported to CMS during the audit and may be considered a mitigating factor when citing or classifying audit conditions. However, CMS is no longer asking that "self-identified" issues be reported on the PAIS document. Please maintain normal reporting with your CMS Account Manager.

CMS Action 2: No changes were made to the Pre-Audit Issue Summary template or protocols in response to this comment. No changes were made to the burden estimates in response to this comment.

Comment 3: One commenter wished to clarify both the types of issues to be included in the PAIS and the timeframe of those issues to be included.

Response 3: As we stated in response to the 60 day comments, for 2017, we are eliminating the reporting of self-identified issues and only asking sponsors to include issues that have been previously disclosed to CMS that may impact the sponsor's audit universes. Disclosed issues should be pulled by program area based on the audit review period for that particular protocol. For example, if a sponsor is submitting 3 months of universes for CDAG, their CDAG disclosure list should include all issues that might affect their Part D coverage determinations, appeals and grievances for that 3 month period. The actual disclosure date may fall outside of the audit review period, but CMS will not accept disclosures made after the engagement letter is issued.

CMS Action 3: No changes were made to the Pre-Audit Issue Summary template or protocols in response to this comment. No changes were made to the burden estimates in response to this comment.

Impact Analysis:

Comment 4: One commenter requested clarification on who would request and verify the accuracy of any requested impact analysis.

Response 4: An impact analysis will be requested by your Team lead or Auditor-in-Charge. It must be submitted as requested by CMS for every issue of non-compliance present during the audit. The impact analysis must identify all of the beneficiaries subjected to or directly impacted by the issue of non-compliance.

CMS Action 4: No changes were made to the protocols in response to this comment. No changes were made to the burden estimates in response to this comment.

SUPPORTING STATEMENT A

Comment 5: One commenter asked if MMP Contracts would be included in the Timeliness Monitoring Project (TMP).

Response 5: No, MMP contracts will not be included in the timeliness monitoring project.

CMS Action 5: No changes to the supporting statement, protocols or burden estimates were made in response to this comment.

Comment 6: One commenter asked which audit elements would be tested during the TMP.

Response 6: The TMP will assess sponsor's timeliness with processing Part C and Part D organization and coverage determinations, and appeals; as well the sponsor's compliance with auto-forwarding cases to the IRE.

CMS Action 6: No changes to the supporting statement, protocols or burden estimates were made in response to this comment.

Comment 7: One commenter asked if the TMP would begin in December every year.

Response 7: Yes, we believe it will begin in December/January of each year.

CMS Action 7: No changes to the supporting statement, protocols or burden estimates were made in response to this comment.

Comment 8: One commenter asked if the universe period for the TMP would be the same timeframe each year.

Response 8: The universe request period for the TMP will likely change each year.

CMS Action 8: No changes to the supporting statement, protocols or burden estimates were made in response to this comment.

Comment 9: One commenter asked if a timeliness discrepancy is uncovered during the review, what would the expected turn-around time be post final report issuance in which a sponsor will be made aware of any data integrity flags for affected plans?

Response 9: Sponsors will receive information on the results of the timeliness tests in advance of these results impacting any Star Ratings measures.

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

Comment 10: Some commenters expressed concern with the TMP project and were concerned particularly that sponsors and their PBMs would be able to handle the request and be adequately prepared to submit the data. The commenters expressed concerns that rushing may lead to erroneous data submissions, especially given that many sponsors have already programmed the 2017 protocols into their system, and CMS is requesting data in the 2016 format. Given the concerns raised above, commenters urged CMS to further delay the start date for the TMP. These commenters also raised concerns about using audit data or data from the TMP for purposes of Star ratings.

Response 10: We thank the commenters for sharing their concerns. We have received a lot of feedback on the TMP and have been extremely sensitive to other workloads or collections that plans are subject to, during our request for data. We have also created a request schedule that breaks up the number of sponsors. CMS is requesting data in 3 waves to make it more manageable. CMS' schedule takes into account audit and validation activities, as well as the sponsors' PBMs, and how many contracts those PBMs service. To the greatest extent possible, we staggered sponsors across one of three waves of requests and ensured PBMs contracts were split across the waves so as to lessen their burden and reduce the likelihood of errors. Additionally, if a sponsor or PBM raises concerns about scheduling or response times, we will attempt to be as flexible as possible in accommodating those requests.

CMS used the 2016 audit protocols to request these data, because we were requesting 2016 data, which sponsors already had programmed into their system. Since 2017 protocols were not finalized, we could not request that sponsors submit data in the 2017 format.

As for the commenter's concern about using audit results to inform Star Ratings, let us be clear that audit results do not inform any Star ratings measure. Instead, if audit data demonstrate that the data reported by the IRE to CMS (for a given sponsor) may be inaccurate or incomplete, then this evidence may be used to support concerns that there are issues related to the data that is used in measures in the Star Ratings, in this instance, cases auto-forwarded to the IRE. In other words, if the audit demonstrates that all cases that should have been forwarded to the IRE were not, then the IRE data relied upon to inform the appeals Star Ratings measures is no longer valid.

CMS Action 10: No changes to the supporting statement, protocols or burden estimates were made in response to this comment.

Comment 11: One commenter stated they believed that this collection was duplicative of the data reviewed via the data validation auditors, which is a separate collection. The commenter was also concerned we may use the data to target sponsors. This commenter also expressed concern that without knowing a sponsor's tolling or mailroom policies, CMS would not be able to accurately assess timeliness as part of the TMP.

Response 11: We appreciate the concerns raised by the commenter. The data collected by the data validation contractors is collected in an aggregate format and is not case specific data that are collected as part of audits and the TMP, so it is not duplicative. We cannot assess timeliness from the aggregate data submitted to the data validation contractor.

We assure the commenter that data collected as part of the TMP is being used to validate the completeness of the IRE data used to inform the appeals Star Ratings measures.

Finally, CMS is collecting the sponsor's tolling and mailroom policies to ensure that during any subsequent validation webinars that we are applying the appropriate timeframes for timeliness purposes.

CMS Action 11: No changes to the supporting statement, protocols or burden estimates were made in response to this comment.

Comment 12: Several comments expressed concerns that CMS' burden estimate for the time it takes to complete an audit and/or the time expended in the TMP project are greatly underestimated, from the commenters' experiences. One commenter recommended CMS survey Sponsors post-audit to obtain a more accurate estimate of the hours the sponsor spent on audit activities. This information could be used to update the burden estimate as appropriate.

Response 12: Thank you for your feedback, we did take sponsor feedback from the 60 day and 30 day comments and adjusted the estimate to 740 hours for a sponsor to undergo an audit. This was a significant increase from our initial estimate of roughly 120 hours, which we agree was not adequate.

We recognize the new estimate will not be representative for all organizations as the sponsors we audit vary greatly in the number of enrollees they serve, size of the organization, staffing, etc. CMS has to develop an educated estimate on an "average" number of hours it would take to go through an audit, taking into account all of the various organizations (large and small) that we audit. We will continue to request sponsor feedback on level of effort in future packages to ensure our estimate is reflective of current experience.

CMS Action 12: We did update the hours in the supporting statement and burden estimate to reflect 740 hours, which is a change from the 701 that were reflected in the burden estimate during the 30 day comment period. In reviewing the comments and our estimates in response to comments, we uncovered a calculation error from the 30 day package. We also changed the burden for the post audit survey from 30 minutes in the burden to 10 minutes. During the design and testing of this survey, it was designed to only take an average of 10 minutes. No changes were made to the protocols in response to this comment.

Comment 13: Some commenters believe that the burden estimate for the TMP are not adequate, and indicated that larger sponsors, whose PBMs are pulling data, may take weeks of time.

Response 13: Thank you for your feedback. We have reviewed the comments received on our burden estimate for the TMP and we believe our burden estimate is representative of the average number of hours it will take a sponsor to undergo the TMP. As mentioned above with our audit estimate, sponsors of all sizes and staffing levels will undergo the TMP. Our estimate will not be a perfect fit for all organizations. We will continue to request feedback on our estimate in future packages to continually refine our estimate.

CMS Action 13: No changes were made to the supporting statement, protocols or burden

estimates in response to this comment.

Comment 14: Some commenters expressed concerns with the timing of the TMP, and indicated that CMS may be violating its duties under the Paperwork Reduction Act (PRA). The commenters asserted that OMB's review of the package is ongoing and any implementation should wait until after OMB approval has been received.

Response 14: We thank you for your feedback. CMS takes very seriously our obligations under the Paperwork Reduction Act. CMS did delay implementation of the TMP in response to industry concerns. While several updates were made to record layouts and definitions in the 2017 protocol packages, including updating the burden estimate for this effort, the same data proposed in this package was collected under the previously approved CMS-10191, which is approved through March 2017.

In addition, it should be noted that CMS received overwhelming feedback from industry, raising serious concerns about CMS' policy of reducing Star Ratings measures based on audit findings showing that the source data for those measures was inaccurate). Industry shared their concern that it adversely impacts only those organizations selected for audit in a given year. We recognize the importance of having complete and accurate data, particularly when developing Star Ratings measures. CMS believes that the timeliness monitoring project will greatly improve the data used to inform appeals measures for the Star Ratings.

CMS Action 14: No changes were made to the supporting statement, protocols or burden estimates in response to this comment.

PART D COVERAGE DETERMINATIONS, APPEALS AND GRIEVANCES (CDAG)

General:

Comment 15: Several commenters noted that CMS is no longer requiring sponsors to provide universes in a standardized time zone, and instead, CMS is allowing sponsors to submit universes in multiple time zones; as long as each case is recorded in the time zone the case was received in. These commenters requested that they continue to be allowed to provide universes in a standardized time zone because they had already programmed their systems to pull data in that way.

Response 15: CMS will accept universes in a standardized time zone or multiple time zones so long as individual cases are in one time zone per case. Sponsors should let the CMS audit team know how they will be submitting the universe.

CMS Action 15: 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.

Call Logs:

Comment 16: Several commenters requested clarification regarding the review period for Part D call logs. These commenters noted that the review period appears to be reversed and that it was different than the review period in Part C ODAG.

Response 16: The review period for Part D Call Logs in the CDAG protocol was an error and

was corrected prior to the 30 day review period closing. The corrected review period is similar to ODAG and requests universes based on the size of the sponsor enrollment. Larger organizations will have a smaller time period of calls to provide during audit because their volume is typically higher.

CMS Action 16: 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 17: One commenter requested that ODAG and CDAG Call Log universes provide consistent guidance regarding which calls are excluded from the request. Specifically, the commenter requested that ODAG include the same exception or exclusions that CDAG listed.

Response 17: CDAG and ODAG are both requesting call logs for 2017, and while we have tried to make the requests as consistent as possible, some differences are necessary given the variances in the program areas. For CDAG, we believe we can exclude physicians and prescriber calls from the request.

CMS Action 17: 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 18: One commenter requested clarification regarding whether CMS would provide translators if audio files were needed and the audit file was not in English.

Response 18: While sponsors are expected to provide call log universes in English, we will work with organizations on providing access to audio files or call transcripts when calls are not in English. If the sponsor believes this will be an issue they should raise it to the audit team.

CMS Action 18: 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 19: One commenter requested clarification regarding whether to include calls that covered both a Part C and Part D question in both the Part C and Part D call logs.

Response 19: If a call relates to both a Part C and a Part D issue and is from an enrollee or representative, then that call should be included in both the Part C and Part D call log universe.

CMS Action 19: 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 20: One commenter stated that some audio files are difficult to access or pull quickly, and recommended that CMS allow sufficient time for the organization to access these files when needed.

Response 20: We agree that sponsors should be allowed adequate time to pull audio files. Audio files will only be requested when the notes regarding the call are not adequate. Sponsors may discuss the timeframe for providing audio files with the audit team.

CMS Action 20: 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 21: One commenter thanked CMS for providing further clarification on the call logs, and limiting the call log universe request based on comments received during the 60 day.

Response 21: We appreciate the support from this commenter.

CMS Action 21: 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 22: One commenter requested clarification on the requirements for sponsors to document incoming calls.

Response 22: CMS will be assessing whether sponsors appropriately identified requests for coverage or oral complaints as either Part D coverage determinations/ appeals/ grievances, and will expect documentation regarding the appropriate classification of these requests in accordance with 42 CFR 423.564(b) 42 CFR 423.564(d) 42 CFR 423.568(a) 42 CFR 423.570(b) and 42 CFR 423.584(b).

CMS Action 22: 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 23: One commenter requested clarification on whether call logs would be validated during the pre-audit validation webinar.

Response 23: CMS will not validate the accuracy of the call logs during the pre-audit webinar, since timeliness will not be run on the call log universe. However, during the call log review, CMS will validate that sponsors provided accurate information in response to the audit protocol request.

CMS Action 23: 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.

Timeliness:

Comment 24: One commenter requested CMS release the internal thresholds used to assess compliance with timeliness requirements in CDAG.

Response 24: At this time we do not share our internal thresholds. While the regulations and statute contemplate 100% timeliness that is not the standard we hold sponsors too during audit. For audit purposes we have created thresholds that we believe are reasonable for a sponsor to meet.

CMS Action 24: 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 25: One commenter requested clarification regarding the timeliness tests in CDAG, specifically if universes were combined when running timeliness tests. This commenter stated that this was different than 2016 and therefore clarification was needed.

Response 25: The CDAG protocol combines all similar compliance standards when running timeliness tests. For example, since all untimely cases require auto-forwarding within 24 hours

of the missed timeframe, all cases eligible for auto-forwarding are merged together to get one overall result. Merging universes allows CMS to completely assess the requirement without penalizing the sponsor multiple times for the same failure. This was done in 2016 and will continue to be done in 2017.

CMS Action 25: 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.

Record Layouts:

Comment 26: One commenter stated that several fields in the record layouts were new and would impact submissions of universes from the PBM.

Response 26: We agree that some new fields were added to the record layouts for 2017. Most of these fields were identified based on comments received during the 60 day comment period in order to make the record layout clearer. While we understand that adding new fields will require altering universes for submission, we feel the fields added in CDAG are important for auditors to receive, and are in response to industry feedback.

CMS Action 26: 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 27: One commenter requested clarification on the oral notification field, specifically what constituted a good faith attempt at oral notification and whether good faith attempts should be reported in the oral notification field for the record layout.

Response 27: Sponsors should refer to Chapter 18 of the Medicare Prescription Drug Manual and the recent HPMS memo, issued February 22, 2017, that discussed updated outreach guidance for a definition of what constitutes a good faith attempt. Sponsors should include good faith attempts at oral notification in the record layout. Sponsors should include the last good faith attempt made within the applicable timeframe (i.e., for standard coverage determinations sponsors would input the last good faith attempt made within the 72 hour timeframe).

CMS Action 27: 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 28: Two commenters requested clarification on how to populate the field relating to whether an enrollee resided in long term care facilities. Specifically, the commenters asked for clarification on whether point of sale information or residence codes could be used to identify long term care enrollees.

Response 28: Sponsors can and should use whatever information is available to them to determine if an enrollee is residing in long term care, including but not limited to point of sale transactions near the date of the coverage request. For example, if a residence code is attached to a POS transaction and indicates the enrollee resides in a long term care facility, the sponsor should indicate “yes” in the long term care field of the record layout.

CMS Action 28: 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 29: One commenter requested clarification on the medical necessity fields in the redetermination record layouts (Tables 6, 7, and 8) as well as the reimbursement record layouts (Tables 3, 7 and 12). Specifically the commenter wanted to clarify that for the redetermination universes the sponsor should fill out whether or not the original coverage determination was denied for lack of medical necessity and not whether the redetermination was denied for lack of medical necessity. For the reimbursement record layouts, the sponsor requested clarification on why there was a medical necessity field in these tables.

Response 29: We appreciate this commenters request for clarification. For the redetermination fields the sponsor should indicate if the original coverage determination was denied for lack of medical necessity. It is the original coverage determination denial that triggers the need for a physician reviewer on appeal, which is what the field is capturing. As for the reimbursement fields, reimbursements are coverage determinations and require the same processing as pre-benefit coverage determinations, including making medical necessity decisions.

CMS Action 29: 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 30: One commenter requested clarification on the reason why CMS was asking whether or not a reimbursement was an exception request, since that seemed to be more clinical in nature, and not relevant to a reimbursement request.

Response 30: As indicated above, reimbursements are coverage determinations and require the same processing as pre-benefit coverage determinations, including requesting supporting statements from physicians for those cases that are exception requests.

CMS Action 30: 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 31: Two commenters requested clarification on the new Authorization of Representative (AOR) fields that were included in the CDAG record layouts. Specifically, one commenter requested these fields be removed since populating them would be burdensome on the sponsor as that information was not easily captured. Another commenter requested clarification on how to populate the field, especially when the AOR was received prior to the coverage determination being received, and whether a pharmacy would need to submit an AOR on behalf of the enrollee when making a request.

Response 31: We appreciate the comments on these new fields. We added these fields based on industry feedback during the 60 day comment period. These fields are important for CMS to know in order to judge timely processing of cases, since the start time for a request begins when the AOR is received. As for populating these fields, a sponsor should enter the information based on the circumstances of the case. If the case is initially received without an AOR, the AOR receipt date and time should be populated once the sponsor receives the AOR. If the sponsor already has an AOR on file, the sponsor should populate the AOR receipt date and time with the date and time the coverage determination or redetermination request was received. A sponsor should include information based on the way they handle or process cases, so if a sponsor requires a pharmacy to submit an AOR, they should indicate that in the

universe.

CMS Action 31: 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 32: One commenter requested clarification on partial approvals in CDAG. Specifically the commenter requested that CMS add a disposition type for partial approvals.

Response 32: Partial approvals are considered partial denials and should be included as partial denials for purposes of reporting them on audit. Please enter "partial denial" in the disposition field.

CMS Action 32: 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 33: One commenter requested clarification on what a "hospice" exception type was.

Response 33: Sponsors are required to indicate the type of exception request in the CDAG record layouts. The types of request include non-formulary, formulary UM, tiering, and hospice. Since hospice enrollees have drug coverage under the hospice benefit, any decision to provide a drug under Part D and not hospice is considered an exception based on CMS guidance.

CMS Action 33: 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 34: One commenter requested clarification on whether a letter being sent to a postal sorting house would be considered "provided" for purposes of populating the written notification fields.

Response 34: For purposes of populating this field, sponsors should indicate the date and time the letter left the sponsor establishment, which can include leaving the organization through a postal sorting house.

CMS Action 34: 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 AND D COMPLIANCE PROGRAM EFFECTIVENESS (CPE)

Regulations and Sub-Regulatory Policy:

Comment 35: One commenter recommended that CMS exempt sponsors from complying with the annual audit of their compliance program in the same year the sponsor undergoes a CMS program audit.

Response 35: Thank you for the recommendation. CMS disagrees with the proposed change. CMS's expectation is that sponsors must audit the effectiveness of the compliance program at least annually.

CMS Action 35: 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 36: One commenter asked CMS to define certain words or terms from Chapters 9 and 21. One commenter requested CMS explain what is considered "reasonable" and "timely" responses and corrective actions for compliance and FWA issues.

Response 36: These questions are outside the scope of the PRA package. We cannot offer policy guidance on what these terms should mean. For audit purposes, sponsors should populate their universes based on how they process or define these terms. For definitions and policy guidance, commenters should refer to 42 CFR 422 and 423 Subpart K, Chapter 9 of the Prescription Drug Benefit Manual and Chapter 21 of the Medicare Managed Care Manual.

CMS Action 36: 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 37: One commenter inquired about CMS having a broader definition for determining when a related entity is acting as a first-tier entity.

Response 37: These questions are outside the scope of the PRA package. We cannot offer policy guidance on what these terms should mean. For audit purposes, sponsors should populate their universes based on how they process or define these terms. For definitions and policy guidance, commenters should refer to 42 CFR 422 and 423 Subpart K, Chapter 9 of the Prescription Drug Benefit Manual and Chapter 21 of the Medicare Managed Care Manual.

CMS Action 37: 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.

Universe Preparation & Submission:

Comment 38: One commenter requested clarification regarding the word "miscommunication" in question #9 of Attachment I-B.

Response 38: For this question sponsors should discuss an experience during the specified audit period when the lines of communication between the Compliance Department and a Medicare operations unit or an employee failed to adequately prevent or identify a Medicare compliance issue, including how the two entities worked together to resolve the issue.

CMS Action 38: 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 39: One commenter requested clarification regarding the types of priorities CMS is seeking to be listed for Question #19 of Attachment I-D.

Response 39: Sponsors should specify its plans to build successful delegation relations and oversee its delegated entities continued compliance with Medicare requirements for the specified timeframe.

CMS Action 39: 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 40: One commenter thanked CMS for clarifying that sponsors should include both compliance and FWA activities in the data universes.

Response 40: We appreciate your comment.

CMS Action 40: 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 41: One commenter expressed appreciation to CMS for reducing the length of the CPE questionnaires which will allow sponsors to streamline their resources.

Response 41: We appreciate your comment.

CMS Action 41: 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 42: One commenter recommended that less detail be requested for the CPE universes.

Response 42: We understand your concerns about the level of detail requested for universes. Conversely, detailed universes are needed for CMS to select appropriate samples that will provide sponsors the best opportunities to demonstrate the effectiveness of their compliance program during the tracer evaluation.

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: One commenter asked CMS to consider only requiring tracer cases for annual CPE audits on a frequency other than annually, for example, every 3 years.

Response 43: Sponsors are not required to use CMS' audit methodology and protocols (i.e. sample selection, tracer evaluation, etc.) when conducting their annual compliance program effectiveness audit.

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.

Tracer Evaluation:

Comment 44: One commenter requested clarification on whether all of the bulleted items for section 2.1 are required to be addressed in the tracer case summaries.

Response 44: We appreciate the commenter's question. Sponsors are expected to provide the requested information for tracer case summaries. If one of the bulleted items do not apply to a tracer case, provide a brief statement indicating why the item is non-applicable.

CMS Action 44: 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.

Record Layouts

All Tables

Comment 45: Three commenters thanked CMS for reducing burden on sponsors by removing monitoring and audit activities performed on a daily basis from the FTEAM, IA and IM universes.

Response 45: We appreciate your comment. Daily monitoring and audit activities are no longer requested and have been excluded from the CPE universes.

CMS Action 45: 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.

Table 1: First-Tier Entity Auditing and Monitoring (FTEAM) Record Layout

Comment 46: One commenter inquired whether it is CMS intent for sponsors to include only those first-tier entities who provide services directly to Medicare enrollees only in the FTEAM universe. Additionally, the commenter asked for clarification regarding the types of providers that should be included.

Response 46: The FTEAM universe should comprise of the first-tier entities that were audited or monitored by the sponsor during the audit period. A first-tier entity is any party that enters into a direct written arrangement, acceptable to CMS, with an MAO or Part D plan sponsor to provide administrative services or health care services to a Medicare eligible individual under the MA program or Part D program. This universe may contain a range of entities, depending on first-tier contractual arrangements between the sponsor and its vendors, including but not limited to pharmacy benefit managers, credentialing, hospital groups, independent practice associations, individual health care providers, etc.

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 requested clarification on whether "initiated" in Column J- Table 1 refers to an activity notice date.

Response 47: CMS acknowledges that sponsors use different terms within their organizations and audit/monitoring activities "start date" may be acknowledged at different stages (e.g. pre-planning work, kick-off meetings, engagement notices, audit fieldwork, etc.). Please provide the date the auditing or monitoring activity is considered to have started at your organization.

CMS Action 47: 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 48: One commenter asked CMS to clarify if the types of audits and monitoring activities that were initiated by allegations are to include just a case investigation which may not include a formal audit or monitor.

Response 48: Due to insufficient information, we were unable to address the commenter's question. We encourage the commenter to resubmit their comment to our audit mailbox with additional information for an appropriate response.

CMS Action 48: 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 49: One commenter requested that CMS provide a broader definition for determining when a related entity is actually acting as a first-tier entity.

Response 49: These questions are outside the scope of the PRA package. We cannot offer policy guidance on what these terms should mean. For audit purposes, sponsors should populate their universes based on how they process or define these terms. For definitions and policy guidance, commenters should refer to 42 CFR 422 and 423 Subpart K, Chapter 9 of the Prescription Drug Benefit Manual and Chapter 21 of the Medicare Managed Care Manual.

CMS Action 49: 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 50: One commenter requested that CMS clarify whether providers who provide pure health care and not a health care related service should be included in Table 1 – FTEAM universe.

Response 50: For audit purposes, sponsors should populate their universes based on how they process or define these terms. For definitions and policy guidance, commenters should refer to 42 CFR 422 and 423 Subpart K, Chapter 9 of the Prescription Drug Benefit Manual and Chapter 21 of the Medicare Managed Care Manual.

CMS Action 50: 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 51: One commenter requested clarification on how to respond to Column F – Table 1 when the activity could be both a compliance and a FWA activity.

Response 51: Please choose one of the two options available for Column F. During the audit engagement process, sponsors will have an opportunity to discuss the universe preparation process and resolve any issues or questions with the CMS Audit Team.

CMS Action 51: 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 52: One commenter requested clarification on which date to enter into Column J – Table 1 when the audit or monitoring activity has two dates (started and reopened).

Response 52: Sponsors should enter the most appropriate date that falls within the audit period.

CMS Action 52: 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 53: One commenter requested whether sponsors must enter deficiencies after the activity was completed or include all deficiencies identified to date even if the activity is still in progress for Columns L, M, N – Table 1.

Response 53: Sponsors should enter the deficiencies that have been identified to date.

CMS Action 53: 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 54: One commenter asked CMS to clarify whether sponsors should include corrective actions that have been implemented or those pending implementation.

Response 54: Sponsors are expected to include both taken and pending corrective actions for the FTEAM, IA and IM record layouts.

CMS Action 54: 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 55: One commenter asked if CMS would clarify the term "questionable behavior" performed by FTEs noted in the Inclusion section of the FTEAM universe – Bullet #5 as they believe the term is too broad to facilitate consistency across MA plans and Part D sponsors.

Response 55: Questionable behavior refers to any action that has the potential to run afoul of an internal policy, procedure, or standard that will cause an internal investigation to confirm any ethical or compliance violations.

CMS Action 55: 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.

Table 2: Employees and Compliance Team (ECT) Record Layout

Comment 56: One commenter requested clarification on how to respond to Table 2, Columns E, F, L, and I that do not apply to members of the governing body.

Response 56: If a column does not apply to governing body members, sponsors may enter "N/A"

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.

PART D FORMULARY AND BENEFIT ADMINISTRATION (FA)

Record Layouts:

Comment 57: One commenter noted that although a beneficiary may change Plan Benefit Packages (PBPs) resulting in a new PBP effective date, the benefit and formulary may remain consistent. In such cases, an organization may not identify this beneficiary as a new enrollee as defined per their transition policy. Because the revised record layout instructions for the "Enrollment Effective Date" and "Effective Disenrollment Date" fields are to populate at the PBP level. The commenter recommended that CMS take into consideration such factors when evaluating universe submissions.

Response 57: CMS recognizes that there may be differences among sponsors in determining new enrollment status for beneficiaries that change plans or contracts under the same organization from year to year or during a contract year. Organizations should identify such members as new vs. continuing for purposes of universe submissions based on their internal policies and procedures. After receipt of a program audit engagement letter, organizations will have an opportunity to discuss their approach to help ensure complete and accurate universe submissions.

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 how sponsors should populate the NDC field with respect to multi-ingredient compound claims where a pharmacy did not include drug

information, but rather a value that contains spaces, hyphens, or other special characters. Another commenter asked how to populate the NDC field for a multi-ingredient compound that does not include a Part D covered drug.

Response 58: For all claims sponsors should include the 11-digit value as submitted by the pharmacy and when applicable, should remove special characters separating the labeler, product, and trade package size. In the event a multi-ingredient compound does not include at least one Part D covered drug, sponsors may populate the NDC field with "00000000000" to remain consistent with the 11 digit NDC drug code.

CMS Action 58: The NDC field description was modified to include additional guidance on populating the NDC field. No changes were made to the burden estimate in response to these comments.

Comment 59: One commenter asked that CMS clarify the distinction between pharmacy messages that are not linked to a corresponding reject code and pharmacy messages that are not paired with a reject reason code, and to provide guidance on how to populate these fields based on that distinction.

Response 59: It has been CMS' experience that reject claim codes can be cross-walked or paired to specific pharmacy messages. However, for some organizations the association between reject codes and messages is not evident or captured in the system. In addition, situations may exist where a rejected claim returns a pharmacy message this is unrelated to a reject code or in the absence of a reject code. For purposes of the universe submissions, if both reject codes and pharmacy messaging exist for a rejected claim, but the exact association between them cannot be identified, the organization is permitted to enter the individual reject code in the "Reject Reason Code" field followed by all of the messaging for that claim in the "Pharmacy Message" field. This should be repeated for all reject reason codes appearing for that rejected claim. When pharmacy messages for a rejected claim exist without a reject code, the organization should enter an "NA" in the "Reject Reason Code" field, followed by the messaging for that claim in the "Pharmacy Message" field. Likewise when a reject code is generate without a pharmacy message, the organization should enter "NA" in the "Pharmacy Message" field.

CMS Action 59: We modified the descriptions for the "Reject Reason Code" and "Pharmacy Message" fields to clarify the different scenarios that may be encountered and how organizations should populate these fields for each scenario. No changes were made to the burden estimate in response to this comment.

PART D MEDICATION THERAPY MANAGEMENT (MTM)

Record Layout:

Comment 60: One commenter asked for clarification about the necessity of the "Was the beneficiary residing in a long term care facility?" field as well as at what point in time the long term care (LTC) status for the beneficiaries should be captured.

Response 60: CMS evaluates the administration of the MTM benefit for MTM enrollees in the long term care setting to ensure that they are not being treated differently as per the MTM requirements. As detailed in the "Was the beneficiary residing in a long term care facility?" field description, sponsors should use all available information to determine LTC status at the time the MTM services are offered and administered, such as patient residence code on drug claims data and the Long Term Institutionalized (LTI) resident report. The LTC status should be identified either at the time the first CMR was offered or administered during the year.

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.

SPECIAL NEEDS PLANS MODEL OF CARE (SNP MOC)

Universe Preparation & Submission:

Comment 61: One commenter requested clarification regarding how the universe should be completed when an entire SNP population is migrated into a new SNP plan and there are two separate entries for that member.

Response 61: Please complete the universe template with one entry per member with the new plan number. Entries in the record layout data fields should be specific to the enrollment into that specific contract. If the initial HRA and/or annual HRA was not yet completed because of the consolidation timing, please enter "NA" in these respective fields. Please advise the audit team of the situation during the universe call.

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.

Record Layouts:

Table 1: Special Needs Plan Enrollees (SNPE) Record Layout:

Comment 62: One commenter recommended that CMS change the description of Column I – "Date the Sponsor Received the Completed Enrollment Request" to request the application received date to be consistent with the data Sponsors are required to capture and submit to CMS.

Response 62: Thank you for the recommendation. CMS cannot use the date the sponsor received the enrollment application, because it is possible that the application could be incomplete on the initial receipt date. CMS needs to know the date that the enrollment application is complete.

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.

PART C ORGANIZATION DETERMINATIONS, APPEALS AND GRIEVANCES (ODAG)

Record Layouts:

All Tables

Comment 63: Several commenters noted that CMS is no longer requiring sponsors to provide universes in a standardized time zone, and instead, CMS is allowing sponsors to submit universes in multiple time zones so long as each case is recorded in the time zone the case was received in. These commenters requested that they continue to be allowed to provide universes in a standardized time zone because they had already programmed their systems to pull data in that way.

Response 63: CMS will accept universes in a standardized time zone or multiple time zones so long as individual cases are in one time zone per case. Sponsors should let the CMS audit team know how they will be submitting the universe.

CMS Action 63: 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 64: One commenter asked whether CMS would consider making the CAR/ICAR timeliness thresholds public.

Response 64: At this time we do not share our internal thresholds. While the regulations and statute contemplate 100% timeliness that is not the standard we hold sponsors too during audit. For audit purposes we have created thresholds that we believe are reasonable for a sponsor to meet.

CMS Response 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: We received several questions regarding the "Was the request denied for lack of medical necessity" field throughout the ODAG universes. Specifically, we were asked how to populate this field.

Response 65: This field should be populated as follows: If the request was denied for lack of medical necessity, answer "Y". If the request was denied for any reason other than lack of medical necessity (e.g., duplicate request, no prior authorization, untimely, etc.), answer "N". If the request was approved and not denied, answer "NA".

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.

Comment 66: We received several questions regarding the "Diagnosis" field throughout the ODAG universes. Specifically, we were asked how to populate this field.

Response 66: Sponsors may populate the "Diagnosis" field in the ODAG universes by providing the ICD-10 code(s), a narrative description, or the ICD-10 and NCD codes.

CMS Action 66: 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 67: We received several questions regarding how to populate the "AOR Receipt Date" and "AOR Receipt time" fields throughout the ODAG universes. Specifically, we were asked whether sponsors should populate the "request receipt date" and "request receipt time" fields with the Appointment of Representative (AOR) receipt date and time or the actual date and time the request was received.

Response 67: Sponsors should populate the "AOR Receipt Date" and "AOR Receipt time" fields with the actual date and time of receipt of the AOR form, or other appropriate documentation. The "request receipt date" and "request receipt time" fields are intended to capture the actual receipt of the request and not the AOR form. Our timeliness tests factor in AOR receipt dates and times to ensure cases are not inappropriately marked as untimely, even if the AOR was received before the request.

CMS Action 67: 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 68: We received several questions and comments regarding how to populate partial approvals and partial denials in the ODAG universes. Specifically, commenters inquired if partial approvals are included in the universes, how to classify partial approvals and partial denials and whether the request should be included in one line or multiple lines (one for approvals and one for denials).

Response 68: For purposes of populating the audit universes, partial approvals and partial denials are considered denials and should be treated the same as denials (where all elements of a given request are denied) in the ODAG universes. Sponsors should enter these denials in one row within the appropriate universe(s) with a request disposition of "denied." If there are multiple notifications related to the request, enter the date and time of the last notification.

CMS Action 68: 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 69: We received several questions regarding how to populate the "Issue description and type of service" field throughout the ODAG universes, specifically, what level of detail is required.

Response 69: For approvals, sponsors should enter a description of the service or drug that was requested and why it was requested, if known. For denials, sponsors should provide this information in addition to an explanation as to why the request was denied (e.g., duplicate request, lack of medical necessity, no prior authorization, etc.).

CMS Action 69: 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 70: We received several questions regarding how to populate the "date of enrollee notification" and "time of enrollee notification" fields when mail is first delivered to a third-party sorting facility, which then places the notification in the mail.

Response 70: If a third-party sorting facility is used to sort or meter the mail before delivering it to the US Postal Service, we would want the date and time the enrollee's notification was actually placed into the hands of the US Postal Service either by the sponsor or by the third-party sorting facility.

CMS Action 70: 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 71: We received several questions regarding what constitutes "reasonable" efforts to obtain a Waiver of Liability (WOL) or an Appointment of Representative (AOR) form and what constitutes a "good faith attempt" to orally notify a beneficiary.

Response 71: Commenters should refer to Chapter 13 of the Medicare Managed Care Manual and the recent HPMS Memo, issued February 22, 2017, which discussed updated outreach guidance for more information with respect to reasonable outreach and good faith attempts. For audit purposes, sponsors should populate their universes based on how they interpret these terms based on the applicable guidance.

CMS Action 71: 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 72: We received several questions regarding whether withdrawn requests, SNF services, concurrent reviews, post-service reviews notifications of admission and requests for extensions of previously approved services should be included or excluded from the ODAG universes.

Response 72: Sponsors should exclude withdrawn requests, requests for SNF services, concurrent reviews, post-service reviews, notifications of admission and requests for extensions of previously approved services from their universes. If sponsors have already programmed their systems to pull in this information, they may include this information in their universes.

CMS Action 72: We have updated the exclusion language above the appropriate universes to clarify that these types of cases should be excluded from the ODAG universes. No changes were made to the burden estimate in response to this comment.

Table 1: Standard Pre-Service Organization Determinations (SOD) Record Layout:

Comment 73: One commenter wanted to confirm that Column N (Request for Expedited Timeframe) was intended to capture requests to upgrade a request from standard to expedited after the initial request was received, but before a decision was rendered on the request by the sponsor.

Response 73: CMS confirms that Column N (Request for Expedited Timeframe) was intended to capture requests that were upgraded from standard to expedited after the initial request was received, but before a decision was rendered.

CMS Action 73: 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.

Table 2: Expedited Pre-Service Organization Determinations (EOD) Record Layout:

Comment 74: We received several questions regarding Column N (Request for Expedited Timeframe), specifically, how to populate this field.

Response 74: This field is intended to capture requests that were received as expedited requests, but later processed as standard requests pursuant to Chapter 13, Section 50.3. If the request was received as an expedited request, but processed as a standard request, this field should be populated with the person who asked that the request be expedited. Similarly, if the plan, on its own, decided to process the standard request as expedited, it is unlikely it would deny its own request to expedite. Therefore, “CP” is not an option in the SOD universe for this field.

CMS Action 74: 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 75: We received several questions regarding Column N (Subsequent Expedited Request), specifically, how to populate this field.

Response 75: This field is intended to capture requests that were received as standard requests, but later processed as expedited requests pursuant to Chapter 13, Section 50. If the request was received as a standard request, but processed as an expedited request, this field should be populated with the person who asked that the request be expedited.

CMS Action 75: 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 76: We received several questions regarding how to populate Column R (Date of sponsor decision) and Column S (Time of sponsor decision) for pending cases and whether pending cases should be included in the universes.

Response 76: If a request is still pending, you may enter "NA" in these fields because they are untimely cases that are still open. Pending requests that are untimely should be included in the appropriate universes.

CMS Action 76: 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.

Table 3: Requests for Payment Organization Determinations (Claims) Record Layout:

Comment 77: One commenter asked us to define “clean claim” in the context of a pharmacy point-of-sale claim.

Response 77: The definition of “Clean claim” can be found in 42 CFR § 422.500.

CMS Action 77: 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 78: One commenter asked us to confirm that this universe should only include non-contract provider paid claims and contract and non-contract provider denied claims.

Response 78: We confirm that this universe should only include non-contract provider paid claims and contract and non-contract provider denied claims.

CMS Action 78: 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 79: We have received several questions regarding the inclusion of Part B drugs within this universe and how to populate this universe for Part B point-of-sale transactions.

Response 79: Sponsors should follow the universe population instructions when inputting data for Part B drug point-of-sale transactions and treat these requests as any other claim.

CMS Action 79: 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.

Table 4: Direct Member Reimbursement (DMR) Record Layout:

Comment 80: One commenter asked whether we should have included "NA" as an option for Column O (Was Interest Paid to the Beneficiary), as they believed interest did not have to be paid to beneficiaries for reimbursement requests.

Response 80: There are some circumstances where interest must be paid to beneficiaries for member-submitted payment requests. If interest was paid to the beneficiary, an entry of "Y" would be appropriate for this field, and if interest was not paid to the beneficiary, an entry of "N" would be appropriate for this field. If interest was not required and interest was not paid to the beneficiary, plans should enter "N" in this field.

CMS Action 80: 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 81: One commenter asked whether a response of "NA" would be appropriate for Columns Q (Date forwarded to IRE if denied or untimely), R (If request denied or untimely, date enrollee notified request has been forwarded to IRE) and S (AOR receipt date).

Response 81: Columns Q and R, are applicable to member-submitted payment requests that are reconsiderations. If a member-submitted payment request is received as an organization determination, then you would populate these fields with "NA." Column S is applicable to all member-submitted payment requests, whether an organization determination or a reconsideration, where the beneficiary has a representative acting on his/her behalf.

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: We received a question regarding how to populate the "Date reimbursement paid" field when the payment goes to a provider and not a beneficiary.

Response 82: Sponsors should enter the date the payment was made to the member or the provider.

CMS Action 82: 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 83: We received a question regarding how to populate Column G (Person who made the request) when there is no distinction between the beneficiary (B) and beneficiary's

representative (BR) in the sponsor's internal system.

Response 83: The vast majority of sponsors are able to make the distinction in their systems between requests submitted by beneficiaries vs. requests made by beneficiaries' representatives. If you cannot do this, either populate these fields manually with B or BR as appropriate or discuss this limitation with your Auditor-in-Charge after you receive your engagement letter.

CMS Action 83: 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.

Table 7: Requests for Payment Reconsiderations (PREC) Record Layout:

Comment 84: One commenter asked how to populate the payment reconsiderations universe (Table 7 – PREC) and direct member reimbursements universe (Table 4 – DMR). In particular, the commenter asked what to do in instances where the member disputes cost-sharing but where favorable appeals would result in the plan adjusting the provider claim (and where the provider is responsible for adjusting the member cost-sharing as they are the ones who collect these amounts).

Response 84: The payment reconsiderations universe (Table 7 – PREC) is populated with all payment reconsideration requests submitted by non-contract providers. The direct member reimbursement universe (Table 4 – DMR) is populated with all member initiated reimbursement requests, regardless of how repayment works or whether the provider has any involvement in how the reimbursement is issued to the beneficiary.

CMS Action 84: 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.

Table 11: Part C Oral & Written Standard Grievances (GRV_S) Record Layout:

Comment 85: One commenter asked whether Columns I (Category of Grievance/Complaint) and K (Was this a Quality of Care Grievance) are duplicative of one another, considering that Column I also has "Quality of Care" as a valid response.

Response 85: Column I is intended to capture the general nature of the grievance or complaint and could result in multiple types of answers (e.g., Enrollment, Access, Quality of care) and Column K is intended to capture whether the grievance or complaint is related to quality of care, which would be forwarded to the Quality Improvement Organization (QIO).

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.

Table 13: Dismissals (DIS) Record Layout:

Comment 86: We received a question regarding reasons for dismissing a request other than those specifically stated in the field description, such as duplicate request or no prior authorization.

Response 86: Column O (Reason for Dismissal) is a free-text field that may be populated with a description of why the request was dismissed. The valid values listed are merely illustrative

and are not intended to capture every possible reason for dismissing a request.

CMS Action 86: 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.

Table 14: Call Logs Part C (CLC) Record Layout:

Comment 87: One commenter asked why Column K (First Tier, Downstream and Related Entity) in this universe references dismissals when dismissals are not handled at call centers.

Response 87: This field is intended to capture the name of the first tier, downstream and related entity (FDR) that processed inbound calls on behalf of the sponsor.

CMS Action 87: We have revised this field in the protocol to say "Insert the name of the First Tier, Downstream, and Related Entity that processed the call". No changes were made to the burden estimate in response to this comment.

Comment 88: One commenter requested clarification regarding whether CMS would provide translators if audio files were needed and the audit file was not in English.

Response 88: Although the organization is expected to provide the call log universe in English, CMS would provide translators if audit files were needed for the review.

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: One commenter requested clarification regarding whether to include calls that covered both a Part C and Part D question in both the Part C and Part D call logs.

Response 89: If a call relates to both a Part C and a Part D issue the call may be included in one or both of the call logs.

CMS Action 89: 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 90: Two commenters requested that ODAG and CDAG Call Log universes provide consistent guidance regarding which calls are excluded from the request as well as whether transferred calls should be included. Specifically, one commenter requested that ODAG include the same exception or exclusions that CDAG listed.

Response 90: CDAG and ODAG are both requesting call logs for 2017, and while we have tried to make the requests as consistent as possible, some differences are necessary given the differences in the program areas. Also, calls that are transferred should be included in this universe as long as they relate to your Medicare Part C line of business and are from beneficiaries or their representatives.

CMS Action 90: 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 91: We received a question regarding whether or not calls from providers and/or prescribers should be excluded from this universe.

Response 91: Calls from providers and prescribers should be excluded from this universe.

CMS Action 91: 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 92: We received a question asking whether CMS would consider revising the call logs universe to only request grievances as not as much information is tracked for other types of calls.

Response 92: CMS recognizes there is no requirement for the information you must collect on all calls. The information we request in the call logs record layout is a recommendation for the types of information we would like to see in your call logs universe. However, please be sure to submit your call logs universe, in one of the approved file formats (e.g., .xls, .txt, etc.)

CMS Action 92: 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.