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

CMS received 43 public submissions, which included 570 comments on the June 13, 2016 (CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests proposed information collection. We then combined the 570 comments into 236 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 COMMENTS

### Disclosed/ Self-Identified Issues:

**Comment 1:** Several commenters asked about the reporting of disclosed and self-identified issues in the program areas and suggested improvements that could be made to this section of the protocols. Some commenters requested an extended timeframe for reporting these issues. These commenters argued that 5 business days was not sufficient for compiling these issues, especially issues that might be identified while pulling universes (i.e., self-identified issues). A few commenters suggested that the reporting of these issues is inherently unfair as sponsors that report honestly and transparently may be adversely impacted and receive an increased audit score.

**Response 1:** CMS appreciates the points raised by these commenters and agrees that changes should be made to the request for disclosed and self-identified issues. The original purpose in having this section in our protocols was to avoid sampling already corrected issues during our audit, which we considered beneficial to sponsors. CMS has always recognized the importance of a robust internal monitoring system in order for a sponsor to ensure ongoing compliance with CMS regulations. As such, it is important that a sponsor can quickly identify and correct issues of non-compliance before a program audit is conducted. It is also important for sponsors to maintain communication with CMS about these issues, and disclose them promptly to their Account Manager or other CMS personnel as appropriate. Therefore, 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 their audit universes. 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. We are changing the instructions for submitting disclosed issues in all of the program area protocols to reflect this new guidance. We are also updating the Pre-Audit Issue Summary template to reflect these changes.

With the elimination of reporting self-identified issues, sponsors should be able to easily submit a list of disclosed issues within the already established 5 business days. This list of disclosures should be a running list of issues maintained by the sponsor. Since an issue may only be disclosed prior to the date of the audit engagement letter, there would not need to be additional time given for issues discovered after the date of the audit engagement letter. Therefore we are not changing the timeframe for sponsors to submit the Pre-Audit Issue Summary to CMS.

**CMS Action 1:** We modified the disclosed and self-identified issues section of all the program area protocols to reflect this new guidance. We also updated the Pre-Audit Issue Summary template to reflect these changes.

**Comment 2:** A few commenters requested clarification on the disclosed and self-identified issues section. One commenter asked for clarification on what self-identified means and whether self-identified issues discovered following the engagement letter should be reported (i.e., issues discovered while pulling universes). Another commenter asked what timeframes should be followed for reporting disclosed and self-identified issues, as different program areas might have different audit review periods. Another commenter requested clarification on whether issues should be reported regardless of whether they are open or closed.

**Response 2:** We have modified this section of the protocols to only request issues that were disclosed to CMS prior to the engagement letter. Therefore, sponsors will not need to report self-identified issues, including issues that may be discovered during the pulling of universes. Instead, CMS wants all issues that were disclosed to CMS that might impact the audit universes, regardless of whether these issues are open or closed. 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 2:** We modified the disclosed and self-identified issues section of all the program area protocols to reflect this new guidance. We also updated the Pre-Audit Issue Summary template to reflect these changes.

**Comment 3:** Three commenters asked for clarification on the scope of the disclosed and self-identified issues that should be reported to CMS. One commenter asked how a sponsor would know what issues were relevant to the audit since samples and/or tracers had not yet been selected. Another commenter requested clarification that only issues related to program areas (CDAG, ODAG etc.) should be included and not issues related to areas like enrollment. The last commenter asked for clarification on what issues should be provided for the CPE protocol, and wanted to know whether issues related to other program areas (like ODAG, CDAG, etc.) should be included as a CPE disclosed issue if the compliance program monitoring discovered the issue.

**Response 3:** Sponsors should not determine what is within the scope of the audit based on samples or tracers, but instead that should be determined based on the program audit protocols and universes. For example, if the sponsor disclosed a transition fill issue, and transition is being reviewed as a part of the FA audit, that should be reported on the Pre-Audit Issue Summary for FA. Similarly, if an issue does not relate to one of the program areas (i.e., sponsor failed to submit enrollment transactions timely), that disclosure would not need to be included. Since two of the commenters specifically referenced either tracers or CPE, we want to clarify that disclosed issues for the CPE protocol are not issues discovered by the compliance team, but rather they are issues relating to the sponsor's compliance program. For example, the sponsor fires their compliance officer and as a result were unable to resolve several compliance issues timely. Another example, the sponsor disclosed an issue to CMS that during the audit review period the SIU failed to comply with a number of requests for additional information from the MEDIC and

enforcement agencies. Since CPE is so unique, we added examples of these disclosures into the CPE protocol. We also added a column into the Pre-Audit Issue Summary template asking for the program area impacted where sponsors will be required to identify CPE as the program area for issues impacting their compliance program.

**CMS Action 3:** Modified the disclosed language in the CPE audit protocol. Modified the Pre-Audit Issue Summary template to ask for program area impacted.

**Comment 4:** One commenter asked for clarification on how CMS defines "correction" for purposes of the audit. One commenter requested we clarify that validation of correction might be conducted by CMS or an independent auditor.

**Response 4:** We have removed the language relating to correction from this section of the protocols. Because we removed the section on how to define and validate "correction", we are not adding in text about third party auditors. Any corrective action or remediation should be identified in the Pre-Audit Issue Summary.

**CMS Action 4:** No change was made to the protocol in response to this comment. No changes were made to the burden estimates as a result of this comment.

**Comment 5:** One commenter suggested that we get a list of disclosed issues from the Account Manager instead of the sponsor. This same commenter suggested that if the AM could not provide the list, CMS should build a reporting module into HPMS so that sponsors could report disclosed issues year round.

**Response 5:** We appreciate this commenter's suggestion on how we could collect disclosed issues. For 2017, CMS will continue requesting a list of disclosed issues from the sponsor. While the Account Manager will still be responsible for validating the list of disclosures, we believe that the sponsor is in the best position to fully explain these issues and give an accurate update on the status of remediation. Also, while we appreciate the suggestion on building a new reporting module in HPMS, a project of that magnitude would vastly increase the burden on sponsors. While we are not able to accommodate this request at this time, we will take this suggestion under advisement for the future.

**CMS Action 5:** No changes were made to the protocol in response to these comments. No changes were made to the burden estimates as a result of this comment.

## Responding to Document Requests:

**Comment 6:** We had three commenters who suggested that sponsors were not given enough time to respond to documentation requests made during the audit. Two commenters specifically referenced impact analysis (IA) templates, while the third commenter referenced the Document Request Log (DRL). All three of these commenters asserted that the same staff that are participating in the audit, are also responsible for providing these document requests. As such, these commenters felt more time was needed to ensure that staff were not working long hours during the audit week. The two commenters that referenced the IA templates suggested that the IAs not be collected until the week after Week 1 of the audit.

**Response 6:** We agree with these commenters that it is often the staff involved in the audit that are also responsible for providing the follow-up documentation requests. As such, we agree that more time should be allotted for staff to pull this information. We are extending the

timeframe for the document request log (DRL) from 24 hours to close of business on the second calendar day following the request. In other words, if the DRL request is made Monday, the documentation would be due by close of business Wednesday. This DRL would include screen shots, narratives, and root cause analyses. We are also extending the timeframes for IA templates to be submitted from 5 days to 10 business days. Additionally, although auditors may identify an issue that requires submission of an IA during the audit week, the timeframe for that submission will not start until the end of week 1 (Friday of week 1). Although this timeframe was not originally specified in the audit protocols, we have included this new timeframe into the revised protocols to clarify expectations for sponsors.

**CMS Action 6:** We have made adjustments to the supporting statement and all protocols to accommodate these changes. We have also increased the burden estimate to include additional hours post audit to populate IA templates.

## Supporting Statement:

**Comment 7:** We had three commenters ask for clarification on the Provider Network Accuracy protocol. Two commenters requested the protocol (referenced in the supporting statement) be released to the industry. Another commenter requested more information on the pilot.

**Response 7:** The PNA pilot evaluation efforts will continue into 2017 and will remain separate from program audits through CY2017. On March 16, 2016, CMS issued the HPMS Memo entitled "CY 2016 Pilot Audit Protocol Release and Updates**:** Medication Therapy Management (MTM) and Provider Network Accuracy (PNA)", which describes the current PNA pilot process. There have been no updates to the process since the March 16, 2016 Memo. CMS will issue updates as the PNA pilot progresses. There is currently not a protocol to release to the industry. Additionally, although we do not have a protocol for PNA, we represented the burden on sponsors (with producing HSD tables) in the increased burden on sponsors.

**CMS Action 7:** We updated the burden estimate based on all comments, and included in the new burden is the impact of provider network accuracy.

**Comment 8:** We had one commenter suggest that our audits duplicate other CMS efforts, specifically that the transition piece of our FA audit is duplicative of the Part D Transition Monitoring Program done by CMS.

**Response 8:** We appreciate the commenter's concern and we agree that we do not want our audits to duplicate other work done by the agency. However, we do not believe that the auditing of transition fills that is conducted as a part of the FA protocol is duplicative of the transition monitoring program conducted by CMS. Our audits are a more in depth review of a sponsor's systems and more interactive than the monitoring efforts that are done.

**CMS Action 8:** 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 9:** We had one commenter disagree with our assertion that 70% of information requested from sponsors comes from their internal systems, while the remaining 30% comes from CMS systems. This person referenced compliance program questionnaires that need to be filled out manually as support for their comment.

**Response 9:** We agree that while most of the information we collect during audit is located in internal systems, not all of the information is. The CPE protocol currently has 4 questionnaires that sponsors are required to submit, and CDAG and ODAG each have one questionnaire. These questionnaires need to be filled out manually and cannot be pulled from internal systems. However, these questionnaires are a small part of the audit, and we do not think they account for more than 10% of the documents requested. We are therefore modifying our estimates to suggest that 60% of documents requested are from internal systems, 30% are from CMS systems, and 10% are manually populated.

**CMS Action 9:** We revised our supporting statement to show this change in information collected.

## Burden Estimate:

**Comment 10:** We had multiple commenters comment on our burden estimate in the supporting statement. These commenters indicated that we had underestimated the burden on a sponsoring organization for one of our program audits. Along with general comments, we had a few commenters that offered specific feedback on what they felt was the true burden of a program audit. These commenters offered a staffing burden ranging from 27 to 60 staff. Additionally, some commenters provided input on our hourly estimates, with suggested estimates ranging from approximately 400 to 6,000. A few of these commenters suggested that CMS collect burden information in the post-audit survey as a way of ascertaining the true burden of audits. One commenter asked if the survey was included in the PRA package.

**Response 10:** We appreciate theses commenters input on the burden estimate, especially the comments that included suggested revisions. We agree that adding a collection of this information into our post audit surveys is a great idea, and we will be looking to collect this information from any sponsors audited in 2017. We also recognize that the burden will likely differ greatly depending on the size of the organization being audited, and whether that organization has any FDRs. In an effort to more accurately reflect the burden on sponsors, we took the commenters suggestions and looked to the median of suggestions in order to revise our estimates. We have therefore changed our estimates from 8 staff to 30 staff needed for an audit, and revised the total audit hours from 341 to 701. The breakdown of the staff and hours necessary for an audit is included in the revised supporting statement document. Additionally, we have adjusted the burden estimates to account for new industry wide timeliness monitoring that will be done for all sponsors each year. The new burden estimates reflect the additional costs associated with this monitoring effort. The survey is not included in the PRA package as it is an optional survey that sponsors are not required to submit.

**CMS Action 10:** We made changes to the burden estimates to reflect an increase in staff and hours for sponsors during audit. We also made changes to the burden estimate to reflect the new costs associated with the industry wide monitoring effort.

**Comment 11:** We had a few commenters request that we consider not conducting a program audit if another CMS audit is simultaneously being conducted (i.e., a 1/3$^{rd}$ Financial Audit).

**Response 11:** Unfortunately due to the nature of some other CMS audits, we cannot always avoid our audit overlapping another audit. If CMS conducts a program audit at the same time another audit is being conducted we encourage the sponsor to share that with CMS so that we may take that into account during our review.

**CMS Action 11:** 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 12:** We had one commenter suggest that we also consider the cost of hiring an independent auditing firm for validation audits into the burden estimate for sponsoring organizations.

**Response 12:** We agree that some sponsors will have to incur extra costs with the hiring of an independent auditing firm on validation. We are therefore revising our burden estimate to include these extra costs. We estimate that 65% of the 40 sponsors (26 sponsors) will have to hire an independent auditing firm. While we know the price of hiring an independent firm can vary, we are estimating that the cost will be approximately $250,000 per sponsor.

**CMS Action 12:** We changed the burden estimate to account for the cost of hiring an Independent Auditing Firm.

## Comments Impacting All Protocols:

**Comment 13:** One commenter asked for clarification of the word "legend" which was used in a few of the protocols in reference to the supporting documentation that would be requested by CMS.

**Response 13:** We are deleting the sentence that refers to "legend" in all the applicable protocols. All protocols should have similar language now in the "Responding to Documentation Requests" section.

**CMS Action 13:** We deleted all references to a “legend” in the audit protocols.

**Comment 14:** Two commenters asked for the methodology of how CMS would cite IDS conditions. One commenter specifically asked how IDS conditions would be used in CPE.

**Response 14:** IDS conditions will only be cited when a sponsor has attempted three times to submit a universe of data to CMS, but has failed to do so in a manner that allows all elements to be tested. For example, if a sponsor submits their standard coverage determination universe three times, and on the third time CMS notes that the dates and times provided in the universe are still wrong, CMS would not be able to test the timeliness element for that universe. When we are unable to test an element due to incomplete or inaccurate universes, the sponsor will be cited an IDS for the universe. The IDS for this example would be the related to the inability to test timeliness due to the invalid data submission. For CPE, an IDS condition may be cited if on the third submission a universe contains inaccurate or incomplete information that does not allow the audit team to test a specific element (or pick a tracer).

**CMS Action 14:** 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 15:** Several commenters requested that we review and change the record layout fields less frequently so as to reduce the operational burden on sponsors each year. One commenter suggested we provide a marked-up version of the protocol to allow sponsors an easier time of tracking the changes made.

**Response 15:** We agree with these commenters on both points. We recognize that sponsors implement system programming for purposes of pulling audit universes based on the fields

included in the record layouts. We also agree with these commenters that we should try and limit making substantive changes to the record layouts, however, we also have to be responsive to public comments and take into account requested revisions. We always try to balance being responsive to public requests with being sensitive to limiting changes when feasible. In an effort to reduce the number of changes, once the protocols in this PRA package are finalized, they will be utilized for multiple audit years, and they will no longer be updated every year. Instead, we anticipate these protocols being used for 2017, 2018, and 2019 audits. Because the Medication Therapy Management (MTM) program audits are in the pilot phase the likelihood of protocol modifications is higher in this protocol than for other program areas, and we anticipate more substantive changes for this pilot protocol. In response to the other commenter, we are releasing a crosswalk of all changes made to each protocol, all other audit attachments, and the supporting statement. We cannot release a red-lined version of the protocol as that would not be 508 compliant.

**CMS Action 15:** We removed the specific reference to audit year 2017 on the title page of the protocols. We deleted references to specific years for universes in FA and MTM.

**Comment 16:** One commenter asked why Contract ID was removed from the first MTM table (CY 2015 Medication Therapy Management Program).

**Response 16:** This field was left out of the table by error. However, this table has since been removed from the protocol so no changes were made based on this comment.

**CMS Action 16:** 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 17:** One commenter asked if the 800 series PBPs should be included for all universes and whether those PBPs would be tested.

**Response 17:** Yes, sponsors should include the 800 series PBPs into all applicable universes. These PBPs may be selected during sampling.

**CMS Action 17:** 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 18:** One commenter wanted to thank us for posting these audit protocols publicly, and encouraged us to continue doing so. This commenter also thanked us for the other educational tools and opportunities such as the ODAG and CDAG job aids, HPMS memos, the annual audit and enforcement conference, and the audit email box.

**Response 18:** We greatly appreciate this commenter's feedback and praise. We hope that our audits and the tools that we release will help drive industry improvements and performance, and we are committed to continuing to be as transparent as possible with releasing our protocols, tools, and any other guidance we can provide.

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

**Comment 19:** One commenter noted that CMS removed the reference to informing sponsors of the classification of conditions during the audit. This commenter wanted to confirm that we would no longer be sharing the classification of conditions with the sponsor.

**Response 19:** While CMS strives to be as transparent as possible in our audits, we are no longer sharing the classification of conditions with the sponsor during the first two audit weeks. CMS is committed to ensuring consistency in our audits, and as such, we take every condition found on audit back to the Program Audit Consistency Team (PACT) to discuss the finding and the classification. Sponsors will still be told of every condition found during the audit, but the actual classification of the conditions will not be shared until the draft audit report, following the team discussion with the PACT.

**CMS Action 19:** 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 20:** We had two commenters request that we standardize language wherever possible in all audit protocols. These commenters suggested making any like-fields similar in the protocols (such as the record layouts) but also standardizing language in the main body of the protocol (like in the Review Period section).

**Response 20:** We agree with these commenters that we should strive to be as consistent as possible, and so we have reviewed all protocols for areas that we could standardize. We balanced the need for consistency with the comments received concerning limiting changes to record layouts whenever possible. We have made a few changes to the protocols in order to make certain record layout fields consistent, or standardized language in the main sections. However, due to the nature of the different program areas, some language was kept unique so as to accurately reflect the nature of that particular protocol. Additionally, we have refrained from making too many substantive changes that might impact a sponsor's programming for 2017.

**CMS Action 20:** We made some minor changes to the protocols to ensure consistency wherever possible. Changes are discussed in the crosswalks.

**Comment 21:** One commenter requested that we release more information on how sponsors are selected for audit. Additionally, this commenter requested that we release our audit schedule for when we expect to send engagement letters (dates).

**Response 21:** CMS appreciates this comment, and we agree that we can release some information about our intended audit schedule. While we cannot release the full schedule since audits can change or shift throughout the year, we will release information to sponsors regarding when we expect to send the first and last engagement letter of the audit year, so that sponsors can know what period of the year audits will be conducted. This information will likely be sent out through an HPMS memo prior to the audits starting in 2017. In regards to being transparent in the sponsors we select, we feel we are already transparent with the industry on our methodology for selecting sponsors. We discuss this selection in our annual audit report, including how we utilize a risk assessment, regional office referrals, and other tools for sponsor selection.

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

**Comment 22:** We had multiple commenters request clarification on how CMS applies our compliance standards. A few commenters asked for clarification on when we may assess factors not addressed in our compliance standards. Two commenters asked for clarification on

how conditions would be applied (and what one-to-one versus one-to-many meant), including one specific comment relating to how this applied to CPE. One commenter also requested information on the thresholds in CPE that would be used during audit to pass an element. One commenter suggested the CPE compliance standards were more global than specific to an element.

**Response 22:** We appreciate these commenters requesting clarification on CMS compliance standards. We provide the compliance standards to the industry as a way of being transparent in what we are primarily assessing during our audits. However, during the review, CMS may note items outside of the specific compliance standards that warrant review or that indicate a condition of non-compliance. In those instances, CMS may review information outside of the specific compliance standards noted in the protocol. Additionally, during a review of a case or a tracer, CMS may review multiple compliance standards. For example, during the review of a denied coverage determination, CMS may review that the case was appropriately classified (exception versus attempt to satisfy a PA), that outreach was conducted, that the denial rationale was appropriate, and that the denial letter contained appeal rights. This one case (or denied coverage determination) may lead to multiple conditions being cited (e.g., failure to do outreach, insufficient denial rationale, etc.). Likewise, a case may only have one condition cited if that particular case only indicated one issue of non-compliance. For CPE the same approach is utilized, so during a tracer review, more than one condition may be cited if there are multiple issues of non-compliance noted. As one commenter noted, the compliance conditions in CPE are more global, however, auditors will still utilize those in reviewing the tracers. Elements no longer receive a pass or fail for the overall element, so there are no thresholds for elements, other than the internal thresholds used during CDAG and ODAG to assess timeliness of cases.

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

**Comment 23:** We had one commenter request that we update all page numbers in the protocols for consistency.

**Response 23:** We updated all page numbers in all protocols.

**CMS Action 23:** We updated all page numbers in all protocols.

## CALL LOGS

We received numerous comments about the inclusion of call logs into the Part C Organization Determinations, Appeals and Grievances (ODAG) protocol and the Part D Coverage Determinations, Appeals and Grievances (CDAG) protocol. Since the comments were very similar in nature across the protocols, we have combined both sets of comments and are answering all comments in this one section.

**Comment 24:** We received numerous comments regarding our addition of call logs into the CDAG and ODAG protocols. The majority of commenters indicated concern that the addition of a call log request would be overly burdensome to plans. Commenters mentioned that call logs for some organizations can be massive in size, and also mentioned that pulling this information could be time consuming and difficult. Some of these commenters requested that we not include call logs into the 2017 CDAG or ODAG protocols due to the burden outweighing the potential benefit. Other commenters suggested that if we include call logs, we greatly limit the

amount of calls requested and clarify what calls we are requesting. One commenter suggested if we keep call logs it should be a separate section of the protocol.

**Response 24:** We appreciate all of the comments on the proposed addition of call logs into the CDAG and ODAG protocols. We proposed this addition as a way of testing the appropriate classification of oral calls from enrollees (i.e., are sponsors appropriately identifying coverage determinations/ organization determinations and grievances from enrollee calls). Due to the large number of comments concerning the burden of this request, we are modifying our protocol in several ways. First, we are limiting what calls will need to be submitted. We will only be requesting calls from enrollees and/or representatives (i.e., your customer service line(s)), not prescribers or calls unrelated to an enrollee request. Second, we are limiting the amount of calls we are requesting. Instead of having calls submitted based on the audit time period (1 to 3 months depending on the size of the organization), the timeframe for the call logs will be based on the size of the organization, and will be limited to 2 to 4 weeks depending on the organizations size. This universe information has been included in the protocol in the record layouts section for the call logs. Third, we are allowing sponsors to submit universes in formats other than the one suggested by the protocol. We understand and appreciate that call systems may vary greatly in how information is received and recorded. Since timeliness tests will not be done on the call logs universe, we are allowing sponsors in 2017 to submit call logs in whatever format is generated by their system, so long as the minimum information needed by CMS is included. The information required is identified in the call logs universe. We updated the record layout to show when a field is required and also when a field (i.e., Contract ID) is optional and may be excluded if a sponsors system does not capture this information. For 2017, call logs will continue to be included in the element testing grievances and misclassification of requests.

**CMS Action 24:** The CDAG and ODAG protocols have been updated to reflect the changed approach to reviewing call logs in 2017.

**Comment 25:** Some commenters requested that we clarify what calls we would be requesting in our call logs, indicating that the call logs would be too massive if we included all calls relating to Part C for ODAG or Part D for CDAG. Some of these commenters suggested we limit the calls requested to calls from enrollees and/ or representatives. Other commenters asked if they should only include customer service calls or all calls from enrollees including oral grievances and oral coverage requests. A few commenters asked for clarification on whether we would need calls made to FDRs or delegated entities.

**Response 25:** As mentioned above, we agree with these commenters that requesting all Part C or Part D calls for the entire audit period would be too massive. We will therefore limit the calls that we are requesting to calls from Part C or D enrollees and/or representatives. However, we want all calls from enrollees and/or representatives, including calls that were identified as oral coverage requests and/or grievances. We would also need calls made to FDRs or delegated entities if these entities handled customer service inquiries or coverage requests (i.e., if your PBM processes coverage determinations).

**CMS Action 25:** The CDAG and ODAG protocols have been updated to reflect the changed approach to reviewing call logs in 2017.

**Comment 26:** Several commenters asked about CMS's expectations relating to audio files for the call logs. One commenter asked what our timeframes for receiving audio files would be, mentioning that sometimes audio files are not readily available. Several commenters also

asked what CMS's expectations were if the audio files were not available. A few commenters asked if audio files needed to be translated into English for the auditors. Another commenter asked what documentation in addition to audio files needed to be provided for auditors. One commenter asked if calls that are not recorded should be excluded from the call log.

**Response 26:** All incoming calls from enrollees and representatives should be included in the submission to CMS, regardless of whether the call was recorded or not. We will not be requesting audio files to be submitted before the audit to CMS. Rather, during the review of call logs, auditors may request to listen to a call if the audio file is available or the documentation of the call is insufficient to determine what happened. If an audio file is not available, auditors will utilize the call notes available. If a translation into English is needed, auditors will provide their own translator. CMS will be reasonable with timeframes when requesting access to audio files from sponsors.

**CMS Action 26:** No changes were made to the protocol in response to these comments. No changes were made to the burden estimates as a result of this comment.

**Comment 27:** A few commenters asked for clarification on what we would be reviewing during the call log review, and how we would assess compliance. Some other commenters asked that we define the word "quickly" and what it means to quickly transfer the call to the appropriate process.

**Response 27:** Auditors will assess the calls to determine if they were appropriately classified and if not, was the error quickly identified and routed to the correct process. What will be considered "quickly" may vary depending on the nature or type of call. For example, an expedited request for coverage may need to be more quickly identified than a standard grievance.

**CMS Action 27:** No changes were made to the protocol in response to these comments. No changes were made to the burden estimates as a result of this comment.

**Comment 28:** A few commenters mentioned that providing calls in the format provided by the record layout would be difficult, as systems can vary and trying to manually enter data would lead to errors and be overly burdensome.

**Response 28:** We agree with these commenters. Therefore CMS will allow sponsors to submit call logs in formats other than the one provided in Appendix A so long as the minimum information needed for the logs is provided.

**CMS Action 28:** We have made the record layout for call logs a “suggested” format not required.

**Comment 29:** A few commenters requested that the fields in the call log record layout be made consistent with the other record layouts (similar fields will have similar lengths).

**Response 29:** We agree and whenever possible, we have made the call log record layout similar to the other layouts. However, as mentioned above, this record layout is a suggested format only and sponsors will be allowed to submit call logs in other formats.

**CMS Action 29:** We have modified the record layout for call logs to be consistent with the other record layouts whenever possible.

**Comment 30:** We received several questions regarding the "Category of the call" and "Description of the call" fields in the Call Logs universes (Table 14 in ODAG and Table 16 in CDAG). Specifically, we were asked if we could combine these two fields into one field.

**Response 30:** As mentioned above, we have made the call logs record layout a suggested format. Additionally, we have identified required data (fields that sponsors must include in the call logs) and optional data (fields that may be included if the sponsor has that information). Category of calls was included as an optional field for 2017.

**CMS Action 30:** We have modified the call logs record layouts to include both required and optional information.

**Comment 31:** A few commenters asked how they should include calls that might relate to Part C and Part D.

**Response 31:** Sponsors may include calls relating to both Part C and D in both the Part C and D call log universes.

**CMS Action 31:** No changes were made to the protocol in response to these comments. No changes were made to the burden estimates as a result of this comment.

**Comment 32:** A few commenters requested specific clarification on the types of calls that should be included, specifically asking if IVR calls, outgoing calls, or warm transfers should be included in the call logs.

**Response 32:** We appreciate the commenters questions and want to clarify that we want all calls received (incoming only) from enrollees or their representatives. We do not need IVR calls or outgoing calls. If a call is transferred that can be indicated in the description field or resolution field. For example, if an incoming call from an enrollee was a request for coverage and the sponsor transferred that call to the department that processes organization determinations or coverage determinations, that transfer should be noted in the description or resolution field.

**CMS Action 32:** No changes were made to the protocol in response to these comments. No changes were made to the burden estimates as a result of this comment.

**Comment 33:** One commenter requested that if there are multiple requests made in one call, that the requests can be separated in the call log as separate calls to prevent confusion and help identify categorization.

**Response 33:** We agree with this commenter that reporting multiple issues as separate calls may help alleviate confusion and help identify how specific issues were classified. For sponsors that want to separate calls by issue, they certainly can. However, sponsors will not be required to separate these calls into multiple calls if that would be too burdensome. If a call involves multiple issues, and is selected for review, the auditors will ask how the sponsor dealt with each of the issues.

**CMS Action 33:** 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 34:** One commenter requested clarification on how calls should be categorized.

**Response 34:** In ODAG, CMS will be assessing whether sponsors appropriately identified oral requests for coverage or oral complaints as either Part C organization determinations/ appeals/ grievances in compliance with 42 CFR 422.566(b), 42 CFR 422.566(d), 42 CFR 422.568(a), 42 CFR 422.570(b), 42 CFR 422.584(b). In CDAG, CMS will be assessing whether sponsors appropriately identified requests for coverage or oral complaints as either Part D coverage determinations/ appeals/ grievances in line 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 34:** No changes were made to the protocol based on this comment. No changes were made to the burden estimates as a result of this comment.

**Comment 35:** One commenter requested clarification on which compliance standards will be used to assess calls. Specifically, the commenter asked if we would be reviewing the second compliance standard (does the notification reference all issues identified in the grievance).

**Response 35:** For calls, only the first compliance standard of whether the call was appropriately classified would apply. We will not be looking at notification for the call log review.

**CMS Action 35:** No changes were made to the protocol based on this comment. No changes were made to the burden estimates as a result of this comment.

**Comment 36:** One commenter asked if an oral grievance was received would it appear in both the grievance universe and the call log.

**Response 36:** Yes, an oral grievance may appear in both the grievance universe and the call log universe if the grievance was oral and filed by the enrollee and/ or representative.

**CMS Action 36:** No changes were made to the protocol based on this comment. No changes were made to the burden estimates as a result of this comment.

**Comment 37:** One commenter asked if all incoming calls had to be documented and recorded per CMS guidance. This commenter stated that they track incoming grievance calls, but not all other member calls. The commenter asked CMS's expectation on tracking and recording calls.

**Response 37:** Record keeping and documentation is essential for demonstrating sponsor compliance with Part C and Part D regulatory requirements. As a part of this regulatory compliance, sponsors are required to accept and document oral requests for coverage (organization determinations, coverage determinations, and appeals) as well as oral grievances. During an audit, a sponsor would need to provide any evidence (i.e., call notes, recorded calls, transcripts, etc.) available that shows they are able to satisfy these regulatory requirements, including when the request is made via phone.

**CMS Action 37:** No changes were made to the protocol based on this comment. No changes were made to the burden estimates as a result of this comment.

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

### Policy Questions:

**Comment 38:** Multiple commenters asked us to define certain words or terms from Chapter 18. A few commenters requested CMS explain what "re-openings" or "dismissals" are in Part D, and

what those requests would look like. A few other commenters requested CMS define "immediately" in terms of written confirmation of oral notification.

**Response 38:** These questions are outside the scope of our 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 example, we would want all cases processed as a coverage determination, regardless of whether it was eventually dismissed, approved, denied, or withdrawn. For policy guidance commenters should refer to 42 CFR 423 Subpart M and Chapter 18 of the Prescription Drug Benefit Manual.

**CMS Action 38:** No changes were made to the protocol in response to these comments. No changes were made to the burden estimates as a result of this comment.

**Comment 39:** Several commenters asked for policy clarifications on Part D appeal issues. One commenter asked if notification should be provided to enrollees for reimbursement cases that are dismissed, withdrawn, or re-opened. One commenter asked if we could define medical necessity for purposes of exception requests. Another commenter argued that the policy of auto-forwarding late cases to the IRE can actually cause a delay in access to the enrollee when the IRE or ALJ may be late in processing these cases.

**Response 39:** These questions are outside the scope of our PRA package. For policy guidance commenters should refer to 42 CFR 423 Subpart M and Chapter 18 of the Prescription Drug Benefit Manual. For audit purposes, CMS will look to ensure that sponsors are in compliance with those requirements.

**CMS Action 39:** No changes were made to the protocol in response to these comments. No changes were made to the burden estimates as a result of this comment.

## Supplemental Questionnaire:

**Comment 40:** Two commenters asked about the supplemental questionnaire. One commenter asked if question 4 should have referred back to question 3 (not question 6). Another commenter asked if the sponsor or an FDR should fill out the questionnaire.

**Response 40:** Sponsors are responsible for filling out and submitting the questionnaire, but they can have their FDRs assist whenever needed. Question 4 should have referred back to question 3 not question 6. This error has been fixed.

**CMS Action 40:** Updated the questionnaire with a new question 4.

## Universes:

**Comment 41:** Three commenters asked if we would consider not using a standardized time zone for CDAG and ODAG universes, and instead maintaining our 2016 approach of utilizing a case specific time zone approach. These commenters argued that using a standardized time zone could impact the reliability of the universes and increase the chances for universes to be deemed inaccurate due to manually changing cases.

**Response 41:** We agree with the commenters that using a standardized time zone may increase the chance for error when submitting universes to CMS. We therefore are eliminating the requirement for sponsors to use one standardized time zone. Instead, cases should be submitted so that each case is submitted in the time zone for which the case was received.

**CMS Action 41:** We modified the universe instructions to clarify that sponsors should not submit universes in all one standardized time zone, rather each case must be in a consistent time zone.

**Comment 42:** A few commenters asked why CMS removed the language from the beginning of the protocol relating to how to pull universes (which dates to use). These commenters thought the information was helpful and asked that it be re-included in the protocol.

**Response 42:** We appreciate the commenters' thoughts on this section. We agree that it is important to give instructions on how to populate and pull the universes. We therefore moved the instructions to the record layout section of the protocol and created tailored language for each table at the beginning of the table. The bullets above each table explains how to pull the universes and what cases to include and exclude. After adding this language into the tables, we deleted the repetitive language in the beginning section of the protocol, however we added a sentence referring readers to the appendix for instructions.

**CMS Action 42:** Added a sentence referring people to the appendix for universe instructions.

**Comment 43:** Multiple sponsors requested clarification on what type of cases should be included in various universes. Specifically we had a few commenters request clarification on whether dismissals and withdrawals should be included in the CDAG universes (including grievances). Also we had two commenters ask if, like in ODAG, sponsors could exclude specific types of cases from redetermination universes or reimbursement universes (such as duplicate claims, billing errors, etc.).

**Response 43:** For audit purposes, in CDAG, we want all cases included in the universes as they were processed, regardless of the disposition of the case, or what the request was about. For example, we want all cases processed as redeterminations, regardless of the reason for the redetermination (billing error, duplicate, etc.) to be included with the disposition of the case. Although ODAG excludes cases from certain universes, in CDAG, all universes are all-inclusive except for items specifically excluded in the bullets above the tables.

**CMS Action 43:** 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 44:** One commenter asked if a case may appear in multiple universes or if it should only be included in one universe.

**Response 44:** Sponsors should include cases in all applicable universes. For example, during a three month audit universe, a sponsor may have a standard coverage determination come in and a standard redetermination. That case should be included in both the standard CD and standard RD universes. Likewise, if a redetermination is untimely and auto-forwarded, it must be included in both the redetermination universe and the auto-forward universe.

**CMS Action 44:** 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 45:** We had one commenter ask why CMS allows for cases that were not processed to be included in the redetermination tables if the table asks for cases by how they were processed.

**Response 45:** We appreciate this commenters questions regarding how to populate cases in the universes. CMS requests that cases be included based on when they were processed or should have been processed. This means that most, if not all, cases should have a final disposition when submitting the universes. However, we have gotten some questions from sponsors regarding how to submit cases that are late and still open. In CDAG, late cases once identified should be auto-forwarded, however based on sponsor questions, we allowed the option of NA for cases not yet resolved or processed.

**CMS Action 45:** 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 46:** Several commenters asked about re-openings and how re-openings should be included in the universes. One commenter asked if they should enter an NA for re-openings in the field asking if the request was denied for lack of medical necessity. One commenter also asked if we only wanted re-openings that were issued a new (revised) decision. Two other commenters asked what the receipt date and time should be for a re-opening. Specifically, they asked whether it should be the original receipt date and time or the date and time the sponsor re-opened the request.

**Response 46:** We appreciate these commenters questions, and want to clarify that we are requesting all cases processed as coverage determinations or redeterminations, including re-opened decisions (whether they are approved or denied). For the 2017 protocols, CMS clarified in the request disposition field that any re-opened case should be identified as re-opened approved or re-opened denied. Sponsors should use those identifiers to help populate the rest of the record layout as relevant. For example, if the re-opened CD was denied, the sponsor would have to enter whether the case was denied for lack of medical necessity. When populating the receipt date and time of the re-opening, sponsors should use the date and time the sponsor re-opened the request, not the original date and time of the previous coverage request.

**CMS Action 46:** No changes were made to the protocol in response to these comments. No changes were made to the burden estimates as a result of this comment.

## Timeliness:

**Comment 47:** Multiple sponsors asked us to share our internal timeliness thresholds that we use to assess whether a sponsor gets a CAR, ICAR or observation for timeliness.

**Response 47:** We appreciate the comments, however at this time we do not share our internal thresholds. Sponsors should strive to achieve timeliness in all cases and the regulation is written to expect 100% timeliness. For audit purposes, we have created thresholds that we believe are reasonable for a sponsor to meet.

**CMS Action 47:** No changes were made to the protocol in response to these comments. No changes were made to the burden estimates as a result of this comment.

**Comment 48:** We had several commenters ask about our timeliness tests. A few commenters asked for clarification on how the tests are run, and how the results are combined (if they are combined). One commenter noted that CDAG combines some tests, but ODAG does not. That commenter requested that ODAG also combine timeliness tests if possible.

**Response 48:** Each universe has at least one timeliness test that is run on that universe. Most have at least two. For example, standard coverage determinations will have a test done to determine notification timeliness (was notification provided within 72 hours) as well as effectuation timeliness (was the approval effectuated within 72 hours). Those two tests will also be run on standard coverage determination exception requests (table 2) using the supporting statement as the "receipt" date. Since the two compliance standards are the same (standard CDs should be decided, notified and effectuated within 72 hours) the results will be combined. For example, if the sponsor is untimely in notifying standard coverage determinations and standard exception request coverage determinations, the results will be combined so the sponsor only has one untimely condition for being untimely (not meeting the 72 hour timeframe). At this time, ODAG does not combine or merge any of their timeliness results.

**CMS Action 48:** No changes were made to the protocol in response to these comments. No changes were made to the burden estimates as a result of this comment.

**Comment 49:** One commenter asked when the "clock starts" for purposes of the timeliness tests. Specifically, the commenter asked if the day the request was received would be counted as day one or day zero when determining whether a request was timely.

**Response 49:** When a request is deemed "received" is a policy decision, and policy issues are outside the scope of this protocol. For audit purposes we consider the request received the moment the request comes into any part of plan via any method (fax, electronic, or phone). For timeliness calculations we would use the start time as the exact time it came into the plan for compliance standards involving hours (e.g., standard coverage determinations) and we would use the next calendar day to count as day one for compliance standards involving days. For example, for standard redeterminations that must be resolved in 7 days, if the request comes in on Monday, Tuesday would be counted as day 1 for purposes of the timeliness test.

**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 asked if CMS would identify the rows in the record layouts used to conduct the timeliness test for each universe.

**Response 50:** We are not currently including the rows that CMS uses for the timeliness test as it could lead to confusion as the timeliness test may change depending on the type of case. Sponsors should review policy guidance on what constitutes a timely decision and audit their own universes to ensure timeliness. We compare all applicable rows in determining whether a case is timely, including oral notification, written notification, and any fields that might change the calculation such as if a request was upgraded from standard to expedited.

**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.

## Clinical Appropriateness:

**Comment 51:** We had one sponsor ask about the clinical appropriateness sampling, and asked for clarification on why there may be 40 to 45 samples selected.

**Response 51:** CMS will select a minimum of 40 clinical appropriateness samples to review during the audit, 10 approvals and 30 denials. However, auditors may select an additional 5

samples of other types of cases (dismissals, withdrawals, or re-openings) if the auditor feels it is warranted. This means that there may be anywhere from 40 to 45 cases reviewed during the clinical appropriateness portion of the CDAG audit.

**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 recommended we add what tables CMS would use to pull each sample from into the clinical appropriateness element.

**Response 52:** Samples may be pulled from any applicable universe as the auditor determines necessary. For example, denied coverage determinations may be pulled from any universe of coverage determinations.

**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:** Two commenters requested clarification on IRE, ALJ or MAC overturns. Specifically, one commenter requested clarification on whether these cases would be considered denials or approvals for purposes of sampling. The commenter pointed out that CMS seems to consider these denials, even though the overturn is a favorable decision for the enrollee. Another commenter asked how CMS would review the overturns and how CMS would consider the overturn a "pass" for the plan.

**Response 53:** We agree with the commenter that these cases are favorable decisions to the enrollee (and therefore are technically approvals), however, the sponsor's decision in the underlying coverage determination or redetermination was a denial. Therefore the case is sampled by the CMS physician to assess the plan's clinical decision making in denying the case. During the overturn review, the CMS physician will review the plan's outreach processes and the documentation they had available to them in making their decision. If the plan denied the case appropriately based on existing documentation, and the IRE overturned the case, the case will not be considered deficient for clinical decision making.

**CMS Action 53:** No changes were made to the protocol in response to these comments. No changes were made to the burden estimates as a result of this comment.

**Comment 54:** One commenter asked why CMS inquires as to whether an enrollee got a formulary alternative as a compliance question in clinical appropriateness. The commenter wanted to know if they were required to give a formulary alternative, and if so, when that requirement would apply.

**Response 54:** We agree with the commenter that this compliance standard implies that offering a formulary alternative is required in order to be in compliance with our requirements. We are therefore deleting this compliance standard from the protocol.

**CMS Action 54:** We deleted the compliance standard that asked if a formulary alternative was given.

**Comment 55:** One commenter noted that we referred to a reconsideration in one section of the protocol instead of a redetermination. The commenter requested we change the word to "redetermination" in CDAG to stay in line with language from Chapter 18.

**Response 55:** We agree and made this change.

**CMS Action 55:** We changed “reconsideration” to “redetermination”.

## Grievances:

**Comment 56:** Several commenters requested clarifications regarding the auditing of grievances, both standard and expedited. One commenter asked for clarification regarding how the auditors would select samples when the sponsor did not have expedited grievances. Another commenter asked what compliance standards would be used for grievances versus call logs. Lastly, two commenters requested clarification on the categories listed in CDAG for expedited grievances. These commenters noted that sponsors are only required to expedite grievances when they deny an enrollee's request to expedite a coverage request. These commenters thought the inclusion of other reasons was confusing.

**Response 56:** We appreciate these comments on the grievance element, and hope we can provide clarification on the areas of confusion. We agree with the first commenter that we could be clearer on how auditors will sample when there are no expedited grievances. When there are not enough expedited grievances to sample (less than 3), auditors will select additional standard grievances to review. This change has been made in the protocol. For both standard and expedited grievances, these cases will be assessed using both compliance standards in this section (was the case correctly categorized/ processed and was appropriate notification sent). We have re-worded the first compliance standard to specifically reference grievances in order to clear up that confusion. Lastly, we agree with the two commenters that thought the grievance categories for expedited grievances were confusing. We originally included all categories because, although sponsors are not required to expedite grievances for issues other than the one identified by the commenters, some sponsors choose to expedite grievances for other reasons. We have modified this field to allow for only two options now, the first is for when a sponsor refuses to expedite a coverage request, and the second is "other" for any sponsor that may expedite grievances for other reasons.

**CMS Action 56:** We have made several changes to the CDAG protocol. First, we have clarified our sampling methodology when sponsors do not have expedited grievances. Second, we clarified the compliance standards that will be used to assess grievances. Third, we eliminated the categories for expedited grievances, and instead listed only two categories as options.

**Comment 57:** One commenter requested that the extension field be removed from CDAG and ODAG for expedited grievances.

**Response 57:** We agree that this field is not necessary since extensions are not allowed in CDAG or ODAG for expedited grievances. Therefore we have removed this field from ODAG. There was never an extension field in CDAG.

**CMS Action 57:** No changes were made to the protocol in response to this comment in CDAG. However, the extensions field was removed from ODAG.

**Comment 58:** One commenter asked why we refer to the sponsor sending an acknowledgment of the grievance which is not required under Chapter 18.

**Response 58:** We agree with the commenter that it is not required that the sponsor send an acknowledgment of the grievance upon receipt. Therefore we have modified this language to eliminate this reference.

**CMS Action 58:** Modified language in CDAG protocol to remove reference to acknowledgment of grievance.

## Record Layouts:

**Comment 59:** Two commenters asked about how to include reimbursements in the universe that were approved but no reimbursement was actually due to the enrollee, specifically what to enter in the field for "date reimbursement provided". One commenter requested that we clarify the options in the record layouts to include an option for a reimbursement that was not due to the enrollee. The other commenter asked how these cases would impact the timeliness test.

**Response 59:** Originally, sponsors were instructed to enter NA for the "date reimbursement provided" if the request for reimbursement either was not approved, or if a check did not need to be mailed. We have clarified those instructions in tables 3, 7, and 12 to include two different options. First, sponsors may enter NA if the request was not approved. Second, sponsors may enter NRD (no reimbursement due) if the request was approved but no reimbursement needed to be issued. For purposes of the timeliness test, all cases that were either not approved, or reimbursement was not due, will be excluded from the timeliness test for effectuation once the universes have been validated.

**CMS Action 59:** We modified tables 3, 7, and 12 to allow for sponsors to enter NRD when a reimbursement request was approved but reimbursement was not actually owed to the enrollee (it did not need to be provided).

**Comment 60:** We had numerous comments regarding the record layouts and fields that were similar in multiple tables. Multiple commenters recommended that all like-fields should be consistent in every table. Additionally, a few commenters asked that fields that are similar in CDAG and ODAG be made consistent.

**Response 60:** We appreciate the comments and agree with commenters that, whenever possible, like-fields should be consistent in all applicable tables. As such, we have gone through the record layouts and made revisions accordingly to any fields that may appear multiple times in the record layouts. We have tried to make these fields consistent whenever it is possible to do so. We also compared any similar fields in ODAG and CDAG and made the field descriptions, names, and field lengths consistent when possible, taking into account the different program areas and a need for some different fields. However, some changes were substantial (i.e., re-ordering fields) and we chose to not make some changes in order to limit sponsors needing to re-program their systems.

**CMS Action 60:** We reviewed and revised tables in ODAG and CDAG to make sure they were as consistent as possible.

**Comment 61:** Multiple commenters inquired about the 4,000 character limit in the tables, and asked for clarification on this limit, as well as the limits placed in specific fields. A few commenters requested some fields to be given larger character limits, including fields for descriptions or resolutions.

**Response 61:** While CMS appreciates the commenters' questions and concerns regarding the limit to 4,000 characters, we are required to implement a 4,000 character limit per row in order to make these universes accessible. In doing so, for the 2017 audit protocol we revised every table to make sure each row had a maximum of 4,000 characters. We had to decrease some individual fields in order to meet this maximum row length. We have again reviewed the tables, and tried to make every allowable expansion, while still maintaining the 4,000 character limit for a row. In doing so, we have expanded the field length of some individual fields when possible.

**CMS Action 61:** Expanded some individual field lengths in the CDAG record layouts.

**Comment 62:** One commenter asked if CMS could clarify why table 6 asked if the request was denied for lack of medical necessity whether a physician made the decision. The commenter indicated that they thought the field should include the option for an appropriate health care professional like tables 1, 2, 4 and 5 did.

**Response 62:** While we appreciate the commenter's question, table 6 is a redetermination table not a coverage determination table. Redeterminations must be made by a physician when the underlying coverage determination was denied for lack of medical necessity. Therefore we are not making this change, however, in reviewing this field, we believe that clarity can be added to the record layouts and have changed "case" to the "underlying coverage determination" in the description fields.

**CMS Action 62:** We changed "case" to "underlying coverage determination" to offer clarity on when a physician must make the decision.

**Comment 63:** We had several commenters ask about the oral notification fields, and whether good faith attempts should be put into the field if the good faith attempt is not successful. One commenter also asked if more than one good faith attempt is made, what attempt should be included.

**Response 63:** Sponsors should include good faith attempts at providing oral notification in this field, even if the attempt is not successful. Sponsors should list the most recent (last) good faith attempt that falls within the timeframe for decision making or notification. For example, if a sponsor makes 3 good faith attempts during the 72 hour standard coverage determination timeframe, one attempt at hour 60, one attempt at hour 71, and one attempt at hour 75- the sponsor should enter the attempt made at hour 71 (it is the last attempt that falls within the 72 hour timeframe).

**CMS Action 63:** No changes were made to this protocol based on this comment. No changes were made to the burden estimates as a result of this comment.

**Comment 64:** We had multiple sponsors ask about the field regarding the patient's residence code in the CDAG universes. One commenter asked if we meant to delete this field from the redetermination universes. Another commenter asked if sponsors could use whatever value they have for the field, since the instructions regarding how to populate the code were removed from the description field. One sponsor also asked if we could retire this field, as this information is usually not found on a coverage determination or redetermination. The last commenter asked if they could still use rejected claims within 3 days of the CD to help identify the patient residence.

**Response 64:** CMS did remove the patient residence code from the redetermination fields. We are only collecting this information for coverage determinations. Additionally, we are modifying this field further to help clarify the information needed from sponsors. We are looking to obtain whether or not the enrollee is in the long term care (LTC) facility. Therefore, we have changed this field to no longer reflect patient residence code, and instead we are asking whether or not the beneficiary is in a LTC facility. Sponsors will be required to choose between yes, no, and unknown when responding. Finally, sponsors may continue to use whatever information they have to populate this field, including rejected claims within a few days of the coverage determination.

**CMS Action 64:** Modified the patient residence code field to reflect a yes/ no question of whether the enrollee was in a LTC facility.

**Comment 65:** One commenter asked a clarifying question for cases that were received as standard but later upgraded to expedited. For these cases, the commenter requested clarification on whether the "date request was received" should be the original date the request was received.

**Response 65:** The date and time the request was received should be the original date and time the request was received (i.e., the date and time the standard request came in). There are additional fields in the record layout to capture the date and time the request was upgraded to expedited which will be used for the timeliness calculations.

**CMS Action 65:** No changes were made to this protocol based on this comment. No changes were made to the burden estimates as a result of this comment.

**Comment 66:** A few commenters asked why a time field is included in some record layouts but not others. Specifically, one commenter asked why we allowed for an NA option for time in SIRE (standard IRE overturns) but not EIRE (expedited IRE overturns). Another commenter asked if we meant to remove time from the SRD (standard redeterminations) and not the ERD (expedited redeterminations).

**Response 66:** For the 2017 protocols, we attempted to eliminate any unnecessary rows, including the time field for universes where time is not necessary to judge timeliness. Therefore we removed time from universes like SRD because standard redeterminations are measured in days and not hours. We kept time in ERD because expedited redeterminations must be made in 72 hours. Likewise, for SIRE we allowed an option for sponsors to enter NA for cases that might not have a time (standard redeterminations or reimbursement requests) but we did not need this option in EIRE since all expedited cases are done in hours.

**CMS Action 66:** No changes were made to the protocol based on these comments. No changes were made to the burden estimates as a result of this comment.

**Comment 67:** Two sponsors asked why we changed the field in the reimbursement universes from "reimbursement mailed" to "reimbursement provided". Also, one sponsor asked if in this field NA would be an appropriate response for auto-forwards.

**Response 67:** Although we expect that most reimbursements are "provided" through the mail, we changed this language to a general "provided" in case sponsors issue reimbursements through other means. Also, NA is an appropriate response in this field whenever the case is not approved (therefore for an auto-forward NA would be acceptable).

**CMS Action 67:** No changes were made to the protocol based on these comments. No changes were made to the burden estimates as a result of this comment.

**Comment 68:** Two commenters requested clarification on the issue description fields. One commenter thought we should add another comment with categories of denials as well as asking for a description. Another commenter requested clarification on what level of detail is appropriate for denial descriptions.

**Response 68:** We appreciate the commenters' questions on these fields. We left the description field free text as a way of allowing sponsors to enter the information available to them in their system. These descriptions do not need to be overly detailed, rather it should be enough information for the auditor to have some understanding of what happened in the case. For example, request denied due to not being used for a medically accepted indication. We do not want to burden sponsors with requiring two fields to be filled in, when one field would suffice.

**CMS Action 68:** No changes were made to the protocol based on these comments. No changes were made to the burden estimates as a result of this comment.

**Comment 69:** Several commenters requested that AOR fields be added into the CDAG tables to make them consistent with ODAG and to help with timeliness calculations.

**Response 69:** We agree with commenters that knowing if an AOR was required, and also what day and time it was received is useful. Therefore we have added those columns into tables 1-10.

**CMS Action 69:** We added rows for AOR receipt into tables 1-10.

**Comment 70:** One commenter requested we add a field for FDRs in CDAG to make it consistent with ODAG.

**Response 70:** Although we have tried to make ODAG and CDAG consistent wherever possible, we do not feel an FDR field in CDAG would be beneficial. Usually the only FDR relevant to CDAG is the PBM, and we do not need to differentiate cases processed by the PBM versus the plan sponsor in order to conduct our review.

**CMS Action 70:** No changes were made to the protocol based on this comment. No changes were made to the burden estimates as a result of this comment.

## PART C AND D COMPLIANCE PROGRAM EFFECTIVENESS

### Policy Questions:

**Comment 71:** One commenter inquired about the release of an updated Chapter 9 and 21 that includes the extensive changes of the 2017 CPE Audit Protocol.

**Response 71:** While the approach and structure of the protocol has changed, the audit elements and compliance standards align with the current version of Chapter 9 of the Prescription Drug Benefit Manual and Chapter 21 of the Medicare Managed Care Manual.

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

**Comment 72:** Two commenters asked us 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. Another commenter requested CMS to define "sufficient support and resources" needed to implement an effective compliance program.

**Response 72:** These questions are outside the scope of this 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 72:** No change was made to the protocol in response to these comments. No changes were made to the burden estimates as a result of these comments.

**Comment 73:** Several commenters asked for policy clarifications for the definition of "delegate" or "delegated" that CMS audit teams would apply across all audits. One commenter asked CMS to make the distinction between the types of FDR oversight conducted by the compliance department and operational departments. Another commenter suggested that sponsors should provide only general oversight activities and reports related to regulatory compliance for the CPE universes.

**Response 73:** For each record layout, there is criteria that specifies which compliance activities and data elements should be included or excluded from the universe. The definition-related questions are outside the scope of our PRA package. We cannot offer policy guidance on what these terms mean. For audit purposes, sponsors should populate their universes based on how they process or define these terms. For policy guidance and examples of the various types of internal and FDR auditing and monitoring activities, 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 73:** No change was made to the protocol in response to these comments. No changes were made to the burden estimates as a result of these comments.

## Universe Preparation and Submission:

**Comment 74:** One commenter noted that we will be restricting interviews to certain key roles and positions. The commenter requested that a list of specific individuals to be interviewed during the CPE audit is included in the protocol.

**Response 74:** A key component of evaluating the implementation and effectiveness of a compliance program is to discuss processes and outcomes with key staff that are accountable and involved with compliance efforts. We have modified our approach to compliance interviews. First, in an effort to be fully transparent, our interview questions are now available to sponsors in the form of questionnaires. The Medicare Compliance Officer, individual(s) responsible for FDR oversight and the individual(s) responsible for FWA operations must submit completed questionnaires with the universe submission. Secondly, while onsite, we will schedule time to discuss the responses of each questionnaire with the appropriate individuals. Lastly, we expect the individuals involved in the sample cases to attend and actively participate in the tracer reviews.

**CMS Action 74:** No change was made to the protocol in response to this comment. No changes were made to the burden estimates as a result of this comment.

**Comment 75:** One commenter requested CMS to update the page numbers in the protocol.

**Response 75:** We appreciate your comment and have updated the page numbers.

**CMS Action 75:** We revised all documents within the CPE protocol as a result of the comment.

**Comment 76:** One commenter asked CMS to provide examples of the types of "Compliance Performance Mechanisms" that should be submitted for the documentation request.

**Response 76:** Compliance Performance Mechanisms refer to the tools used by sponsors to track and measure the performance of Medicare operations and FDRs with meeting compliance standards and satisfying CMS requirements. Examples include self-assessments, scorecards, dashboards, software, etc. For policy guidance, commenters should refer to Chapter 9 of the Prescription Drug Benefit Manual and Chapter 21 of the Medicare Managed Care Manual.

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

## Tracer Evaluation:

**Comment 77:** Several commenters asked whether a PowerPoint template will be provided to sponsors that incorporates the required information for tracer summaries.

**Response 77:** Given the feedback we received from the industry during the 2016 CPE audits, we eliminated the use of a PowerPoint template from the 2017 CPE audit protocol. Many sponsors expressed that the template required all seven elements of a compliance program to be addressed for every case, regardless if it was not necessary for all of the core elements to be implemented. As a result, we are allowing sponsors to develop customized tracer summaries to document the specific facts of how the issues of each case were addressed. While PowerPoint presentations is the most utilized tool for the tracer reviews, sponsors are encouraged to use the most effective tool that works best for documenting their narratives.

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

**Comment 78:** One commenter asked us if CMS would accept the submission of tracer summaries and its supporting documentation via the SFTP.

**Response 78:** We appreciate the commenter's question. We understand that sponsors were previously allowed to submit documentation via the SFTP. However, for 2017 CPE audits, we expect sponsors to provide the requested information via HPMS or onsite.

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

**Comment 79:** One commenter recommended we add language specifying when sponsors will receive notification of the cases selected for the tracer evaluation.

**Response 79:** CMS will select 6 sample cases to review during the audit. The cases may be pulled from any applicable universe as CMS auditors determine necessary. For example, FWA

related cases may be pulled from the IA or IM universes. Once the auditors complete the selection process, the sponsor will be immediately notified of the samples. Sponsors will have 5 business days to prepare and submit their tracer summaries and supporting documentation. Additionally, CMS will schedule a conference call with the sponsor to answer any questions about deadlines and documentation submission.

**CMS Action 79:** No change was made to the protocol in response to this comment. No changes were made to the burden estimates as a result of this comment.

**Comment 80:** One commenter stated that a request for a root cause is mentioned twice in the Tracer Summary section of the protocol.

**Response 80:** We agree with the commenter and removed the second reference.

**CMS Action 80:** We removed the duplicative "root cause" from the 2nd bullet under the Tracer Summary section of the protocol. There were no burden estimates as a result of this comment.

**Comment 81:** One commenter asked if only the employees and/or FDRs involved with the tracer evaluation will be selected to provide evidence of monthly screenings.

**Response 81:** We appreciate this comment on the employee/FDR records and hope we can provide clarification on this process. We will randomly select a small number of employees and FDRs from the universes to evaluate a sponsor's compliance with training requirements, OIG and GSA monthly exclusion checks and receipt of the sponsor's standards of conduct within the required timeframes. The sample may include employees and entities involved with the tracer evaluation.

**CMS Action 81:** No change was made to the protocol in response to this comment. No changes were made to the burden estimates as a result of this comment.

**Comment 82:** One commenter recommended that CMS select 5 cases for the tracer evaluation instead of 6.

**Response 82:** Due to industry feedback received during the 2016 audit year, we determined that we needed to provide sponsors multiple opportunities to demonstrate the effectiveness of their compliance programs with a variety of compliance scenarios and issues. We are therefore going to continue sampling 6 cases for the tracer evaluation in 2017.

**CMS Action 82:** No change was made to the protocol in response to this comment. No changes were made to the burden estimates as a result of this comment.

## Audit Elements:

**Comment 83:** One commenter mentioned that there are several compliance standards that could apply or have aspects that apply to multiple audit elements, for example, OIG and GSA exclusions screenings of employees and FDRs could be considered a prevention or a detection activity.

**Response 83:** CMS acknowledges that several compliance activities could apply to more than one of the audit elements. We also understand that some cases may present circumstances where some of the compliance standard questions do not apply. During the audit, CMS auditors

will consider the structure and operations of a sponsor's compliance program when reviewing the facts of each case to determine whether the compliance standards were met.

**CMS Action 83:** No change was made to the protocol in response to this comment. No changes were made to the burden estimates as a result of this comment.

**Comment 84:** Two commenters thanked CMS for providing the additional questionnaires and instructions for each record layout. The commenters expressed that the questionnaires will allow sponsors to provide key information about their compliance program and encourage fruitful discussions between CMS and sponsors.

**Response 84:** We appreciate your comments.

**CMS Action 84:** No change was made to the protocol in response to this comment. No changes were made to the burden estimates as a result of this comment.

## Record Layouts:

### All Tables

**Comment 85:** Five commenters asked whether it is CMS's intent for sponsors to include activities that are conducted on a weekly basis only once in the universes for all tables.

**Response 85:** Due to the magnitude of comments received, we removed the request for daily activities from the CPE universes. All other frequencies of audit and monitoring activities (e.g. weekly, monthly, quarterly, and annually, ad-hoc) must have a separate record in the universe for each time it was performed during the audit review period. Additionally, we noticed that "weekly" was omitted from the instructions and field description examples for Tables 1, 3, and 4.

**CMS Action 85:** Modified language in the CPE protocol to remove references to daily activities and added the weekly option into the instructions.

**Comment 86:** One commenter stated that listing a response for each identified deficiency in the "Description of Deficiencies", "Corrective Action Required", "Corrective Action Description", and "Monitoring/Audit Results Shared" fields for all of the tables has the potential to be administratively burdensome on sponsors. The commenter requested that we allow sponsors to provide one response encompassing all the corrective actions required for all deficiencies.

**Response 86:** We agree with the commenter that whenever possible the sponsor should provide one response that summarizes the requested information. The instructions for the fields asks the sponsor to provide additional information when multiple issues are involved. The level of detail requested for these fields will mitigate some of the issues CMS encountered with selecting appropriate cases for the tracer evaluation. To alleviate potential burden on sponsors, we will modify the field descriptions to advise sponsors to summarize their responses, when possible.

**CMS Action 86:** Modified the language in the field descriptions for Table 1**:** Column M, Column O, Column P; Table 3**:** Column K, Column M, Column N; Column K, Column M, Column N to instruct sponsors to provide a summary of their audit and monitoring deficiencies, corrective actions and sharing of audit/monitoring results.

**Comment 87:** One commenter inquired about the audit or monitoring start date for Column G of Table 3 and Table 4 using a specific scenario.

**Response 87:** Due to insufficient information, we were unable to address the commenter's question. We encourage the commenter to resubmit their comment with additional information for an appropriate response.

**CMS Action 87:** No change was made to the protocol in response to this comment. No changes were made to the burden estimates as a result of this comment.

**Comment 88:** Three commenters inquired about a N/A option for employees that do not have direct telephone numbers for Table 2, Column G. Two commenters inquired if it is still necessary for sponsors to include employee phone numbers in the universe as random employee interviews have been excluded from the 2017 audit protocol.

**Response 88:** CMS agrees with the commenters and will remove this field from Table 2.

**CMS Action 88:** We have modified the record layout to remove the "Direct Phone Number" field from Table 2.

### Table 1: FTEAM Universe

**Comment 89:** Two sponsors requested clarification on how to respond to the "activity start date" and "activity completion date" for daily monitoring and auditing activities for Table 1, Column I.

**Response 89:** Due to the magnitude of comments received, we removed the request for daily activities from the CPE universes. All other frequencies of audit and monitoring activities (e.g. weekly, monthly, quarterly, and annually, ad-hoc) must have a separate record in the universe for each time it was performed during the audit review period. Additionally, we noticed that "weekly" was omitted and we added it back to the instructions and field description examples for Tables 1, 3, and 4.

**CMS Action 89:** Modified language in the CPE protocol to remove references to daily activities.

**Comment 90:** Two commenters indicated that a request for a root cause is repeated twice in both the Corrective Action Description and Description of Deficiencies fields.

**Response 90:** We agree with the commenters and will remove root cause from the "Description of Deficiencies" field.

**CMS Action 90:** We modified the language for Table 1- Column M, Table 3- Column K, and Table 4 – Column K by removing the request for a root cause.

**Comment 91:** One commenter asked for clarification as to what type of compliance committee member would satisfy Table 2- Column L as many sponsors have more than one compliance committee where Medicare issues are addressed and discussed.

**Response 91:** CMS acknowledges that there are many different types of compliance committees that serve various oversight functions. If an employee is a member of a general or specialized compliance committee, sponsors should indicate a "Yes" in the record layout.

**CMS Action 91:** No change was made to the protocol in response to this comment. No changes were made to the burden estimates as a result of this comment.

**Comment 92:** One commenter noted that the ECT universe, Column I, Employee Type does not include governing body members.

**Response 92:** We agree and will revise this column to include governing body member in the list of options.

**CMS Action 92:** We modified the language in Table 2 – Column I to include governing body member.

**Comment 93:** Ten commenters requested clarification as to whether a Fraud, Waste and Abuse specific universe will be requested during the 2017 CPE program audits. Two commenters asked CMS to confirm how FWA cases will be selected during the 2017 CPE audits.

**Response 93:** Due to industry feedback and the number of questions we received during the 2016 audits regarding the FWAM universe, we removed the FWAM record layout from the protocol. While multiple commenters thought the SIU-FWA Questionnaire was helpful for providing CMS with an overview of a sponsor's FWA operations, many commenters expressed that the questionnaire does not provide the level of detail of actual prevention, detection, and correction activities performed by a sponsor. As a result, CMS reassessed the need to collect FWA-specific data from sponsors and have incorporated FWA into the FTEAM, IA and IM universes. FWA cases may be selected for a tracer review during the 2017 program audit.

**CMS Action 93:** We modified the language in the CPE protocol and updated Tables 1, 3, and 4 to include fields that capture data specific to FWA activities and monitoring.

**Comment 94:** For the IA Universe – Column D, the commenter requested clarification as to what frequency should be selected for "incident/event-based" activities?

**Response 94:** If an activity is initiated outside of the organization’s routine or scheduled monitoring and/audit work plans, sponsors may enter “ad-hoc” as the monitoring frequency.

**CMS Action 94:** No change was made to the protocol in response to this comment. No changes were made to the burden estimates as a result of this comment.

**Comment 95:** Two commenters inquired how to populate Table 3 – Column J if there no deficiencies were identified.

**Response 95:** If no deficiencies were identified, the sponsor may enter 0.

**CMS Action 95:** No change was made to the protocol in response to this comment. No changes were made to the burden estimates as a result of this comment.

**Comment 96:** One commenter asked for clarification regarding when to enter NA for field descriptions for all tables. The commenter inquired how to indicate monitoring or audit activities that are in progress at the time of the universe submission.

**Response 96:** We left the description field free text as a way of allowing sponsors to enter the information available from their system. If no deficiencies were discovered or if activities are in progress, please provide a short statement affirming such. For example, 2016/01/01 monitoring

of our pharmacy network mail order benefit identified no issues. Additionally, sponsors may enter NA when no data is available. Sponsors may provide clarification for NA responses during the walkthrough portion of the audit.

**CMS Action 96:** No change was made to the protocol in response to this comment. No changes were made to the burden estimates as a result of this comment.

**Comment 97:** One commenter requested clarification regarding the term "primary compliance liaison" and if it the term applies to all staff responding to Compliance inquiries or communicating with Compliance and operational area staff responding to a compliance request.

**Response 97:** We agree with the commenter that the term "primary compliance liaison" is confusing and removed it from Table 2.

**CMS Action 97:** We modified the language in Table 2- Column 2 by removing the reference to primary compliance liaison.

**Comment 98:** One commenter noted that several columns within Table 2 did not have a governing body member option.

**Response 98:** We appreciate the comments and agree with the commenters that Table 2 columns should include options for board members. As such, we have gone through the record layout and made revisions accordingly to the appropriate fields.

**CMS Action 98:** We will modify the columns in Table 2 to include options for governing body members.

**Comment 99:** For Table 1, one commenter noted that related entities should have be included in the exclusions list.

**Response 99:** We agree and will revise the instructions to exclude related entities.

**CMS Action 99:** We will modify Table 1 instructions to exclude related entities from the universe.

**Comment 100:** One commenter requested that CMS consider changing the name of the FTEAM universe to FDRAM as they believe it is more consistent with CMS language used throughout regulations related to this topic. It is also less confusing as organizations use the acronym of FTE to refer to employees and the CPE protocols contain a separate employee universe.

**Response 100:** While sponsors must monitor and audit all of its first-tier, downstream and related entities (FDRs), for purpose of the audit protocol, we are evaluating the compliance activities of first-tier entities (FTE). As a result, we believe FTEAM is an appropriate name for the universe in the CPE protocol.

**CMS Action 100:** No change was made to the protocol in response to this comment. No changes were made to the burden estimates as a result of this comment.

**Comment 101:** One commenter expressed the first bullet in Table 1 instructions does not state for sponsors to include first tier entities (FTEs) that are delegated to provide administrative or healthcare services.

**Response 101:** We agree with the commenter. In response, we have modified the criteria to clarify that sponsors should include in the FTEAM universe first-tier entities that provide administrative or health care service function on behalf of the sponsor.

**CMS Action 101:** We updated Table 1 instructions to state that First tier entities (FTEs) that provide an administrative or health care service related to the sponsor's Medicare Parts C and/or D contracts.

**Comment 102:** A commenter asked CMS to remove Column I from Table 1 as it may be difficult for some sponsors to recall the exact date that a monitoring activity began. The commenter asked whether sponsors should report the most recent activity for daily monitoring or all monitoring activities conducted daily for the 12 month universe period.

**Response 102:** At this time, we are not removing the activity start date from Table 1 as this information is important for the universe and sample selection process. However, due to the magnitude of comments received, we removed the request for daily activities from the CPE universes. We understand your concerns about reporting weekly activities. Conversely, there are many sponsors who initiate weekly monitoring and auditing activities of their FTEs and we want to give them the opportunity to demonstrate the effectiveness of their compliance program with these activities.

**CMS Action 102:** Modified language in the CPE protocol to remove references to daily activities.

**Comment 103:** One commenter requested that "weekly" and "ad-hoc" options are added to the examples in bullet #4 of Table 1 instructions for consistency with the record layouts.

**Response 103:** We agree and will revise the instructions to account for the additional frequency options.

**CMS Action 103:** We will modify the instructions for Table 1.

**Comment 104:** One commenter asked if CMS would provide CMS-defined list of Medicare business functions for which the sponsor should focus its auditing and monitoring activities (as was the case in 2014 and prior) as they believe a more equitable process is to assess all plans against a set of CMS-defined list of audits and monitoring.

**Response 104:** We would like to clarify that we consider many factors and circumstances when evaluating a sponsor's compliance program (i.e. compliance history, adequate staffing/resources, universes, discussions with key compliance personnel, etc.). We understand that each sponsor has unique characteristics (i.e. membership size, business model, delegation of responsibilities to other entities, recent changes in the marketplace, etc.) and levels of risk that must be taken into account when developing its risk assessments and monitoring/audit work plans. Per feedback from the industry, CMS does not limit sponsors by providing a defined list of required audits and monitoring because risks change over time and we believe a sponsor is in the best position to determine which operational areas are a priority monitoring and audit activities.

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

**Comment 105:** One commenter noted that Table 2 – Column H should include a date of appointment for governing body members.

**Response 105:** We agree and made this change.

**CMS Action 105:** Modified Table 2 – Column H to include appropriate language for governing body members.

**Comment 106:** One commenter noted that many of the universes have become more extensive for data needs and field changes are problematic as they are costly and use extensive resources in order to produce the universe for CMS.

**Response 106:** We appreciate the comments and agree with commenters that whenever possible, like-fields should be consistent in all applicable tables. As such, we have gone through the record layouts and made revisions accordingly to any fields that may appear multiple times or request similar information. We have tried to make these fields consistent whenever it is possible to do so. We also compared any similar fields from 2016 CPE protocol and made the field descriptions, names and field lengths as consistent as possible, taking into account the different criteria and a need for some different fields. Lastly, as mentioned above, we are committed to using our audit protocols for several years without modifications, and as such, this audit protocol will be used for longer than just the 2017 audit year.

**CMS Action 106:** We reviewed and revised record layouts in CPE to make sure they were as consistent as possible.

## Questionnaires:

### GENERAL

Due to the comments received regarding the three new CPE questionnaires (Attachments I-B, I-D, and I-E) these questionnaires have been significantly modified. Any references to specific questions in the comments and responses below refer back to the previous version of the questionnaires that were released in the 60 day comment period.

**Comment 107:** One commenter asked a clarifying question for instances where there may be multiple individuals responsible for an operational area. In these cases, the commenter requested clarification on whether each individual must complete the questionnaire or provide one questionnaire incorporating the responses from multiple individuals.

**Response 107:** Sponsors should provide one questionnaire incorporating the responses from multiple individuals.

**CMS Action 107:** We updated each questionnaire with instructions for consolidating responses from multiple individuals.

**Comment 108:** Similar questions are asked in the Organizational Structure and Governance Presentation Template (Attachment I-C) and the CPE Questionnaires. CCA encourages CMS to cross-reference materials to remove duplicate information.

**Response 108:** CMS agrees, and we have cross-referenced materials to remove duplicative information.

**CMS Action 108:** We reviewed and revised the CPE materials to remove duplication whenever possible.

**Comment 109:** One commenter requested clarification regarding whether the new questionnaires will be used in lieu of interviews or to supplement interviews.

**Response 109:** The CPE questionnaires will be used to supplement the compliance interviews. The questionnaires are designed to assist CMS with understanding how specific compliance personnel and business areas are vested in the day-to-day operations of the Medicare compliance program. Furthermore, the questionnaires help the sponsor prepare for the discussions with CMS auditors about critical processes and outcomes. After the sponsor submits its completed questionnaires to CMS, the responses will be discussed during the onsite compliance interviews and tracer sample reviews with the responsible parties. If multiple individuals are responsible for a business function (e.g. FDR oversight), the sponsor should consolidate responses and incorporate into one document.

**CMS Action 109:** We will update the all the questionnaire instructions to inform sponsors to consolidate responses when more than one individual is responsible for the CO, SIU, and FDR operations.

## Attachment I-A CPE Self- Assessment Questionnaire:

**Comment 110:** One commenter recommended that given the addition of the new questionnaires, CMS remove the duplicative or unnecessary information from Attachment I-A, or removing it from the protocol altogether.

.**Response 110:** While the new and existing compliance questionnaires may appear similar, each document highlights a different level of information about a sponsor's compliance program effectiveness. While it may seem inefficient, the questionnaires provide valuable insight to CMS and diverse viewpoints about a sponsor's internal policies, processes and outcomes which will contribute to meaningful discussions with compliance personnel during the CPE audit process and tracer case reviews. At this time, CMS will not be removing any of the questionnaires from the CPE Audit Protocol.

**CMS Action 110:** No change was made to the protocol in response to this comment. No changes were made to the burden estimates as a result of this comment.

**Comment 111:** One commenter requested clarification as to whether NA can be entered in the Yes/No column of Attachment I-A.

**Response 111:** Previously, "NA" was an option available when questions did not apply to the sponsor's compliance program. However, several sponsors abused this option by marking the entire SAQ with NA responses. In the limited situations where a question is non-applicable for your organization, sponsors may enter NA in the "Yes/No" column. Briefly explain why the question is not applicable in the "Documentation" column.

**CMS Action 111:** No change was made to the protocol in response to this comment. No changes were made to the burden estimates as a result of this comment.

**Comment 112:** One commenter noted that some of the information in the new questionnaires is somewhat duplicative of the information in the applicable sections of the Attachment I-A. The

commenter requested Attachment I-A is revised to remove duplicate or unnecessary information, or removing it from the protocol altogether.

**Response 112:** While the new and existing compliance questionnaires may appear similar, each document highlights a different level of information about a sponsor's compliance program effectiveness. The questionnaires provide valuable insight to CMS and diverse viewpoints about a sponsor's internal policies, processes and outcomes which will contribute to meaningful discussions with compliance personnel during the CPE audit process and tracer evaluation. At this time, CMS will not be removing any of the questionnaires from the CPE Audit Protocol. However, we reviewed all documents for consistency.

**CMS Action 112:** CMS cross-referenced materials to remove duplicative information.

**Attachment I-B Compliance Officer Questionnaire:**

**Comment 113:** One commenter noted that the same question was asked for #17 and #20 in Attachment I-B.

**Response 113:** CMS removed the duplicate question.

**CMS Action 113:** We deleted Question #20 from Attachment I-B.

## Attachment I-C Organizational Structure and Governance PPT:

**Comment 114:** One commenter requested clarification regarding whether Attachment I-C should be used as a template when developing their presentation for the audit entrance conference.

**Response 114:** CMS is clarifying that the Organizational Structure and Governance PowerPoint Presentation (Attachment I-C) is a guide to assist sponsors with developing a customized presentation about their Medicare business, organizational structures, key personnel and operations for the CMS program audit. This presentation may be discussed or referenced during the CMS program audit, including the entrance conference.

**CMS Action 114:** No change was made to the protocol in response to this comment. No changes were made to the burden estimates as a result of this comment.

**Comment 115:** A few commenters recommended that in addition to the tracer summaries, CMS allow sponsors to create a generic PowerPoint presentation that provides an overview of how the sponsor has aligned its compliance structure and operations with the core elements in the regulations and Compliance Program Guidelines. These commenters expressed that this presentation would remove a lot of the repetition within the tracer evaluation that was experienced during the 2016 audits and streamline tracers stick to their specific story of the case.

**Response 115:** We agree with the commenters that discussing and understanding the fundamentals of the sponsor's compliance program structure and operations is important and should take place before the review of sample cases. This allows the tracer evaluation to focus on the specifics of each case and removes the repetitive discussion. As a result, CMS will include additional questions in Attachment I- A template for sponsors to address about how they adopted and implemented the fundamentals of a compliance program (e.g. standards of

conduct, policies and procedures, high level oversight, training and education, communication, risk assessments, auditing and monitoring work plans, corrective actions, OIG-GSA exclusions list checking, etc.)

CMS auditors will walk through this presentation with the sponsor on the first day of the onsite CPE audit.

**CMS Action 115:** We modified Attachment I-C to include questions regarding the sponsor's adoption and implementation of CMS compliance program requirements.

## Attachment I- D FDR Oversight Questionnaire:

**Comment 116:** One commenter requested that CMS remove all "personal" questions from Attachment I-D and I-E by only asking how the "organization" does the work, not the individual. Additionally, the commenter demanded that the same contact information for Attachment I-A is requested for the other questionnaires for consistency purposes.

**Response 116:** As noted in the directions for the completing the interview questionnaires, the word "You" refers to the organization, not necessarily a specific person. Where appropriate, CMS changed the "you' to "your organization" in the questionnaires.

**CMS Action 116:** We updated the questionnaire with references to the organization rather than the individual(s) completing the questionnaire.

**Comment 117:** One commenter requested clarification for Question #4 of Attachment I-D, specifically asking about the term "Vendor Oversight Program" and whether if this term refers to first-tier entities (FTE).

**Response 117:** We agree with the commenter that is confusing to use the word "vendor" for this questionnaire and removed it from the question.

**CMS Action 117:** Modified the question to remove reference to "vendors".

## Attachment I-E FWA/SIU Questionnaire:

**Comment 118:** One commenter noted that Attachment I-E, Questions 10, 11, 12, 13 and 14 ask about hotlines for noncompliance and/or FWA issues. The commenter requested clarification regarding how to respond to the questions when a sponsor maintains separate hotlines for noncompliance and FWA and the answers may be different.

**Response 118:** We agree and modified the instructions.

**CMS Action 118:** We modified the instructions to clarify CMS expectations to assist the sponsor with providing appropriate responses to the questions when multiple hotlines are utilized by a sponsor.

**Comment 119:** One commenter requested clarification for circumstances when multiple individuals responsible for an operational area and whether each individual has to complete a questionnaire or should combined responses be submitted.

**Response 119:** If multiple individuals are responsible for a business function or operational area (e.g. FDR oversight), the sponsor should consolidate responses and incorporate into one document.

**CMS Action 119:** Modified questionnaire instructions to inform sponsors to consolidate responses when more than 1 individual is responsible for the CO, SIU, and FDR business functions.

**Comment 120:** One commenter requested CMS to provide examples of what types of communication it tends to capture under the term "FWA studies" for Question 49.

**Response 120:** We agree with the commenter and combined the two questions to include examples of FWA studies.

**CMS Action 120:** We removed this question from the questionnaire.

**Comment 121:** One commenter requested clarification regarding the time period under review for Question 23 and 25.

**Response 121:** For purposes of this questionnaire, "time period" refers to the sponsor's audit review period. To eliminate any confusion, we replaced "time period" with "audit review period".

**CMS Action 121:** We changed "time period" and "12 months" to "audit review period".

**Comment 122:** One commenter requested clarification for Question 8 and the percentage of workload spent on Medicare.

**Response 122:** We agree that the question is confusing and we deleted it from the questionnaire.

**CMS Action 122:** We removed this question from the questionnaire.

**Comment 123:** One commenter requested clarification as how to respond to Questions 10, 11, 12, 13, and 14 when a sponsor maintains separate hotlines for noncompliance issues and potential/suspected FWA.

**Response 123:** We appreciate the comment. If multiple hotlines are utilized for specific functions, the sponsor should consolidate responses and incorporate them into one document.

**CMS Action 123:** We updated all the questionnaire instructions to inform sponsors to consolidate responses when more than one hotline used by the sponsor. For the Hotline/Reporting Mechanisms section of the questionnaire, we added the following instructions:

"If the organization utilizes multiple hotline numbers to report various categories of compliance and FWA inquiries for questions 6 and 7.

**Comment 124:** One commenter requested clarification for responding to Question 19. The commenter stated that a plan will be scrutinized if they respond with a negative.

**Response 124:** For audit purposes, we want to understand the full scope of a sponsor's compliance program, including any resource or time constraints that may indirectly or directly affect the sponsor's ability to satisfy Medicare program requirements. We understand that personnel policy, technology and Medicare business practices change frequently and encourage sponsors to be forthcoming with this information.

**CMS Action 124:** We modified the language and restructured the questionnaire with open-ended questions to allow sponsors to fully describe their structure, processes and outcomes instead of providing "yes" or "no" response.

**Comment 125:** One commenter noted that the numbering is incorrect for Attachment I-E.

**Response 125:** Attachment I-E has been updated to reflect correct numbering of questions.

**CMS Action 125:** We updated the questionnaire with the correct numbering system.

**Comment 126:** One commenter requested clarification on the level of detail required for the status of fraud cases.

**Response 126:** We agree that this question is confusing and removed it from the questionnaire.

**CMS Action 126:** We removed this question from the questionnaire.

**Comment 127:** Several commenters asked about condensing entries for monthly and weekly monitoring and auditing activities.

**Response 127:** At this time, condensing these specific activities into one entry would make it more difficult for CMS auditors to select the most appropriate sample of cases.

**CMS Action 127:** No change was made to the protocol in response to these comments. No changes were made to the burden estimates as a result of these comments.

**Comment 128:** One commenter expressed that the inclusion in the FTEAM data universe of daily and/or weekly monitoring activities (including deficiencies) for the full spectrum of our FTEs may result in a resource intensive process for sponsors. The commenter recommended that CMS revise the instructions for this record layout to exclude reporting of FTE audit and monitoring activity at the daily and weekly levels and only require reporting of monitoring activities performed on a monthly, quarterly or less frequent basis.

**Response 128:** Due to the magnitude of comments received, we removed the request for daily activities from the CPE universes. We understand your concerns, however, there are many sponsors who initiate weekly monitoring and auditing activities of the FTEs and we want to give them the opportunity to demonstrate the effectiveness of their compliance program with these activities.

**CMS Action 128:** Modified language in the CPE protocol to remove references to daily activities.

## PART D FORMULARY AND BENEFIT ADMINISTRATION (FA)

### Policy:

**Comment 129:** Two commenters requested clarification regarding requirements for MMPs. One commenter asked whether MMP data should be included in the universes and another asked if MMPs were exempt from the website review.

**Response 129:** Medicare-Medicaid Plans (MMPs) are subject to Part D requirements and therefore, all rejected and paid Part D claims for these plans should be included in the universe

submissions. The website review may include review of a selected sponsor's MMP formulary websites.

**CMS Action 129:** The protocol was changed to include clarifications about inclusion of MMP beneficiaries in the universes and MMP formularies in the website review element.

**Comment 130:** One commenter asked for additional guidance about providing transition fills in 2017 for members who were newly enrolled the last two months of 2016 and received a transition fill before the end of the contract year.

**Response 130:** This question is outside the scope of our PRA package. For policy guidance commenters should refer to Chapter 6 of the Prescription Drug Benefit Manual. For audit purposes, CMS will look to ensure that sponsors are in compliance with those requirements.

**CMS Action 130:** No change was made to the protocol in response to this comment. No change was made to the burden estimate in response to this comment.

**Comment 131:** One commenter asked whether a change from one Plan Benefit Package to another within the same contract is considered a new enrollment.

**Response 131:** CMS does not determine 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.

**CMS Action 131:** No change was made to the protocol in response to this comment. No change was made to the burden estimate in response to this comment.

**Comment 132:** One commenter asked for clarification regarding the term "prior authorization" and whether it is intended to mean coverage determination/redeterminations or any claim authorizations.

**Response 132:** For purposes of the formulary administration program area review "prior authorization" refers to the utilization management edits and criteria submitted for review and approval by CMS for formulary medications. For policy guidance on formulary prior authorizations commenters should refer to Chapter 6 of the Medicare Prescription Drug Benefit Manual.

**CMS Action 132:** No change was made to the protocol in response to this comment. No change was made to the burden estimate in response to this comment.

## Universe Preparation and Submission:

**Comment 133:** One commenter asked for clarification related to dates and time periods for claims in the audit universes. Specifically, whether the universes should include claims based on whether they were a fill attempt within the audit period or whether they were processed within the audit period.

**Response 133:** The rejected claims and prescription drug event (PDE) universes should be submitted based on the dates of service that fall within the review period.

**CMS Action 133:** The protocol was updated to include "dates of service that fall within the applicable review period".

**Comment 134:** One commenter asked for clarification regarding the timeframe for claims included in the PDE universe.

**Response 134:** As noted in the protocol, the PDE universe should include all final action PDEs accepted by CMS with dates of service from September through December of the prior year for those beneficiaries submitted in either of the rejected claims transition universes. For example, for the 2017 audit year, the PDE universe should include all final action PDEs accepted by CMS with dates of service from September 2016 through December 2016.

**CMS Action 134:** We modified the instructions for the PDE record layout to include this clarification.

## Case Documentation:

**Comment 135:** One commenter asked for clarification about what CMS considers a "comment log."

**Response 135:** The comment log is where we expect to see the pharmacy messages for rejected claims in the sponsors' system.

**CMS Action 135:** We included a clarification about displaying pharmacy messages in the comment log.

**Comment 136:** One commenter asked whether the claims history reference listed under the Rejected and/or Paid claims section of the transition element included claims for all of CY2016 or only November and December.

**Response 136:** CMS will evaluate how claims for the same drug paid or denied before and after the selected sample. The look back and forward review timeframe during the webinar could vary based on the drug and its dosing interval as well as the issue identified.

**CMS Action 136:** The bullet related to claims history will be revised to include "paid" claims in addition to rejected claims.

## Record Layouts:

**Comment 137:** One commenter asked CMS to clarify whether they may substitute the HICN with other beneficiary information.

**Response 137:** As noted in the "Beneficiary HICN" field description, the sponsor should submit the Health Insurance Claim Number assigned by the Social Security Administration. CMS will evaluate each request on a case by case basis before making a determination if an exception is necessary.

**CMS Action 137:** No change was made to the protocol in response to this comment. No change was made to the burden estimate in response to this comment.

**Comment 138:** Two commenters asked about the new "Effective disenrollment date" field. These commenters wanted clarification on how this field should be populated when there are multiple disenrollment dates and at what level this date should be reported.

**Response 138:** Both the effective disenrollment and enrollment date should be reported at the Plan Benefit Package level. The enrollment and disenrollment dates submitted in the rejected

claims universes should be relevant to the contract and plan ID of the beneficiary at the time of each claim. In the new member universe, a separate record should be entered each time a beneficiary is enrolled and considered a new member. The enrollment and disenrollment dates for each of these records should also be relevant to the associated contract and plan IDs submitted by the sponsor for the beneficiary.

**CMS Action 138:** The disenrollment date field description was revised to indicate that it should be populated based on PBP level data.

**Comment 139:** Two commenters asked for clarification about NDCs. One commenter asked which NDC code should be submitted for compounds and one asked what should be included in the rejected claims universes if the NDC is invalid.

**Response 139:** When populating the NDC field for claims of multi-ingredient compounds, sponsors should include the NDC of the most expensive Part D covered drug. The rejected claims universes should include the NDCs that were submitted on that claim regardless of whether the NDC was determined to be invalid after processing. The pharmacy messaging should reflect all reasons for the claim rejection.

**CMS Action 139:** The "NDC" description field was updated to clarify submissions for multi-ingredient compounds.

**Comment 140:** A few commenters requested clarification regarding the Claim Quantity field in the record layouts. These commenters asked if fractional values are permitted, if units of measurement should also be included, and whether the field length could be extended to 11 characters to match the NCPDP standard.

**Response 140:** The claim quantity should be submitted as it appears on the rejected or paid claim, including decimal values, when applicable. However, units of measurement should not be included in the Claim Quantity field. We also agree that the Claim Quantity field length may be increased to 11 characters in accordance with NCPDP.

**CMS Action 140:** The description for this field was revised to include this clarification and the field length was increased to 11 characters in accordance with NCPDP.

**Comment 141:** One commenter requested the removal of the possessive character of the "Claim Days' Supply" field because it would require considerable resources to modify universe queries, record layouts, and quality monitoring processes.

**Response 141:** We appreciate the recommendation and removed the possessive character from the field name.

**CMS Action 141:** We removed the possessive character from the "Claim Days' Supply".

**Comment 142:** Three commenters requested clarification about the reject reason codes and pharmacy message fields. Two commenters asked how to complete the fields when the pharmacy messages are not linked to the individual rejected reason codes and one commenter asked what is meant by "all messages."

**Response 142:** CMS expects sponsors to report both the NCPDP reject reason codes and pharmacy messages as well as any claim processor/plan-specific reject reason codes and pharmacy messages. Each reject code should be populated in a unique column followed by a

separate column for the associated pharmacy message. This pair of reject code/pharmacy message columns will be repeated as often as needed depending on the number of unique reject codes. If there are multiple messages attached to a single reject code, sponsors should include all applicable messaging in the same message field. When pharmacy messages cannot be linked with the corresponding reject code, the sponsor should include all pharmacy messages in this field and repeat for each reject reason code submitted.

**CMS Action 142:** The "Pharmacy Message*" field description was updated to include instructions for populating when the pharmacy messages are not linked with the reject reason codes.

**Comment 143:** Four comments were received regarding the patient residence and pharmacy service type fields. Commenters asked whether CMS still expects plans to use NCPDP values in these fields and what to fill in if there are no data.

**Response 143:** As noted in the record layout description fields, the patient residence and pharmacy service type values should reflect what was submitted by the pharmacy on the claim. While this may typically be an NCPDP value, we would accept other values included on the claim.

**CMS Action 143:** No changes were made to the protocol in response to these comment. No changes were made to the burden estimate in response to these comments.

**Comment 144:** Two commenters asked whether the "Part D Defined Qualified Facility" field was intentionally omitted from the record layouts.

**Response 144:** We confirm that the "Part D Defined Qualified Facility" field was removed from the record layouts.

**CMS Action 144:** No change was made to the protocol based on these comments. No changes were made to the burden estimate in response to these comments.

## PART D MEDICATION THERAPY MANAGEMENT (MTM)

### Record Layouts:

**Comment 145:** Several commenters asked whether CMS would consider using information submitted through Part D reporting in place of information collected in the MTM universes and asked for clarification about how to populate fields that are not currently required as part of MTM reporting. Some of these commenters recommended appending the universe elements that are not currently captured in MTM software programs onto existing reports or to consider expanding the requirements for annual data validation to eliminate the MTM audit protocols.

**Response 145:** Based on these comments and recent audit experience, we have reevaluated the universes requested in the MTM protocol. We agree that the CY 2015 information requested in table 1, can be obtained from MTM reporting data. We have also identified fields unique to table 2 of the record layouts that may be difficult for sponsors to populate or that may be omitted from the universe request without compromising the audit process. We intend to remove most of these fields and therefore, will not provide additional clarification about how to populate. We note that it is not feasible to use MTM reporting data for 2016 because these data would not be available in time to conduct 2017 MTM audits. Lastly, although similar information may be

collected for data validation and audits, audits allow for a more in depth review of the sponsors' systems and processes and therefore provide distinct insight and information about the programs being evaluated.

**CMS Action 145:** The CY 2015 Medication Therapy Management Program Record Layout and any reference to it was removed from the MTM protocol, leaving only a single record layout. Data related to CY 2015 MTM programs will be obtained through other sources for any audits conducted in 2017. For the remaining record layout, we renamed the table, removed all of the following fields and reassigned column IDs accordingly**:** "Beneficiary MTM Enrollment Type", "MTM Disenrollment Date", "Number of CMR offers declined", "TMR Intervention Description(s)", "TMR Intervention Delivery Method(s)", and "TMR Intervention Resolution(s)". In addition, we simplified the instructions for population of" TMR Interventions Delivered?" and "TMR Intervention(s) Delivery Date" fields.

**Comment 146:** Several commenters asked about omissions and potential typographical errors in the MTM record layouts (Tables 1 and 2). Specifically the commenters asked whether the fields for the "CMS Part D Defined Qualified Facility" and "Contract ID" (table 1 only) were inadvertently removed and whether there was a contract year typo in the field description for the "1st CMR Delivery Method" field.

**Response 146:** We confirm that the CMS Part D Defined Qualified Facility field was intentionally omitted from the MTM record layouts; however, the "Contract ID" field was deleted from table 1 in error. We also confirm that the there was an incorrect reference to CY 2015 in the field description for the "1st CMR Delivery Method" field. We have taken out specific references to the years (CY 2015 or CY 2016) because we anticipate using this protocol for multiple audit years.

**CMS Action 146:** No change will be made with respect to the "Contract ID" field for table 1 because this table will be removed from the MTM protocol. We modified field descriptions to remove specific references to years.

**Comment 147:** Three commenters suggested removing or providing additional guidance for the record layout field "Was the beneficiary residing in a long term care facility?". These commenters stated that a history of the beneficiary residence status is not maintained and that it can be difficult to know the residence status, especially for stand-alone prescription drug plans relying on drug claim-level data.

**Response 147:** Sponsors should use all available information to determine LTC status at the time the MTM services are offered and administered, such as the patient residence code on drug claims data and the Long Term Institutionalized (LTI) resident report. As noted in the field description for the beneficiary residence field, sponsors may enter U (unknown) in the event they are unable to identify the residence status.

**CMS Action 147:** We modified the description for the field "Was the beneficiary residing in a long term care facility?" to include additional guidance about determining beneficiary residence status.

**Comment 148:** One commenter questioned the logic of evaluating information related to the last MTM program enrollment in CY 2015 versus the first MTM program enrollment for CY 2016.

**Response 148:** For purposes of evaluating beneficiaries enrolled in the same contract and associated MTM program across two consecutive years, information for the last MTM program enrollment of 2015 and the first for 2016 were reasonably the most closely related for continuing members. In response to comments regarding minimizing changes to protocols, we are removing specific dates from the record layouts.

**CMS Action 148:** The CY 2015 Medication Therapy Management Program (MTM-2015) record layout will be removed in its entirety as noted in a previous response. We will continue to request information related to the first contract and associated MTM program enrollment of the contract year immediately prior to the audit year for the remaining record layout.

**Comment 149:** One commenter asked why there were separate fields for MTM eligibility dates and MTM enrollment dates, when in their opinion all members should be enrolled the same day they are deemed eligible.

**Response 149:** Although systems could be developed to auto-enroll beneficiaries into MTM programs immediately after they have been flagged as eligible, it may not always happen in practice. These two fields will remain in the protocol consistent with information collected for the CY 2016 Part D MTM program reporting requirements.

**CMS Action 149:** No change was made to the protocol in response to this comment. No change was made to the burden estimate in response to this comment.

**Comment 150:** Two commenters recommended removing the "MTM disenrollment reason" field because it is not captured in a reportable format and one recommended removing "death" as an opt-out or disenrollment reason, stating that is rare to receive accurate information on the date of death for any beneficiary and therefore, difficult to complete the "MTM opt-out date" field.

**Response 150:** We will modify both the "MTM disenrollment reason" and any related field names and descriptions to better align with the opt-out related variables in the technical specifications for CY 2016 MTM reporting. Death will remain as an option consistent with these specifications. We will also replace "disenrollment" with "opt-out" as applicable throughout the protocol. With respect to the "MTM opt-out date" field, when death is identified as the opt-out reason, the sponsor may enter the date they become aware of the beneficiary's status, if the actual date of death is not known.

**CMS Action 150:** The field names "MTM Disenrollment Reason" and "MTM Disenrollment Explanation of Reason" were changed to "MTM Opt-out Reason" and "MTM Opt-out Reason Explanation", respectively. The response options in these fields were modified to be consistent with the options described for the 2016 MTM reporting requirements and where applicable in the protocol, "disenrollment" was replaced with "opt-out". The "MTM opt-out date" field was updated to include clarifying instructions for populating when the option opt-out reason was death.

**Comment 151:** One commenter recommended removing the "TMR Intervention Recipient(s)" field from table 2 stating that the information is already captured in the next field.

**Response 151:** As noted in a previous comment we will be removing the "TMR Intervention Description(s)" field; therefore, the information requested in the "TMR Intervention Recipient(s)" field will no longer be duplicative.

**CMS Action 151:** The "TMR Intervention Description(s)" field was removed from the MTM record layout.

**Comment 152:** One commenter was seeking clarification on how to properly account for a mailed CMR that was not returned, but was also not acted upon by the beneficiary. Another commenter thought that asking for both the number of CMRs and written CMR summaries was duplicative and questioned why these numbers would be different.

**Response 152:** As noted in the field description for the "Number of CMRs offered", in order to count as a CMR offer it must have been received by the MTM program member (e.g., returned mail or incorrect phone numbers do not count as an offer). For audit purposes if a CMR offer is successfully delivered it may be counted regardless of whether a response was received or an action was initiated by the beneficiary or their authorized representative. Because a summary may either be provided immediately following a CMR or distributed separately within 14 days of the CMR, the CMR administration and written summary dates may be different.

**CMS Action 152:** 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 153:** One commenter asked if CMS would consider collecting the information outlined in the sample case documentation section of the MTM elements as part of annual reporting requirements. The commenter stated this would result in additional time saved during the short interval between the audit engagement letter and the universe due date and free up resources to focus on the many other audit requirements.

**Response 153:** The sample case file documentation evaluated during the audit are limited to the samples or issues identified for each element and are reviewed live via the sponsor's claims processing system. Not all case reviews will result in a request for screenshots of the information displayed during the webinar and these screenshots are not collected in advance of the audit. CMS does not have a need to collect the case documentation for every beneficiary auto-enrolled into an MTM program by the sponsor over a given contract year and we believe such a request would be overly burdensome for sponsors to produce annually.

**CMS Action 153:** No changes were made to the protocol in response to this comment. No change was made to the burden estimate in response to this comment.

**Comment 154:** One commenter asked CMS to clarify whether "TMR performed" should be interpreted as a review of the medication profile either automated or manual which may result in an intervention and follow-up. One commenter asked about how to populate the "Date of the 1st TMR Intervention" field and another recommended striking the "NA" response option in the "Was the 1st TMR intervention declined?" field.

**Response 154:** We would like to confirm that by "TMRs performed" we mean the targeted medication reviews (TMRs) conducted by the sponsor no less than quarterly for all beneficiaries enrolled in the MTM program. These assessments could be person-to-person and/or system generated. Part D sponsors will assess the TMR findings to determine if a follow-up intervention is necessary and whether the intervention is warranted for the beneficiary and/or the prescriber. The two TMR fields referenced by the commenters were not included in the revised MTM protocol; therefore, no clarification will be provided for these fields.

**CMS Action 154:** 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 155:** One commenter asked if CMS would consider striking the instruction to answer "NA". The commenter stated that it would be operationally more difficult to retrospectively label fields with "NA" based on whether or not the CMR was administered or offered and that provision or offer of a CMR does not directly impact of these fields.

**Response 155:** We are unclear about whether the commenter is referring to all CMR related fields which include the "NA" response option or only specific fields. However, in response to these comments, where we ask for CMR or TMR related counts, we will change the field description instructions to enter a zero instead of an "NA" when no CMR was offered or administered, when no CMR summary was provided or when no TMR was performed. We have also evaluated the other remaining CMR and TMR related fields and determined that the "NA" option is necessary to ensure that fields are not null and to provide a response option when a field does not apply to a specific case. Therefore, the remaining "NA" options will be unchanged.

**CMS Action 155:** The following record layout fields will no longer include "NA" as an option**:** "Number of CMRs offered", "Number of CMRs administered", "Number of written CMR summaries" and "Number of TMRs performed".

## Case Documentation:

**Comment 156:** One commenter asked CMS to clarify the distinction between "Documentation of notification to beneficiary regarding the comprehensive medication review" and "Copy of the written summary of the comprehensive medication review". The commenter states that reviewing the CMR letter would cover both and requests clarification about what CMS expects to be displayed.

**Response 156:** Under the sample case documentation section of the protocol elements a variety of data or documents are listed that may be requested during the live audit webinar. Although the two bullets referenced under the CMR element are similar, the notification documentation could include a system display of when the written CMR summary was sent. In the absence of a copy of the written CMR summary the notification documentation could also be alternative evidence of the beneficiary communication about the sponsor administered CMR. We recognize that there may be other seemingly duplicative documentation requests for the CMR and TMR elements. In addition, these elements share a number of requests in common. Based on these comments, experience from the 2016 pilots and the interrelated nature of these elements, we believe it is more efficient to combine the TMR and CMR elements into one for the 2017 pilot. In doing so we would consolidate the duplicative or related case documentation requests and reduce the number of cases evaluated from 30 to 20.

**CMS Action 156:** Elements two and three of the MTM protocol were combined into a single element. The case documentation section of this element was consolidated and the sample total was reduced from 30 cases across two elements to 20 cases for the combined element. In addition, the instructions for the case documentation was made consistent across all elements.

## Impact Template and Questionnaire:

**Comment 157:** One commenter noted that the fields in the impact template included much of the same information that is requested in the MTM universes and seemed more relevant to

sample selection. The commenter recommended using pilot data or compliance standards to determine what fields were needed to demonstrate impact and to only include what is necessary and relevant to improve turnaround time.

**Response 157:** Given that we are in the very early stages of the pilot, we do not have enough data at this time to determine the final set of fields for the impact templates. When an impact analysis is required, the auditors will at a minimum request the information on the summary tab of the template and if necessary will request more detailed information using the member impact tab. When this occurs, the auditor will provide instructions about the specific fields to populate, which would include those that are necessary and relevant to the issue of non-compliance identified. We appreciate the comments and suggestions for the member impact portion of the template and we will consider them for future development after the pilot phase is completed.

**CMS Action 157:** Consistent with the actions from a previous comment and response, we removed fields from the MTM impact template that no longer exist in the MTM record layout, replaced "disenrollment" with "opt-out" and revised dates, as applicable.

**Comment 158:** One commenter asked if CMS would be developing a supplemental MTM questionnaire similar to other program areas.

**Response 158:** At this time, we do not intend to develop a supplemental MTM questionnaire for use during the 2017 pilot audits.

**CMS Action 158:** No change was made to the protocol in response to this comment. No change was made to the burden estimate in response to this comment**.**

## SPECIAL NEEDS PLANS MODEL OF CARE (SNP MOC)

### Audit Purpose and General Guidelines:

**Comment 159:** Seven commenters noted the audit review period example given did not reflect a period of 13 months. One commenter requested confirmation that the review period will be limited to the 13 month period preceding the audit engagement letter.

**Response 159:** The audit review period will be the 13 month period preceding and including the date of the engagement letter (for example, for an engagement letter sent on January 25, 2017, the universe review period would be December 1, 2015 through January 25, 2017. CMS reserves the right to expand the review period if needed.

**CMS Action 159:** The protocol was revised to include an updated example of the universe review period.

**Comment 160:** One commenter inquired which version of the Model of Care (MOC) CMS auditors will be reviewing samples against.

**Response 160:** CMS will be using the CMS approved MOC as well as redlined versions of any revisions to the approved MOC.

**CMS Action 160:** 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 161:** One commenter requested instructions for completing SNP-MOC Impact Analysis templates and confirmation regarding the term "team lead".

**Response 161:** Instruction and guidance for completing impact analyses are provided to sponsors during the audit in the event that an impact analysis is necessary. The term "Team Lead" is referring to the auditor that is leading the SNP-MOC audit team.

**CMS Action 161:** 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.

## Universe Preparation & Submission:

**Comment 162:** Three commenters requested clarification regarding which members should be included in the universe and what CMS means by continuous enrollment.

**Response 162:** The universe applies to all members who have been enrolled in any of the sponsoring organization's SNPs for the 13 month period preceding the date of the audit engagement letter with no breaks in enrollment (continuously enrolled). Members may have switched from one SNP plan to another so long as there were no breaks in enrollment. This also includes members who have been continuously enrolled for many years.

**CMS Action 162:** The universe instructions in the protocol were modified to clarify the meaning of continuous enrollment.

**Comment 163:** One commenter asked if the listing of FDRs that assist with the MOC and their functions/deliverables relates to FDRs who are responsible for any aspect of the MOC from a claims, enrollment clinical perspective or only FDRs as it relates to key components of the clinical aspects of the MOC.

**Response 163:** For purposes of SNP-MOC, the listing of FDRs that assist with the MOC and their functions/deliverables should be limited to those that are contracted to perform enrollment, Health Risk Assessments (HRAs), Individualized Care Plans (ICPs), and Individualized Care Team (ICT) functions.

**CMS Action 163:** 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 164:** One commenter requested clarification as to whether or not sponsors should submit a Plan Performance Monitoring and Evaluation (PPME) universe for each unique MOC.

**Response 164:** PPME universes should be submitted for each unique MOC. To aid in the review process, sponsors may submit one workbook with a separate tab for each unique MOC.

**CMS Action 164:** The protocols were revised to state that sponsors may opt to submit one workbook with a separate tab for each unique MOC.

## Sample Selection:

**Comment 165:** Seven commenters noted the removal of Medicare Medicaid Plan (MMP) information from the SNP-MOC protocol and requested further clarification.

**Response 165:** MMPs will have a separate protocol and will no longer be evaluated under the SNP-MOC protocol. CMS is revising the SNP-MOC protocol to ensure that all references to MMPs have been removed.

**CMS Action 165:** MMP references were removed from the protocol in response to this comment.

**Comment 166:** One commenter requested information regarding how sponsors can project what the percentile distribution will be for sample selection.

**Response 166:** CMS will use the SNP type percentages represented in the universe for purposes of sample selection.

**CMS Action 166:** The protocol was updated to reflect that sample selection will be based off the SNP type percentages represented in the universe.

## Element I. Population to be served – Enrollment Verification:

**Comment 167:** One commenter requested clarification regarding what types of documentation could be used for proof of "receipt of the enrollment request" for all beneficiaries and for D-SNP beneficiaries.

**Response 167:** Documentation of the enrollment request can be a copy of a paper application with date/time stamping; dated and timed system notes citing telephonic administration of the application and the results or a printed copy of a dated/timed online application.

**CMS Action 167:** 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.

## Element II. Care Coordination:

**Comment 168:** Two commenters requested clarification regarding what CMS means by Care Coordination, what activities are included and whether all MOCs need to be updated with this requirement.

**Response 168:** Care Coordination is one of the required Model of Care elements outlined in Chapter 5 of the Medicare Managed Care Manual which includes HRA tools, ICPs, the ICT, and Care Transition Protocols. Sponsors should refer to Chapter 5 to obtain detailed information regarding this element.

**CMS Action 168:** 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 169:** Four commenters requested clarification regarding the completion of initial HRA's within 90 days before or after the enrollment effective date.

**Response 169:** Due to industry feedback, CMS has determined to interpret the regulatory language stating "within 90 days" to mean up to 90 days before or after the effective enrollment date for completion of the initial HRA. This change is reflected in the Part C reporting requirements. CMS is currently in the process of updating chapter 5 in the Medicare Managed Care Manual to indicate as such.

**CMS Action 169:** 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 170:** Two commenters inquired how revised HRA tools will be accounted for during the audit and whether CMS will have a process in place to approve HRA tool revisions outside of the SNP application process.

**Response 170:** During a CMS audit, sponsors should provide the original CMS approved Health Risk Assessment tool (HRAT) as well as redlined versions with any revisions/updates. CMS does not currently have a process in place to review updated/revised HRATs outside of the SNP application process. Sponsors are advised to maintain a record of the most updated HRAT.

**CMS Action 170:** 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 171:** One commenter requested clarification as to whether or not CMS would expect to see initial HRA's for members who have been continuously enrolled prior to January 2010.

**Response 171:** CMS would not expect to see initial HRA's for members who have been continuously enrolled prior to January 1, 2010. However, CMS would expect to see HRAs as a result of a change in the member's health condition or status as well as annual reassessments.

**CMS Action 171:** 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 172:** One commenter recommended that Care Coordination compliance standard question 2.1.2 be split into two separate questions.

**Response 172:** We appreciate the recommendation. However, we believe the compliance standard question should remain as presently stated.

**CMS Action 172:** 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 173:** Two commenters recommended that CMS modify the language of Care Coordination compliance standard question 2.2.2. to include the words "measurable" and "all".

**Response 173:** CMS modified the language of compliance standard 2.2.2 to reflect the regulations. As such, 2.2.2 will now state "Did the sponsor develop a comprehensive ICP designed to address needs identified in the HRA, consistent with the MOC?"

**CMS Action 173:** Compliance standard question 2.2.2 was updated in the protocols to reflect what is stated above.

**Comment 174:** One commenter requested clarification as to what type of documentation would demonstrate Care Coordination compliance standard question 2.3.1.

**Response 174:** Documentation demonstrating compliance standard question 2.3.1 include ICT meeting minutes, care coordination notes, and "sign-off of the ICP by ICT members.

**CMS Action 174:** 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 175:** One commenter requested clarification regarding which transition protocols CMS is requiring in relation to compliance standard question 2.4.1. and what CMS would expect to see for documentation.

**Response 175:** Documentation of care transition activities may include**:** case manager and ICT notes, letters to/from providers/specialists, SNFs or assisted living facilities, ICT meeting minutes, and/or screen shots to show appointment scheduling and/or phone outreach, as well as ICP updates. Care transitions include but are not limited to when a member is discharged from the acute care or inpatient setting, skilled nursing or rehabilitation facility and moves back to his/her residence in the community (i.e. home, SNF, assisted living). Additional guidance regarding transition protocols in the Model of Care (MOC) can be found in the Medicare Managed Care Manual Chapter 5, Section 20.2.1, E.

**CMS Action 175:** 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 176:** One commenter inquired whether Care Coordination compliance standard question 2.5.2. relates to both the initial HRA and the annual HRA.

**Response 176:** This question relates to both the initial HRA and the annual HRA.

**CMS Action 176:** 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 177:** One commenter inquired whether or not sponsors must have documented evidence that providers completed training or if provider training materials were sufficient for meeting Care Coordination compliance standard questions 2.5.4 and 2.5.5.

**Response 177:** CMS would not expect sponsors to show completion training certificates of all contracted/non-contracted providers in their networks. Instead, sponsors may provide MOC training content/presentations, provider outreach/meeting minutes, online training modules, newsletters, and other hard copy training materials as evidence of their provider training and outreach.

**CMS Action 177:** 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 178:** One commenter inquired whether or not evidence that sponsor confirmation has occurred for MOC training of network providers and ICT members includes vendors who own a core function of the MOC.

**Response 178:** Yes, this includes vendors who own a core function of the MOC.

**CMS Action 178:** 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.

## Element III. Plan Performance Monitoring and Evaluation of the MOC:

**Comment 179:** One commenter inquired whether or not compliance standard question 2.1 relates to Plan Performance Monitoring and Evaluation of the MOC (PPME) or overall MOC performance and outcome.

**Response 179:** PPME compliance standard question 2.1 relates to the overall MOC performance and outcome.

**CMS Action 179:** 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 180:** One commenter inquired whether or not compliance standard question 2.5 refers to the appropriate personnel per the MOC or per CMS.

**Response 180:** Compliance standard question 2.5 refers to the appropriate personnel per the CMS approved MOC.

**CMS Action 180:** 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: Special Needs Plan Enrollees (SNPE) Record Layout:

**Comment 181:** Two commenters recommended that passive enrollments be added to Column ID H**:** Enrollment Mechanisms.

**Response 181:** CMS agrees and will revise this column to include "passive" in the list of options.

**CMS Action 181:** Column ID H**:** Enrollment Mechanisms was revised to include passive enrollments.

**Comment 182:** One commenter inquired what should be entered in Column ID L**:** Date Initial HRA was completed in cases where an HRA did not occur within 90 days of the enrollment effective date.

**Response 182:** Sponsors should enter the date the initial HRA was completed even if the date is beyond the 90 day period.

**CMS Action 182:** 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 183:** One commenter requested clarification on how the date should be formatted in Column L**:** Date initial HRA was completed.

**Response 183:** Fields requesting dates should be formatted in this manner CCYY\MM\DD.

**CMS Action 183:** Slashes were added to all dates in the protocol.

**Comment 184:** Two commenters inquired how Column N**:** Date of completion for HRA conducted during current audit period should be completed if the member has never had an HRA or if no HRA was conducted during the audit period. One commenter recommended that CMS allow sponsors to enter NA if an HRA was not conducted during the audit period.

**Response 184:** CMS has modified the description in Column N**:** Date of completion for HRA conducted during current audit period to allow sponsors to enter NA if no HRA was conducted during the audit period.

**CMS Action 184:** Column N**:** Date of completion for HRA conducted during current audit period was updated in the protocol to include the option to enter NA when no HRA has occurred during the audit period.

**Comment 185:** One commenter requested that CMS clarify how to populate Column ID O**:** Date of previous HRA/reassessment if the date of the previous HRA/reassessment falls outside of the audit period.

**Response 185:** Sponsors should enter the date of the previous HRA/reassessment even if the date falls outside of the audit period.

**CMS Action 185:** 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 186:** One commenter requested clarification regarding Column ID P**:** Was an ICP completed?

**Response 186:** This question is inquiring whether or not an ICP was developed and implemented as a result of the most recently conducted HRA.

**CMS Action 186:** 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 187:** One commenter requested clarification on the types of claims that should be excluded in Columns Q - T.

**Response 187:** Sponsors should exclude data related to the types of claims cited; duplicate claims and payment adjustments to claims, claims that are denied for invalid billing codes, billing errors, denied claims for bundled or not separately payable items, denied claims for beneficiaries who are not enrolled on the date of service and claims denied due to recoupment of payment.

**CMS Action 187:** The descriptions in Columns Q-T have been updated with the information above to provide clarification of which claims should be excluded from the totals.

**Comment 188:** One commenter requested clarification regarding whether sponsors should include the number of capitated paid/denied claims in Columns S and T.

**Response 188:** Capitated payments and denials should be included in these counts.

**CMS Action 188:** Columns S and T descriptions have been revised to demonstrate that capitated payments and denials should be included in these counts.

## Table 2: Plan Performance Monitoring and Evaluation (PPME) Record Layout:

**Comment 189:** One commenter noted that the instructions for Column L**:** Goal Met/Not Met, do not account for metrics where a lower threshold equals the goal being met. For example, a goal of maintaining a hospital readmission rate of 14% or less would be met if the readmission rate was less than 14%.

**Response 189:** We agree and have revised the instructions to be more general allowing for various instances of the goal being met.

**CMS Action 189:** Column L**:** Goal Met/Not Met and Column Q**:** Goal Met/Not Met description now have general descriptions.

**Comment 190:** One commenter requested clarification as to whether or not NA can be entered in Rows E, L and Q when no data is available.

**Response 190:** Sponsors may enter NA when no data is available. Sponsors may provide clarification for NA responses during the walkthrough portion of the audit.

**CMS Action 190:** Rows E, L and Q have been updated to allow for NA responses.

**Comment 191:** One commenter requested that CMS clarify whether "not applicable" responses should be abbreviated as N/A or NA.

**Response 191:** To promote consistency throughout the protocols, not applicable responses will be abbreviated as NA.

**CMS Action 191:** Changed protocol to reflect NA as allowable response.

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

### Organization Determinations:

**Comment 192:** We received a question regarding organization determinations. Specifically, we were asked whether a referral request is considered an organization determination.

**Response 192:** This is a policy question and is outside the scope of this PRA package. Please refer to Chapter 13 of the Medicare Managed care Manual for guidance on what constitutes an organization determination.

**CMS Action 192:** 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 193:** We received numerous comments regarding the "Subsequent expedited request" field in the Standard Organization Determination (Table 1 – SOD) and Standard Pre-Service Reconsideration (Table 5 – SREC) universes. Specifically, we were asked to clarify the purpose of this field, how to populate this field and whether the contract provider and sponsor response options should be removed in the Standard Pre-Service Reconsideration universe (Table 5 – SREC).

**Response 193:** We have revised the name of this field to "Request for expedited timeframe" to clarify how to populate this field. Also, we have removed "S" as a response option for both of these fields, and we have removed "CP" as a response to this field in both of these audit universes.

**CMS Action 193:** We revised the name of this field consistent with the comments above, and removed "S" as an option for this field in Tables 1 and 5 (SOD and SREC, respectively), and removed "CP" as an option for this field in Tables 1 and 5 (SOD and SREC, respectively).

**Comment 194:** We received a comment regarding populating the "Who made the request," "Subsequent expedited request" and "Date the request was received" fields in the Expedited Organization Determination universe (Table 2 – EOD).

**Response 194:** The "Date the request was received" and "Time the request was received" fields in the Expedited Organization Determination (Table 2 – EOD) and Expedited Pre-Service Reconsiderations (Table 6 – EREC) universes have been clarified to include a note indicating that if the request was received as a standard organization determination request, but later expedited, to enter the date and time of the request to expedite the organization determination or reconsiderations. The "Who made the request" field should be populated with the individual who made the first request and the "subsequent expedited request" field should be populated with the individual who later requested that the organization determination be expedited.

**CMS Action 194:** We clarified the field description for "Date the request was received" to indicate this field should be populated with the date the request was received to expedite the case if it was subsequently expedited. We also clarified that the "Who made the request" field should be populated with who made the initial request and the "Subsequent expedited request" field should be populated with who made the subsequent request to expedite the case.

**Comment 195:** We received a question regarding the "Was request made under the standard timeframe but processed by the plan under the expedited timeframe?" field in the Expedited Organization Determination universe (Table 2 – EOD). Specifically, we were asked how to populate this field when a contract provider submits a request on behalf of a beneficiary.

**Response 195:** We have removed this field from Table 2.

**CMS Action 195:** We removed this field from Table 2 (EOD).

**Comment 196:** We received a comment regarding the "Subsequent expedited request" field in the Expedited Organization Determination universe (Table 2 – EOD). Specifically, we were asked to remove the option of "NA" for this field.

**Response 196:** We do not believe removing "NA" as an option for this field is appropriate. However, we have revised this field to clarify that a response of "NA" is appropriate if the requests came in as expedited originally and there was no subsequent request to expedite.

**CMS Action 196:** We revised the "subsequent expedited request" field in Table 2 (EOD) to clarify that a response of "NA" is appropriate if a case came in as expedited originally and there was no need to expedite it subsequently.

**Comment 197:** We received a comment regarding the "Was request made under the standard timeframe but processed by the plan under the expedited timeframe?" and "Subsequent expedited request" fields in the Expedited Organization Determination (Table 2 – EOD) and Expedited Pre-Service Reconsiderations (Table 6 – EREC) universes. Specifically, the commenter suggested that these fields are redundant because an affirmative response to the first field would always yield a response of "S" for the second field.

**Response 197:** We have removed the "Was request made under the standard timeframe but processed by the plan under the expedited timeframe?" field from these audit universes.

**CMS Action 197:** We have removed the "Was request made under the standard timeframe but processed by the plan under the expedited timeframe?" field from Tables 2 and 6 (EOD and EREC, respectively).

## Claims and Direct Member Reimbursement Requests:

**Comment 198:** We received a comment regarding the allowable responses in the "Date written notification provided to enrollee" field in the Claims universe (Table 3 – Claims). Specifically, we were asked how sponsors should populate this field for D-SNP members who do not have any cost sharing liability.

**Response 198:** We have clarified this field to include both EOB notifications and IDN notifications.

**CMS Action 198:** We have clarified this field to include both EOB notifications and IDN notifications.

**Comment 199:** We received a comment regarding the "Is this a clean claim" field in the Claims universe (Table 3 – Claims). Specifically, the commenter suggested adding the option of "NA" for claims where the clean or unclean status has not yet been determined.

**Response 199:** We have revised this field to allow for a response of "NA" where the clean or unclean status of the claim has not been determined.

**CMS Action 199:** We have revised this field in Table 3 (Claims) to allow for a response of "NA" where the clean or unclean status of the claim has not been determined.

**Comment 200:** We received several questions regarding how to pull the Claims (Table 3 – Claims) and Direct Member Reimbursement Request (Table 4 – DMR) universes. Specifically, we were asked to confirm that these universes should be populated based on the notification date that the claim or reimbursement request was paid or denied or the decision was made to pay or deny the request. Commenters also noted that for the 2016 protocols we asked sponsors to submit requests based on the date the decision was made to pay or deny the request.

**Response 200:** We are asking sponsors to populate this universe based on the date the claim was paid or denied based on the notification date. For paid claims and payment requests, the notification date is the date the claim is actually paid. For denied claims and payment requests, the notification date is the date of the denial notification.

**CMS Action 200:** We have revised the instructions for populating Tables 3 and 4 (Claims and DMR, respectively) to indicate these universes should be populated based on the notification date the claim or reimbursement request was paid or denied.

**Comment 201:** We received several questions regarding the "Date the claim was paid or denied" field in the Claims universe (Table 3 – Claims), the "Date the reimbursement was issued or denied" field in the Direct Member Reimbursement Request universe (Table 4 – DMR) and the "Date the claim was paid or denied" field in the Requests for Payment Reconsiderations universe (Table 7 – PREC). Specifically, we were asked if these fields refer to the date the decision was made to pay or deny the claim or if these fields refer to the date the notifications or payments were sent. We were also asked to clarify when CMS considers a notification "mailed."

**Response 201:** The "Date the claim was paid or denied" and the "Date the reimbursement was issued or denied" fields refer to the date the claim or payment request was paid or denied. For paid claims and reimbursement requests, this will be the date the payment request was paid. For denied claims and reimbursement requests, this will be the date the provider or enrollee was notified of the denial. CMS considers notifications "mailed" once the correspondence leave the sponsor's facility, which may be a batch mailing or processing date.

**CMS Action 201:** 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 202:** We received several comments regarding direct member reimbursements. Specifically, we were asked to clarify the term “direct member reimbursement”, whether a member must pay out of pocket before requesting a reimbursement and if we could modify the language in the Direct Member Reimbursement universe (Table 4 – DMR) to clarify what is considered a direct member reimbursement.

**Response 202:** A "Direct Member Reimbursement" is a payment organization determination or reconsideration request submitted by a member or their representative. Any time a member faces financial liability and they make a request, it should be treated as a direct member reimbursement request for purposes of populating the audit universes. While we understand the commenters’ concerns, we believe the language in this universe does not need to be revised.

**CMS Action 202:** 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 203:** We received a question regarding the dismissal of non-contract provider claims. Specifically, we were asked when it would be appropriate for a sponsor to dismiss a non-contract provider claim, rather than approve or deny the claim.

**Response 203:** This is a policy question and outside the scope of this PRA package, please refer to Chapter 13 of the Medicare Managed Care Manual for policy guidance on dismissals.

**CMS Action 203:** 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 204:** We received a comment regarding the “Date forwarded to IRE if denied or untimely” and “If request denied or untimely, date enrollee notified request has been forwarded to IRE” fields in the Direct Member Reimbursement Request universe (Table 4 – DMR). Specifically, we were asked if a response of “NA” would also be appropriate for these fields if the request was an organization determination.

**Response 204:** We have revised these fields to clarify that a response of “NA” would be appropriate for organization determination requests.

**CMS Action 204:** We have revised these fields in Table 4 (DMR) to clarify that a response of “NA” would be appropriate for organization determination requests.

## Reconsiderations

**Comment 205:** We received several comments regarding references to “claims” in the Payment Reconsideration universe (Table 7 - PREC). Specifically, we were asked if fields in this universe should reference “claims” or “reconsideration requests”.

**Response 205:** We have revised the fields in this universe to reference “reconsideration requests” for clarity.

**CMS Action 205:** We have revised the fields in Table 7 (PREC) to reference “reconsideration requests” for clarity.

**Comment 206:** We received a question regarding member post-service appeals in the Requests for Payment Reconsideration universe (Table 7 – PREC). Specifically, the commenter asked if CMS intended to exclude member-submitted post-service appeals from this universe.

**Response 206:** As per the universe instructions at the top of the record layout, this universe should only contain payment requests submitted by non-contract providers. Member-submitted post-service appeals should be included in the Direct Member Reimbursement Request universe (Table 4 – DMR).

**CMS Action 206:** 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 207:** We received a question regarding the Requests for Payment Reconsiderations universe (Table 7 – PREC). Specifically, we were asked if cases should be submitted based on the date the reconsideration was paid or denied or if cases should be submitted based on the date of the decision to pay or deny the reconsideration.

**Response 207:** Cases in this universe should be submitted based on the date the reconsideration was paid or denied.

**CMS Action 207:** 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.

## IRE, ALJ and MAC:

**Comment 208:** We have received several questions and comments regarding paying interest on direct member reimbursement requests. Specifically, we were asked whether we included the "Was interest paid on the reimbursement" field in error, why "NA" is not an option for this field and why the "Was interest paid on the claim or reimbursement request?" field in the IRE Payment Cases Requiring Effectuation universe (Table 9 – IREClaimsEFF) does not allow an option of "NA" for direct member reimbursement requests.

**Response 208:** While CMS understands the commenters' concerns, we have determined that the Social Security Act and our regulations require Medicare Advantage organizations to pay interest to MA enrollees in some circumstances therefore we did not make edits to this field.

**CMS Action 208:** 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 209:** We received a comment regarding the "Request for expedited timeframe" field in the ALJ and MAC Cases Requiring Effectuation universe (Table 10 – ALJMACEFF). Specifically, the commenter suggested adding the option of "NA" for payment requests.

**Response 209:** We have revised this field to allow for a response of "NA" for payment requests.

**CMS Action 209:** We have revised this field in Table 10 (ALJMACEFF) to allow for a response of "NA" for payment requests.

**Comment 210:** We received a comment regarding the "Time of receipt of IRE decision" and "Time service authorization entered/effectuated in the sponsor's system" fields in the Pre-

Service IRE Cases Requiring Effectuation universe (Table 8 – IREEFF). Specifically, the commenter suggested adding the option of "NA" for non-expedited requests.

**Response 210:** We have revised these fields to allow for a response of "NA" for non-expedited requests.

**CMS Action 210:** We have revised these fields in Table 8 (IREEFF) to allow for a response of "NA" for non-expedited requests.

**Comment 211:** We received a comment regarding pulling the IRE universes. Specifically, the commenter noted that the 2016 protocol asked sponsors to pull these universes based on the date of the sponsor's decision, but the new protocol asks sponsors to pull these universes based on the date of the sponsor's receipt of the IRE decision.

**Response 211:** We are asking sponsors to populate this universe based on the date of the sponsor's receipt of the IRE decision, which is different from our approach outlined in the 2016 protocol.

**CMS Action 211:** We have revised the universe instructions in the protocol to request that sponsors populate the IRE universes (Table 8 – IREEFF and Table 9 - IREClaimsEFF) based on the date of the sponsor's receipt of the IRE decision.

## Grievances:

**Comment 212:** We received a question regarding sampling of grievances. Specifically, we were asked if standard grievances will be substituted for expedited grievances if the sponsor has fewer than three expedited grievances during the audit review period.

**Response 212:** We recognize that the Expedited Grievances universe (Table 12 – GRV_E) may not contain three or more cases. If there are fewer than three expedited grievances to sample, the remaining samples will be chosen from the Standard Grievances universe (Table 11 – GRV_S).

**CMS Action 212:** We clarified our sampling when sponsors do not have enough expedited grievances.

**Comment 213:** We have received several questions regarding the Standard Grievances (Table 11 – GRV_S) and Expedited Grievances (Table 12 – GRV_E) universes. Specifically, we were asked if we could change the name of the "Issue description" field to "Grievance/complaint description", if we could expand this field past 300 characters and if the description for the "Person who made the request" field should be revised to remove contract and non-contract providers as allowable responses.

**Response 213:** We have revised the "Issue description" field to "Grievance/complaint description" in the Standard Grievances (Table 11 – GRV_S) and Expedited Grievances (Table 12 – GRV_E) universes and expanded the field length from 300 characters to 1,800 characters. We have also revised the "Person who made the request" field description to remove contract and non-contract providers as allowable responses.

**CMS Action 213:** We have revised the "Issue description" field to "Grievance/complaint description" in the Standard Grievances (Table 11 – GRV_S) and Expedited Grievances (Table 12 – GRV_E) universes and expanded the field length from 300 characters to 1,800 characters.

This change is also consistent with CDAG. We have also revised the "Person who made the request" field description to remove contract and non-contract providers as allowable responses.

**Comment 214:** We have received several questions and comments regarding the grievance universes. Specifically, commenters questioned why the ODAG Standard Grievances (Table 11 – GRV_S) and Expedited Grievances (Table 12 – GRV_E) had similar fields but differing character limits, why ODAG and CDAG have differing field descriptions for the "How was the grievance/complaint received" field and why the ODAG and CDAG grievance universes were different.

**Response 214:** We agree with commenters that whenever possible, we should make fields consistent within and across protocols. We have therefore revised both ODAG grievance universes to be more consistent with the CDAG grievance universes. Specifically, we have aligned the fields, field names, field descriptions and field character limits between the ODAG and CDAG grievance audit universes.

**CMS Action 214:** We have revised both ODAG grievance universes (Table 11 GRV_S and Table 12 GRV_E) to be more consistent with the CDAG grievance universes. Specifically, we have aligned the fields, field names, field descriptions and field character limits between the ODAG and CDAG grievance audit universes.

## Dismissals:

**Comment 215:** We have received numerous questions and comments regarding the universe pull instructions. Specifically, we were asked how plans are to pull universes without the universe pull instructions in the body of the protocol, whether reopened cases should be included or excluded in the audit universes, whether dismissals should go into the Dismissals universe (Table 13 – DIS) or the universe that corresponds to the type of case that was dismissed and why we excluded various claims and payment requests in tables 1, 2, 5 and 6. Several commenters supported adding reopened cases into the ODAG universes.

**Response 215:** We appreciate these commenters concerns on how to populate the universes. We initially revised the ODAG audit protocol, and populated the universe pull instructions are above the individual record layouts. Re-openings should be excluded from the audit universes on ODAG. We thank commenters for their suggestions regarding the inclusion or exclusion of reopenings and we will consider including reopenings in the ODAG audit universes in 2018. We have revised the audit universes to clarify that dismissals should only be included in the Dismissals universe (Table 13 – DIS). We have removed references to claims and payment requests in tables 1, 2, 5 and 6.

**CMS Action 215:** We have revised the ODAG protocol to clarify the inclusion/ exclusion of reopenings and dismissals. We have removed references to claims and payment requests in tables 1, 2, 5 and 6 (SOD, EOD, SREC and EREC, respectively).

**Comment 216:** We received a comment regarding the "Person who made the request" field in the Dismissals universe (Table 13 – DIS). Specifically, the commenter noted that this field was titled differently than similar fields throughout the audit universes.

**Response 216:** We have revised the title of this field to "Who made the request" for consistency across the audit universes.

**CMS Action 216:** We have revised the title of this field in Table 13 (DIS) to "Who made the request".

**Comment 217:** We received a comment regarding the "Time the request was dismissed" field in the Dismissals universe (Table 13 – DIS). Specifically, the commenter suggested adding the option of "NA" for standard request dismissals.

**Response 217:** We agree with this comment and have revised this field to allow for a response of "NA" for standard request dismissals.

**CMS Action 217:** We have revised this field in Table 13 (DIS) to allow for a response of "NA" for standard request dismissals.

**Comment 218:** We received several comments and questions regarding the timeliness standards that apply to dismissals. Specifically, we were asked if payment dismissal timeframes apply to payment dismissals and if we could revise the Dismissals universe (Table 13 – DIS) to include a field to capture if a timeframe extension was taken.

**Response 218:** We have added a field to this universe to capture whether a timeframe extension was taken prior to dismissing the request. We have also revised the Timeliness Tests section to reflect that payment dismissal timeframes apply to the Dismissals universe (Table 13 – DIS).

**CMS Action 218:** We have added a field to Table 13 (DIS) to capture whether a timeframe extension was taken and revised the Timeliness Tests section to reflect that payment dismissal timeframes apply to the Dismissals universe.

## Protocol Compliance Standards:

**Comment 219:** We received several comments regarding the Clinical Decision-Making compliance standards. Specifically, we received comments that compliance standards 3.2.3 and 3.2.4 appear to be duplicative and compliance standard 3.2.11 may not be applicable to all requests, such as situations where the requested service is not a covered benefit.

**Response 219:** We agree with the commenters and have removed the duplicative compliance standard. We have also revised compliance standard 3.2.11 to clarify that it may not be applicable to all requests.

**CMS Action 219:** We updated the compliance standards in response to these comments.

## Part B Drugs

**Comment 220:** We have received several questions regarding the inclusion of Part B drugs within the audit universes. Specifically, we were asked if sponsors should exclude Part B drugs from the Claims universe (Table 3 – Claims) or the IRE Payment Cases Requiring Effectuation universe (Table 9 – IREClaimsEFF).

**Response 220:** Part B drugs requested or paid for under the Part C benefit should be included in the appropriate ODAG universe(s).

**CMS Action 220:** 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 221:** We received a question regarding how plans should process Part B drugs in MA and how to populate the audit universes. Specifically, whether or not it is acceptable for an MA organization to process Part B drugs using Part D procedures.

**Response 221:** The MA regulations require that a plan process a request as expeditiously as the enrollee's health conditions requires. Therefore, when processing an OD or appeal, if a plan decides they will utilize the shorter Part D processing timeframes in processing coverage requests for Part B drugs that is acceptable. Sponsors should populate the audit universes based on how they process the case (i.e., standard OD, expedited OD) and not by the timeframe they apply.

**CMS Action 221:** 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 222:** We received several questions and comments regarding National Drug Codes (NDCs) in the audit universes. Specifically, commenters questioned whether the ICD-10 or NDC codes should be used if both are applicable, what sponsors should do in the event an NDC is not available for the requested drug and what sponsors should do if their providers use J-Codes instead of NDCs.

**Response 222:** When populating the "Diagnosis" field, please include both the ICD-10 and NDC code if both are available. However, if an NDC or J-code is unavailable, the ICD-10 diagnosis code will be sufficient.

**CMS Action 222:** 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 223:** We received a question about how to count days for timeliness purposes. Specifically, we were asked if the day the plan receives the request is Day 1 or if the day after the plan received the request is Day 1.

**Response 223:** When a request is deemed "received" is a policy decision, and policy issues are outside the scope of this protocol. For audit purposes we consider the request received the moment the request comes into any part of plan via any method (fax, electronic, or phone). For timeliness calculations we would use the start time as the exact time it came into the plan for compliance standards involving hours (e.g., expedited organization determinations) and we would use the next calendar day to count as day one for compliance standards involving days. For example, for standard organization determinations that must be resolved in 14 days, if the request comes in on Monday, Tuesday would be counted as day 1 for purposes of the timeliness test.

**CMS Action 223:** 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 224:** We received a question regarding the timeliness thresholds. Specifically, we were asked to share the timeliness thresholds for each of the audit universes.

**Response 224:** We appreciate the comments, however at this time we do not share our internal thresholds. Sponsors should strive to achieve timeliness in all cases and the regulation

is written to expect 100% timeliness. For audit purposes, we have created thresholds that we believe are reasonable for a sponsor to meet.

**CMS Action 224:** 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 225:** We received a question regarding how the timeliness tests are conducted in ODAG. Specifically, we were asked if more than one universe tests the same compliance standard, multiple timeliness test results will be merged for one overall score.

**Response 225:** While the CDAG protocol does merge multiple timeliness test results from the same compliance standard into one test result, we do not follow this approach in ODAG. We thank the commenter for pointing out this difference and will take this into consideration for future protocol revisions.

**CMS Action 225:** 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 226:** We have received several comments regarding time zones in the audit universes. Specifically, commenters suggested that the time zones be reported where the cases were received.

**Response 226:** We agree with commenters and made this change. The ODAG protocol instructions have been revised to ask for requests based on the time zone where the request was received. Please be aware, however, that both the receipt date and time of a given request and any subsequent dates and times associated with that request must correspond to the same time zone.

**CMS Action 226:** The ODAG protocol instructions have been revised to ask for requests based on the time zone where the request was received.

**Comment 227:** We received numerous questions regarding how to populate pended and untimely cases into multiple ODAG universes. Specifically, commenters questioned how to populate pended cases where a decision has not yet been made, untimely decisions and how to populate the "Was the request denied for lack of medical necessity field?" for these cases.

**Response 227:** For purposes of populating the audit universes, untimely cases are considered denied the moment they become untimely. Therefore, any open, pended untimely cases should be treated as denials throughout the universes. Since these cases are considered denied because of untimeliness, they were not denied for lack of medical necessity.

**CMS Action 227:** 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 228:** 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 228:** 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."

**CMS Action 228:** 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 229:** We have received several questions and comments regarding multi-line requests and duplicate authorization numbers. Specifically, commenters questioned whether multiple-line requests should be listed separately at the line level or together at the case level and how to populate the "Authorization number" field if multiple lines are combined into a single row.

**Response 229:** For purposes of populating the audit universes, sponsors should combine all of a request's line items into a single row. Additionally, sponsors may use an authorization number of any item in the request when populating the "Authorization number" field.

**CMS Action 229:** 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 230:** We received a comment regarding the clarification of the "Who made the request" field. Specifically, the commenter appreciated the clarifications for this field in the protocol.

**Response 230:** We thank the commenter for this comment.

**CMS Action 230:** 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 231:** We received a question regarding the lack of an "Enrollment effective date" field in the audit universes. Specifically, the commenter inquired as to why there is no "Enrollment effective date" field in the ODAG audit universes, as this appears to be inconsistent with the CDAG audit universes.

**Response 231:** CMS has attempted to eliminate unnecessary fields and we have determined that "Enrollment effective date" is unnecessary in the ODAG audit universes. However, it is used in the CDAG universes.

**CMS Action 231:** 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 232:** We received a comment regarding the "Who made the request" field throughout the audit universes. Specifically, we were asked to clarify whether the provider type is the status of the provider performing the service and if facilities may submit a request on behalf of a beneficiary without an Appointment of Representative (AOR) form.

**Response 232:** The field name clearly indicates that this field should be populated with the individual who made the request. When an AOR form from an individual at a facility is required, the expectation is that the facility name alone on the AOR form would not be sufficient for the AOR to be valid. The AOR form must include both the facility name and the individual's name.

**CMS Action 232:** 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 233:** We received several comments and questions regarding the "Issue description and type of service" field throughout the audit universes. Specifically, the commenters requested that this field be separated into separate and distinct fields, such as "Description of service", "Why the service was requested" and "Explanation of denial," and how to populate this field for claims, where it may not be known why a service was requested.

**Response 233:** CMS believes it is less burdensome to keep this limited to one field. Sponsors are only required to populate this field with why the service was requested if it is known to the sponsor. If a sponsor is unaware of why a service was requested, it may populate this field with just the issue description.

**CMS Action 233:** 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 234:** We received a comment regarding Appointment of Representative (AOR) forms. Specifically, we were asked how timeliness will be affected when an existing AOR form is used for a new request and the turnaround time will appear to be negative.

**Response 234:** While CMS understands the commenter's concerns, our timeliness calculations take these scenarios into consideration and a negative turnaround time will not appear as untimely. When an AOR form is received prior to a new request we use the receipt date of the request for calculating timeliness.

**CMS Action 234:** 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 235:** We received several questions regarding row character limits. Specifically, we were asked how to continue data to a new row once the 4,000 character limit has been reached and if spaces count toward the field length limits.

**Response 235:** The audit universe field lengths have been calculated so that it is not possible to have more than 4,000 characters per row. Starting in 2017, the field lengths for the various fields throughout the audit universes are inclusive of both characters and spaces between words/characters. We have revised field lengths throughout the audit universes to account for spaces.

**CMS Action 235:** We have revised field lengths throughout the audit universes to account for spaces between words and letters.

**Comment 236:** We received a comment regarding adding a "test" field to the audit universes. Specifically, the commenter suggested that we add a column to each audit universe to show the timeliness test we will be applying.

**Response 236:** We thank the commenter for this suggestion, but multiple timeliness tests can be applied to a single universe, so it would be difficult and we believe ultimately confusing to add such a field. All timelines assessed are clearly laid out in manual and regulations.

**CMS Action 236:** 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.